ChatGPT

Cursor Study Management Platform — Web & Backend Playbook (v0.1)

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1. Brand Identity & Messaging

Core Message: Cursor's brand stands for **innovation**, **trust**, and **simplicity** in clinical trial site management. The messaging should consistently highlight how Cursor *simplifies complex workflows* and *instills confidence* through compliant, user-friendly technology. We emphasize being a **modern, unified solution** that removes chaos and manual work for site staff. The tone is professional yet approachable – we understand the daily challenges of research coordinators and offer a helping hand. Key values to project include:

- **Efficiency & Automation:** "From protocol to plan in minutes" – showcasing how our platform automates scheduling, reminders, and documentation so staff can focus on patients (innovation angle).
- **Reliability & Compliance:** Stress that Cursor is built with 21 CFR Part 11 and HIPAA compliance at its core, providing a secure and trustworthy workspace (trust angle).
- **Clarity & Ease of Use:** All features are designed to be straightforward and intuitive, reducing training burden and minimizing errors (simplicity angle).

The brand voice should celebrate making site coordinators' lives easier. For example, taglines like *"Run every study with confidence and less effort"* or *"One calendar for all your trials – finally!"* capture our value. The overarching message: **Cursor transforms the messy, high-pressure world of site management into a seamless, organized experience.**

2. Target Audience

Primary Audience: Clinical Research Site staff, especially **Site Coordinators/Managers (CRCs)** who juggle multiple studies. These users deal with scheduling visits, managing study logistics, and ensuring protocol compliance daily. Our site is tailored to their perspective, addressing pain points like calendar clutter, missed tasks, and overwhelming paperwork. We want them to immediately think, "This will make my life easier."

While site coordinators are the focus, secondary audiences include **Principal Investigators (PIs)** and site directors who approve technology, as well as **sponsors/CROs** evaluating site capability. The content should reassure PIs that the platform supports compliance and oversight, and subtly signal to sponsors that sites using Cursor are well-organized and inspection-ready. However, all messaging will be framed from the site's

benefit standpoint (e.g., how the site can streamline operations). In summary, **if you manage or conduct trials at a site, Cursor is built for you.** The landing pages will speak primarily to coordinators' daily struggles and how we solve them, rather than generic sponsor metrics.

3. Marketing Website & Landing Pages

Website Goals: The marketing site should educate visitors on what makes Cursor special, demonstrate industry-leading features, and drive interested sites to take action (schedule a demo or start a trial). We will employ **three key landing pages** to achieve this, each with a clear purpose and tailored content. The design across all pages will be clean and modern – projecting professionalism with minimal clutter.

3.1 Main Landing Page – "Why Cursor"

This is the homepage and primary entry point. It will immediately communicate our unique value proposition: e.g., **"One Platform to Run All Your Studies – Smarter, Simpler, Compliant."** The layout should use a crisp hero section with a concise headline and a call-to-action (e.g., "Get a Demo" button). Key sections on this page:

- **Pain & Solution Summary:** Identify common site coordinator frustrations (multiple calendars, forgetting tasks, compliance risks) and illustrate how Cursor solves them. For example: *"Tired of juggling spreadsheets and calendars? Cursor's unified calendar handles all your study visits, tasks, and reminders automatically."* Use brief bullets or icons to show top benefits (time saved, fewer errors, audit readiness).
- **Feature Highlights:** Introduce our standout features in an easily scannable format. This can include the **multi-study calendar**, automated visit reminders, configurable checklists with photo capture, and integrated payment prompts (more on these in Section 4). Each feature highlight should be 1–2 sentences with an icon or image for quick visual impact.
- **Why We're Best:** A section that positions Cursor as an industry-leading solution. This might include a small comparison against status quo or competitors, emphasizing ease of use and completeness. For example: *"Unlike generic schedulers, Cursor is purpose-built for clinical sites – it's your calendar, visit tracker, supply manager, and eReg binder in one."*
- **Trust & Compliance:** Briefly mention our 21 CFR Part 11 compliance and security credentials to build trust. For instance: *"Built with FDA 21 CFR Part 11 compliance in mind – audit trails, e-signatures, and data security are baked in from day one."* (We can link to a compliance page or details for those interested).
- **Social Proof:** If available, a short testimonial or metric (e.g., "Saved 5 hours/week for our coordinators" or a quote from a pilot site). This builds credibility.

Overall, the main page should give a compelling overview in a few scrolls, with frequent call-to-action buttons (e.g., "Request a Demo" or "Try for Free") placed logically after explaining value points.

3.2 Features & Benefits Page – "How Cursor Helps You"

This landing page dives deeper into what makes Cursor special and the **best in the industry**. It's targeted at visitors who want to evaluate capabilities in detail. Using a clean, sectioned layout, it will cover:

- **Unified Calendar & Task Manager:** A detailed look at our calendar that **aggregates all studies**. We will show how a coordinator can see every visit across all ongoing trials in one color-coded calendar, including study identifiers, visit names, and due windows. Explain how the system flags what's coming next and what needs attention (e.g., overdue tasks or upcoming visit preparations). This addresses the major pain of juggling multiple schedules [1].
- *Visual Element:* Possibly include an illustrative screenshot or mock-up of the calendar interface highlighting multiple studies and tasks on it (with dummy data). A caption might read: "One calendar for all studies – never miss a visit or task."
- **Visit Scheduling & Reminders:** Describe how Cursor auto-schedules visits based on protocol windows and sends reminders. For example: *"When you enroll a subject, Cursor creates their entire visit schedule with allowed date windows. You'll get notified if a visit window is approaching its end. The system also sends SMS/email reminders to subjects before each visit, and alerts you if they confirm or need to reschedule."* Emphasize that this reduces no-shows and keeps visits on track.
- **Visit Checklist & Evidence Capture:** Highlight the day-of-visit mobile checklist. Explain that for each procedure or task during a visit, the coordinator can follow a step-by-step checklist on a tablet/phone, and **capture required evidence** (like taking a photo of a lab kit or a video of a consent process) directly in the app. This ensures protocol adherence and real-time data capture. We will note that evidence is time-stamped and stored securely, making monitoring easier.
- **Automated Task & Supply Prompts:** Explain how the platform reminds staff of prep tasks – e.g., "7 days before a visit, Cursor will prompt you to ensure lab kits and supplies are ready; 1 day before, it reminds you to prepare the room and equipment." Also mention automatic prompts for daily tasks like temperature logs or IP accountability checks. These proactive alerts prevent last-minute scrambles.
- **Integrated Payment Triggers:** Describe the feature where after a visit is completed, the system can prompt the coordinator to **request visit payments** – whether it's invoicing the sponsor/CRO or issuing participant stipends. For instance: *"Once you mark a visit complete, Cursor can remind you to send a stipend to the participant or to log the visit for sponsor billing, ensuring no visit payment is overlooked."* This is a unique value-add that streamlines financial tracking for the site.
- **Compliance & Audit Trail:** Reiterate that every action in Cursor is part of an **immutable audit trail** (who did what, when, on which record) and that electronic signatures are Part 11 compliant. On this page, we can be a bit more detailed: e.g., *"Cursor provides a full audit log and 21 CFR Part 11 compliant e-signatures, so you can confidently go paperless. Permissions are role-based, and all data changes are versioned for transparency [2]."* This assures users that while the system is easy to use, it's also inspection-ready.

Throughout the features page, use small subheadings and bullet points for each capability to keep it digestible. We want to avoid overwhelming text – focusing on the benefits of each feature in practical terms ("what it means for you as a coordinator"). User-centric language like "You get to…", "Your team can…" will keep it relatable. Additionally, maintain the clean design: plenty of white space, an uncluttered layout, and perhaps a consistent icon style for each feature category. This page solidifies *why Cursor is special*, backing the claims from the main landing page with specifics.

3.3 Demo/Trial Signup Page – "Get Started"

The third key landing page is aimed at conversion – getting interested site managers or coordinators to take the next step. This page should be simple and focused, with minimal distractions (consistent with our brand's clean design ethos). Key elements:

- **Concise Pitch:** A short header reinforcing the value: e.g., "Experience Cursor first-hand. See how you can simplify your study operations." Keep this to one or two brief sentences.
- **Demo Scheduling Form or CTA:** Prominently feature a way to schedule a demo or start a free trial. This could be an embedded scheduling widget (to pick a date/time for a live demo) or a contact form collecting basic info (name, email, site name, number of studies) with a "Request Demo" button. If free trials are offered, a "Start Your Free Trial" button could link to account creation.
- **Minimal Copy with Trust Cues:** We might include a few bullet points or a very short list of what the demo/trial will cover or the value they'll get ("In a 30-minute demo, see how Cursor's calendar and visit planner can save you hours each week"). Also, to encourage action, mention any trust signals near the form: e.g., "Trusted by [X] sites" or small logos of known clinics (if available), or simply a note like "No software install required. Your data is secure and HIPAA compliant." This assures them it's easy and safe to proceed.
- **Clean Layout:** No heavy paragraphs – likely a two-column design with a brief bit of text on one side and the form on the other on desktop (stacked vertically on mobile). Use the brand styling (minimalist, lots of white space). Remove any extraneous navigation on this page if possible to keep the user focused on completing the form.

The goal is to minimize friction. If possible, integrate this page with our CRM or scheduling tool so that once a demo is requested, both the user and our team get confirmations. A thank-you message or next steps info should be shown after form submission (e.g., "Thank you! A product specialist will reach out within 1 business day to confirm your demo."). In short, this landing page should convert interest into a tangible lead while reflecting the professional, clean image of Cursor.

4. Key Feature Highlights to Emphasize

To ensure consistency in both the marketing site and the application design, we have identified several **core features** that distinguish Cursor. These are the capabilities we will emphasize repeatedly (the "loud" features) because they directly address our users' needs and set us apart. We will weave these into website content, screenshots, and the app interface prominently:

- **Unified Multi-Study Calendar:** The heart of Cursor is a single calendar that shows all upcoming **visits, tasks, and deadlines across every active study** at the site. Site staff no longer need separate calendars or to mentally juggle schedules for different protocols [1]. This calendar is smart: it highlights what's due today, what's coming this week, and flags any visits at risk of missing their allowed window. It's color-coded by study and can be filtered by staff or resource, providing both a high-level overview and drill-down by study as needed. The calendar also integrates tasks like supply checks or temperature logs due on certain days, making it a centralized operations hub.
- **Automated Reminders & Notifications:** Cursor reduces the burden of manual follow-ups. It automatically sends **appointment reminders** to participants (via SMS/email) at configurable intervals (e.g., 7 days and 1 day before visits). It also notifies coordinators of critical events – such as a participant confirming or declining a visit (so staff can react immediately), or reminders to perform

site tasks (like “time to send that follow-up email” or “log tomorrow’s drug shipment”). These notifications are customizable but come with sensible defaults so sites can “set it and forget it.” By improving communication, Cursor helps achieve a ≥90% visit confirmation rate and timely task completion [3].

- **Visit Execution Checklist:** Every protocol has procedures to be done at each visit. Cursor provides a **digital checklist** for each visit, tailored to the specific study’s Schedule of Assessments. Coordinators can use a tablet or phone during the visit to check off each task (vitals, lab draw, questionnaire, etc.) as they complete it. Importantly, the checklist supports **evidence capture** – if a step requires a photo (say, of a used test kit or a completed paper form) or a timestamp or even a participant’s e-signature, the app prompts for it and attaches it to that step. This feature ensures nothing is missed during visits and creates a robust eSource record. It’s designed to be user-friendly with simple navigation through tasks, so coordinators can easily follow along even during busy visits.
- **Participant & Visit Management:** The platform simplifies the workflow from enrollment to visit completion. When a new subject is enrolled, Cursor automatically generates their visit schedule with target dates (based on the protocol timeline) and allowed date ranges. It tracks each subject’s status (screening, active, completed) in one place. Coordinators can easily reschedule visits within allowed windows through a friendly drag-and-drop or date-picker interface – rules and alerts ensure they don’t violate protocol timing. Additionally, after each visit, Cursor can trigger follow-ups like **marking visit outcomes, initiating participant reimbursement, and preparing data entry**. This comprehensive management means coordinators have a one-stop view of each subject’s journey without getting lost in multiple systems.
- **Task Dashboard & Alerts:** To prevent overwhelming the user with information, Cursor features a **daily ops dashboard** that pulls the most important to-dos into a simple list each day. For example, it might say: “Today: 3 visits scheduled, 2 temperature logs due, 1 drug shipment arriving.” This dashboard is the first thing a user sees on login. It provides direct links to perform each task (e.g., clicking a temp log task opens the logging form). The system also uses visual cues (badges, colors) to draw attention to overdue items or upcoming deadlines. By presenting a clear daily game plan, it ensures nothing falls through the cracks while avoiding the need for the user to dig through menus.
- **Clean, Intuitive Interface:** Across all features, one of Cursor’s hallmarks is a **clean UI design** that favors simplicity. We avoid cramming too many details on screen; instead, we show contextual information as needed. The use of whitespace and a limited color palette makes the interface less intimidating [3]. For instance, the default view might show each visit as a simple card with key info, and the user can click to expand for more details, rather than showing every data point in a giant table. This philosophy – “only what you need, when you need it” – runs through the product. As a result, new users can navigate easily, and experienced users can move fast without feeling lost in a maze of options.

These core highlights should be reflected not just in marketing copy but also in screenshots, demos, and training materials. They are the pillars that demonstrate how Cursor is different: unified, automated, user-friendly, and comprehensive for site operations.

5. Design & User Experience Principles

Our design approach for both the **marketing website** and the **application UI** is guided by modern, minimalist principles that align with our brand of simplicity and professionalism. Key UX/design principles include:

- **Minimalist Aesthetic:** We favor a clean, uncluttered look. This means ample white space, **limited color palette**, and simple, clear typography. By using only a few accent colors (aligned with our brand, e.g., a calming blue or green for highlights) and mostly neutral backgrounds, we ensure the interface looks modern and trustworthy. A minimalist design helps users focus on important content without distraction [3]. In practice, this might mean a lot of white or light backgrounds with occasional bright accents to draw attention to key buttons or alerts.
- **Consistency:** All pages and screens should follow a consistent style guide. Buttons, icons, and fonts will have standard sizes and colors. For example, all primary actions might use a specific bold color, while secondary actions are grey. This consistency helps users learn the interface faster since they can predict what elements do. It also extends to the marketing site – headings, text styles, and imagery should follow a coherent theme.
- **Responsive & Accessible Design:** The website and platform must be fully responsive (usable on various screen sizes from mobile phones to large monitors). Given that coordinators might use tablets on the clinic floor, the app UI needs to be touch-friendly with sufficiently large tap targets and responsive layouts. We also commit to accessibility best practices (clear contrast, alt text on images, support for screen readers) so that no user is left out. Simplicity in design naturally helps here, as fewer cluttered elements means easier navigation on all devices [4].
- **Focus on Functionality:** Design will never trump function. Graphics and animations are used sparingly and only if they serve a purpose (e.g., an icon next to each task in the checklist to indicate its type). We avoid decorative elements that do not provide information. Pages like the calendar or dashboard prioritize *at-a-glance information*: for instance, using readable color codes and icons to indicate visit status (confirmed, pending, completed) directly on the calendar entry. If an element doesn't help the user accomplish a task or understand something, we consider removing it. This aligns with our aim of not overwhelming users.
- **Intuitive Navigation:** Both the marketing site and the platform UI should have logical, shallow navigation structures to prevent users from getting lost in deep menus. On the website, this means a top menu with just a few items (e.g., Why Cursor, Features, Demo, Login) and perhaps footer links for secondary info. On the app, we will implement a clear menu (maybe a sidebar or top nav) with well-defined sections such as Dashboard, Calendar, Subjects, Documents, Settings. Wherever possible, we keep navigation to 1-2 levels deep. For example, under "Subjects" you might directly see a list of subjects; clicking one opens their profile rather than having 3 submenus. We also include quick-search and shortcuts for common actions (like a "+" button always available to add a new subject or log a temperature) to streamline workflow.
- **Visual Feedback & Clarity:** The UI should always give feedback on user actions. If a coordinator checks off a step in a visit checklist, the item visibly crosses out or changes color to indicate completion. If they schedule a visit, the new visit appears on the calendar instantly. Loading indicators and success messages are used consistently, so the user is never guessing if something happened. Clarity also means using plain language in the UI – e.g., avoid technical jargon on buttons; a button says "Send Reminder" instead of "Trigger Notification." Similarly, the marketing site uses non-technical language for broad appeal, except perhaps on a dedicated page for IT/compliance details.

By following these principles, we ensure that **the first impression is positive** – a site or app that looks clean and professional – and that everyday use remains **efficient and frustration-free**. The design and UX are critical in reinforcing our brand message: we make complex things simple.

6. Backend Functional Requirements & Modules

To support the rich front-end experience and ensure all promised features are delivered, the **backend system** will be robust and comprehensive. It must include **all necessary modules and workflows** to handle clinical study operations. Below is a breakdown of key backend functional areas (largely aligned with the previously defined requirements, ensuring "everything is included"):

- **User & Role Management:** Manage user accounts, roles, and permissions. This ties to the roles outlined (Site Manager, PI, CRC/CTA, CRA, etc.). The backend must enforce role-based access control so users only see and do what they're permitted (e.g., CRAs have read-only access to certain data). Admin interfaces to invite users, assign roles per study, and manage login credentials (including SSO integration) are required.
- **Study & Protocol Management:** Ability to create a new study in the system by uploading a protocol document. This triggers either an automated parsing workflow or manual configuration of the Schedule of Assessments. The backend should store study details (title, sponsor, phase, etc.) and version-controlled protocol documents. It should also support amendments (with version tracking of any changes to visits or procedures). Essentially, this is the **study setup module**, potentially leveraging an AI-assisted parser to read protocol documents and populate the schedule, which can then be edited and approved by the user.
- **Visit Scheduling & Calendar Engine:** The logic that calculates visit dates based on an index date (like enrollment or randomization date) and the protocol's timeline rules. It must enforce visit windows (earliest/latest allowed dates) and flag visits outside those windows. The calendar data model should allow viewing by study or all studies, and handle rescheduling logic (with reasons tracking). It also needs to detect conflicts (e.g., two visits needing the same equipment at the same time) and alert or prevent double-booking of resources. Recurring site-level tasks (like daily fridge log) are also part of this scheduling engine.
- **Subject Management:** Manage subject records for each study – including demographics (if collected), contact info, consent status, and linking to their series of visits. This includes tracking screening failures or withdrawals. The backend supports updating a subject's status (e.g., when they complete the study), and stores their eConsent forms and any other subject-specific documents. Each subject's data must be isolated per study for privacy.
- **Visit Execution & eSource Capture:** The system must allow creating **visit instances** from templates and then capturing data for each required procedure. This includes storing checklist definitions (what steps, what data or evidence is required) and recording results or evidence files uploaded. The backend should enforce required fields (e.g., cannot mark visit complete until all required steps are done or formally marked as skipped with a deviation reason). All captured data (vitals, images, notes) are stored as part of the eSource record, with proper audit trails. This module also covers **deviation logging** (when a procedure is not done as per protocol, record the reason) and electronic signatures at visit completion (PI sign-off).
- **Notifications & Reminders:** A module to manage outgoing communications and reminders. This involves templates for SMS/email (for subject reminders, staff alerts, etc.) with merge fields (like visit date). The backend should schedule these notifications based on rules (e.g., T–7 days, T–1 day relative to a visit) and handle responses (like a patient replying "YES" to confirm, which should

update attendance status). Integration with SMS/email gateways is needed here (see Integrations section). The module also handles daily summary notifications to staff (e.g., an email every morning listing tasks due). Logging of all notifications (what was sent, to whom, when, and delivery status) is important for audit purposes.

- **Supply & Equipment Tracking:** Manage an inventory list of site supplies (centrifuge, ECG machine, lab kits, etc.) and **per-visit supply checklists**. For each visit type, the system knows which supplies are needed (based on the procedures). It should alert if supplies are running low (inventory falls below threshold) or if a future visit requires something not currently in stock. There could be a simple inventory database in the backend and possibly the ability to log supply usage or receipts of new stock. While this might be a lighter module in MVP, it's important for the site to plan visits (e.g., ensure the lab kit for Visit 3 is available when scheduling Visit 3).
- **Investigational Product (IP) Management:** This includes logging drug shipments, current drug inventory by lot/kit, storage locations, and dispensing to subjects. The backend should support recording each IP **shipment** (with details like lot numbers, quantities, received date, who verified, and attach packing slips). It should track where IP is stored (which pharmacy or cabinet, temperature-controlled storage etc.), and maintain a chain-of-custody log when a dose is dispensed to a subject or returned. Temperature excursions for IP need to be captured and linked to CAPA (Corrective Actions). Essentially, this module ensures the site can account for every unit of investigational product – a regulatory requirement.
- **Temperature Logging:** Manage the daily temperature checks for refrigerators/freezers that store specimens or IP. The backend should store each temperature log entry (date/time, min/max/current temp, user, and possibly a photo of the thermometer reading). It should enforce schedule (e.g., if a log is due by 10:00 AM daily, flag if missed). If a temperature excursion (out of range) is recorded, the system should flag it and possibly trigger an incident workflow (assign follow-up tasks to investigate and resolve). The ability to generate **temperature reports** (PDF summaries with charts) is a plus for compliance records.
- **Document Management (Study Files & eReg Binder):** A repository for all study-related documents. This includes regulatory documents (protocol, IRB approvals, blank consent forms, training certificates, delegation logs, etc.) and any site records that need to be stored. The backend should organize documents in a folder structure by study, with role-based access (e.g., CRAs can only see certain folders). It should support version control (upload new version of a document while keeping old version with timestamp) and possibly digital signatures on documents if needed. Sharing documents securely with external monitors (read-only access or time-limited access links) is part of this.
- **Monitoring & CRA Portal:** Functionality to allow Clinical Research Associates (monitors) to remotely review certain data. The backend would define what data a CRA user can see for an assigned study – likely a subset such as: subject visit dates and status, signed consent PDFs, certain evidence (maybe snapshots of source data), and logs (temperature, IP accountability). This module might include a "query" feature where a CRA can flag a data point and ask the site for clarification. All interactions should be logged. The portal essentially mirrors some data in a read-friendly format without allowing changes.
- **Feasibility Questionnaire Automation:** Many sponsors send feasibility surveys to sites pre-trial. Our backend can help auto-fill these using a knowledge base of the site's capabilities and past performance. This involves storing data like "how many trials in oncology has this site done" or "how many patients can they recruit in X time." When a new questionnaire (possibly uploaded or templated) comes in, the system tries to map and answer from stored data. This is a more advanced module and uses data from other parts of the system (e.g., how many trials of a certain phase the

site has completed). It should allow manual review/edit by the site manager before exporting the final responses to send back to the sponsor.

- **Reporting & Analytics:** Provide dashboards and reports for key metrics. The backend should aggregate data such as: number of active subjects per study, visit adherence (how many visits happened on time vs late), number of open deviations, confirmation rates of visits, etc. These can feed into site performance KPIs like those in the original plan (visit confirmation ≥90%, etc.). The reporting module might allow site managers to run standardized reports or view graphs on their dashboard. It may also handle scheduled reports (like the weekly temperature log report, or a monthly enrollment report).
- **Audit Trail & Compliance:** Every significant action needs to be recorded in an audit log: who performed it, what changed (before/after values), timestamp, and from which IP or device. The backend must capture this systematically for all regulated data changes (subject data, visit data, document uploads, etc.). Additionally, the system must support **electronic signatures** that are Part 11 compliant – meaning when a PI signs off a visit or a document, it records the user's identity, date/time, and the meaning of the signature (e.g., "approved" or "acknowledged") and locks the record from further edits [2]. There should be functionality to review audit logs by authorized users and to generate an **audit report** if needed for an inspection.

In summary, the backend encompasses a full-fledged **Clinical Trial Management System (CTMS)** tailored for site use. It integrates study setup, scheduling, source data capture, regulatory compliance, and operational logistics into one system. By implementing all these modules, we ensure that the marketing promises (like "everything needed to run a study is generated") are technically fulfilled. The architecture (discussed in Section 8) will support these modules in a secure, scalable way.

7. Integrations

To maximize utility and adoption, Cursor's platform should **integrate seamlessly** with other tools and systems commonly used by sites and sponsors. Key integrations include:

- **Calendar & Productivity Tools:** Integrate with calendar applications like Outlook/Office 365 and Google Calendar. This would allow site staff to see their Cursor schedule alongside personal or hospital calendars if desired (likely by subscribing to an iCal feed for their study calendar). It can also block times on their work calendar for scheduled visits. Similarly, integration with task management tools (e.g., Microsoft To Do or Teams) could push daily task reminders to those platforms, but the primary need is calendar sync for visibility.
- **Communication (SMS/Email Providers):** As our notifications module sends SMS and emails, we need integration with reliable providers. For SMS, we might integrate with Twilio or a similar service for sending texts and processing replies. For email, integration with a service like SendGrid or use of an SMTP server for the site's organization can be options. These integrations should handle opt-outs and logging to comply with communication regulations (e.g., TCPA consent for texting participants).
- **Clinical Trial Platforms (EDC/ePRO):** Many sites use sponsor-provided Electronic Data Capture (EDC) systems (like Medidata Rave, Oracle InForm) and ePRO (electronic patient-reported outcomes) tools. Cursor should be able to **exchange data** with these when possible. For example, if a visit is marked complete in Cursor, it could send a flag to the EDC to indicate data ready for entry. Or if the EDC indicates a query, that could be shown in Cursor to alert the coordinator. Full integration might be complex, but even partial (like pulling subject IDs or pushing visit dates to the EDC) can reduce

duplicate data entry. We should use APIs if available, or at least allow exports in formats that can be uploaded to those systems.

- **Customer Relationship Management (CRM):** For our sales/marketing purposes (not directly the site's operations), integration with a CRM like Salesforce or HubSpot will help manage site leads who sign up for demos/trials on the marketing site. When someone fills the "Request Demo" form, the data should flow into our CRM for follow-up. This ensures no lead is dropped and we can track conversion metrics. On the platform side, a CRM integration is less critical, but if we consider sites as customers, having license management tied to CRM might be useful.
- **Scheduling & Video Conferencing:** If demos are to be scheduled automatically, integration with scheduling tools (e.g., Calendly or Microsoft Bookings) can make the demo scheduling seamless for the user. Also, for remote site initiation visits or training, integrating video conferencing (Zoom/Teams API) could be considered down the line, though not core to the MVP.
- **Electronic Regulatory (eReg) and Document Systems:** Some sites or sponsors use eTMF (electronic trial master file) systems. While Cursor has its own document module, providing an integration or export that aligns with the DIA TMF Reference Model could be helpful. For example, the ability to export all documents for a study in a structured ZIP for upload to an eTMF. Similarly, integration with cloud storage (SharePoint, Box) if a site wants copies of documents elsewhere might be considered.
- **Identity Providers (SSO):** Support single sign-on via SAML or OIDC (Okta, Azure AD, etc.) for larger organizations that want to manage user access centrally. This is especially relevant for hospital-based sites or academic centers where staff accounts are centrally managed. Integration with an IdP also improves security with things like MFA, which is often required.
- **Device Integrations:** To streamline data capture, integrate with devices such as digital thermometers (for automatic temperature logging), barcode scanners (for quick entry of kit numbers or subject IDs), and possibly medical devices (e.g., sync vital sign data from a Bluetooth blood pressure cuff into the checklist). These integrations can often be achieved via companion mobile apps or APIs from device management platforms. While not all will be built in MVP, designing the backend with an API-first approach will make it easier to plug these in.

All integrations must be implemented in a secure and privacy-conscious way (e.g., PHI should not be transmitted to third-party tools without proper safeguards or agreements). The "both" in the requirements indicates we indeed plan to cover **both internal (site-facing) integrations and external (sponsor/CRM facing) integrations**. This dual approach ensures Cursor can fit into existing workflows, rather than forcing users to switch entirely. In technical terms, having a robust API layer for Cursor will facilitate many of these integrations. Where real-time integration is not feasible, providing import/export functionality (e.g., CSV uploads, calendar feeds) as interim solutions is acceptable.

8. Technical Architecture & Compliance Considerations

Scalability & Architecture: The backend will be built with a modern, scalable architecture to support multiple sites (multi-tenant), ensure performance, and maintain data isolation. We plan a cloud-based deployment using a modular microservice or tiered design: e.g., a web application server (for API and

business logic), a database (PostgreSQL for transactional data), and an object storage service for files (for photos, PDFs, etc.). Key components:

- **API-First Design:** All functionality will be exposed via secure APIs (REST/GraphQL) that the front-end web and mobile apps use. This also means external integrations can use these APIs. Authentication and authorization will be enforced at the API level (using tokens, scopes for different roles).
- **Database Design:** A robust relational database to store study data, with proper indexing to handle calendar queries and audit logs efficiently. We will use separate schemas or at least tenant IDs to segregate data by site, ensuring one site cannot accidentally access another's data.
- **Media & File Storage:** All uploaded files (photos, videos from evidence, documents) will be stored in an encrypted form in a secure object store. We'll generate thumbnails or compressed versions for quick viewing in-app as needed, to optimize performance. Files will be tagged with metadata (which study, subject, visit they belong to) for easy retrieval.
- **Performance & Caching:** Use caching (like Redis) for frequently accessed data (e.g., the daily dashboard info, or calendar for the week) to keep the app responsive. Background workers will handle heavy tasks (like generating a large PDF report or parsing a long protocol document) so that the user isn't kept waiting and the system can scale under load.

21 CFR Part 11 Compliance: As a system intended for regulatory work, we design compliance into every layer. Concretely, to comply with Part 11 and similar regulations, the system will [2]:

- **Validation:** We will have documented software validation (testing) for all features to ensure the system works as intended. This includes IQ/OQ/PQ in a formal manner as part of our development lifecycle (per Section 12 of the original plan).
- **Security & Access Control:** Each user has a unique account. Access is limited by roles and additional safeguards like password policies and optional two-factor authentication. Admins can inactivate accounts or reset passwords as needed. The system also auto-logs off users after periods of inactivity to prevent unauthorized use.
- **Audit Trails:** Every create/update/delete of regulated records generates an audit record that includes timestamp, user ID, what was changed (before/after if applicable). These audit logs are immutable (write-once) and can be extracted in human-readable form for inspections.
- **Electronic Signatures:** When a user provides an electronic signature (for example, PI sign-off on a completed visit or signing an electronic consent form), the system will record the meaning of the signature (e.g., "Investigator's approval of data"), attach a timestamp, and require a password re-entry to affirm identity. This meets the FDA requirements that e-signatures are legally binding and tied to a specific individual.
- **Data Integrity & Backup:** All data is stored in servers with automatic backups and redundancy. We implement write protections such that once a record is finalized (e.g., a signed consent PDF or a completed visit checklist), it cannot be altered – any subsequent change (like a correction) has to be appended as a new record with proper justification. Regular backups and disaster recovery plans will be in place to prevent data loss.
- **Privacy (HIPAA/GDPR):** Since we handle PHI (e.g., subject contact information, health data in checklists), we will ensure encryption of data at rest and in transit (TLS for all network communication). Access to PHI is restricted and logged. We provide features like the ability to redact or delete subject personal data if required (for GDPR compliance on data subject rights, within regulatory constraints). Business Associate Agreements (BAA) will be in place with any service providers (e.g., cloud hosts) that might encounter PHI.

Support & Maintenance: The backend will include an admin console for system administrators to monitor system health, manage configurations (like adding a new permitted email/SMS gateway or adjusting integration keys), and support deployments of new versions. We'll implement comprehensive logging and monitoring (using tools for error tracking, performance metrics) so that issues can be detected and resolved quickly. Given the critical nature of clinical operations, we aim for high uptime and will communicate any maintenance windows in advance.

In summary, the technical backend is designed not only for functionality but with an eye toward **regulatory compliance, data security, and reliability**. This "deep backbone" will reassure both site users and their sponsors that adopting Cursor is a safe choice that meets industry regulations. It's the unseen engine that powers the intuitive front-end experience. By aligning our architecture with compliance requirements from the start, we avoid costly retrofits and earn user trust.

By implementing this playbook, Cursor will deliver a cohesive experience: an inviting marketing presence that clearly communicates our strengths, and a powerful yet user-friendly platform that revolutionizes site study management. Every element, from branding to features to technical infrastructure, is aligned with the goal of making clinical research sites more efficient, compliant, and happy in their day-to-day work.

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1 Navigating the Maze: The Daily Challenges of a Clinical Research Coordinator
https://www.proofpilot.com/blog/navigating-the-maze-the-daily-challenges-of-a-clinical-research-coordinator

2 21 CFR 11 Compliance at Investigator Sites
https://www.appliedclinicaltrialsonline.com/view/21-cfr-11-compliance-investigator-sites

3 4 Best Minimalist Website Examples + Why Choose Minimal Design
https://www.hostinger.com/tutorials/minimalist-website-examples