eDiaries in Clinical Trials: A Guide to Best Practices

By Adrien Laurent, CEO at IntuitionLabs • 11/25/2025 • 35 min read

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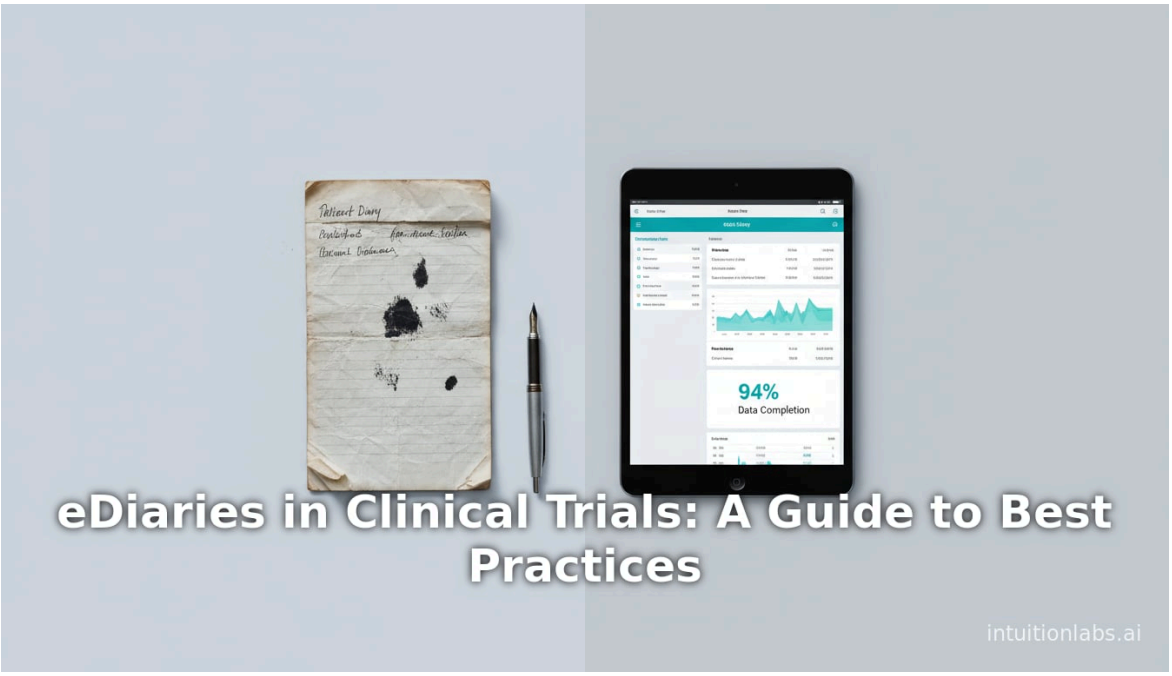

Executive Summary

Electronic diary (eDiary) systems have become increasingly central to modern clinical trial data collection, complementing or replacing traditional paper diaries for capturing patient-reported outcomes (PROs) and safety events. Extensive evidence shows that eDiaries dramatically improve data quality and compliance compared to paper diaries ([1] www.appliedclinicaltrialsonline.com) ([2] pmc.ncbi.nlm.nih.gov). For example, multiple studies have found that paper diaries suffer from severe underreporting and bias (often termed the "parking lot effect"), whereas eDiaries can enforce timely, in-the-moment reporting ([2] pmc.ncbi.nlm.nih.gov) ([3] pmc.ncbi.nlm.nih.gov). Regulators including the FDA and ICH explicitly endorse electronic capture of critical trial data, emphasizing ALCOA+ principles (Attributable, Legible, Contemporaneous, Original, Accurate) to ensure data integrity ([4] pmc.ncbi.nlm.nih.gov) ([5] www.appliedclinicaltrialsonline.com).

This comprehensive report reviews best practices for designing, implementing, and managing eDiary data collection in clinical trials. We begin with historical context and motivation, then detail technical and procedural standards (hardware platforms, software design, scheduling, training, monitoring, data management and compliance) that underlie successful eDiary use. The benefits of eDiaries (high compliance, real-time data, reduced recall bias) are balanced against challenges (participant engagement, technology barriers, privacy/security). Numerous case studies highlight real-world applications in rheumatology, vaccine trials, diabetes management, oncology, and rare diseases, illustrating how eDiaries have been optimized to fit each trial's needs. Finally, we discuss future directions (BYOD, wearables, AI analytics) and regulatory trends, emphasizing that, when properly implemented, eDiaries can markedly enhance trial data quality while reducing costs and burden ([6] pmc.ncbi.nlm.nih.gov) ([7] pmc.ncbi.nlm.nih.gov).

Introduction

Patient diaries have long been a cornerstone of clinical trial data collection, particularly for endpoints that depend on patients' own observations (e.g. symptom logs, medication logs, event counts). Subject diaries capture "medical moments" – the patient's experience required by the protocol – at the time those events occur in daily life ([8] www.appliedclinicaltrialsonline.com) ([9] www.appliedclinicaltrialsonline.com). Traditional paper diaries were widely used (in roughly 25% of trials ([10] www.appliedclinicaltrialsonline.com)), but empirical studies have repeatedly shown that paper diaries are plagued by inaccuracies: subjects often fill them in spurts retrospectively ("parking lot effect") or even fabricate entries ([1] www.appliedclinicaltrialsonline.com) ([2] pmc.ncbi.nlm.nih.gov) ([3] pmc.ncbi.nlm.nih.gov). For example, one seminal study using light sensors found that although patients reported 90% paper diary compliance, the true timestamp-recorded compliance was only 11% ([2] pmc.ncbi.nlm.nih.gov). These issues led to recognition that paper diaries often violate Good Clinical Practice (GCP) and 21 CFR Part 11 expectations for data integrity ([1] www.appliedclinicaltrialsonline.com) ([5] www.appliedclinicaltrialsonline.com).

In response, clinical researchers adopted electronic patient diaries (eDiaries) using technologies such as interactive voice response (IVR), handheld computers (PDAs), and more recently smartphones and tablets. eDiaries automatically timestamp entries, enforce recording windows, and upload data in real time, thus eliminating many paper diary issues ([11] www.appliedclinicaltrialsonline.com) ([2] pmc.ncbi.nlm.nih.gov). Regulatory agencies have endorsed this shift: a 2025 guidance notes that eCOA (electronic clinical outcome assessment) systems – including eDiaries – streamline data collection and improve quality ([12] www.jscdm.org). The rationale is twofold. First, eDiaries capture PROs contemporaneously, reducing recall bias and missing data ([13] pmc.ncbi.nlm.nih.gov) ([2] pmc.ncbi.nlm.nih.gov). Second, they support ALCOA+ data stewardship (including audit trails and security) to satisfy ICH GCP and FDA requirements ([4] pmc.ncbi.nlm.nih.gov) ([5]

www.appliedclinicaltrialsonline.com). Indeed, ICH GCP explicitly classifies patient diaries (electronic or paper) as source documents that must be preserved with the trial file ([5] www.appliedclinicaltrialsonline.com).

While the promise of eDiaries is clear, achieving their full benefit requires careful planning and adherence to best practices at every stage – from study design to deployment and monitoring. This report synthesizes literature, regulatory guidance, and published case studies to delineate those best practices. We cover technical considerations (device selection, user interface, connectivity), human factors (training, engagement, compliance strategies), data management (real-time monitoring, database integration, validation), and operational aspects (site roles, patient support, regulatory compliance). We also highlight empirical data on eDiary performance and patient satisfaction, and examine multiple perspectives (e.g. sponsors, sites, patients). Wherever possible, claims are supported by published evidence or expert consensus ([1] www.appliedclinicaltrialsonline.com) ([4] pmc.ncbi.nlm.nih.gov) ([7] pmc.ncbi.nlm.nih.gov) ([14] pmc.ncbi.nlm.nih.gov). Through this comprehensive analysis, readers will gain a deep understanding of how to effectively create and collect eDiary data that is accurate, complete, and compliant. </current_article_content>

Background: Diaries in Clinical Trials

The Role of Diaries and PROs

Subject diaries enable direct capture of patient experiences between clinic visits, providing insight beyond standard clinical assessments ([15] www.appliedclinicaltrialsonline.com) ([16] www.appliedclinicaltrialsonline.com). They are especially critical when endpoints rely on symptoms or events known only to the patient (e.g. pain intensity, migraine frequency, daily activity restrictions) ([17] www.appliedclinicaltrialsonline.com) ([18] pmc.ncbi.nlm.nih.gov). The ICH Guideline for GCP (Section 1.52) explicitly cites patient diaries as source documents ([19] www.appliedclinicaltrialsonline.com): data entered in the patient's diary is considered original "source data" that inform case report forms (CRFs). This places on investigators the responsibility to ensure accuracy, completeness, and archiving of diary data ([5] www.appliedclinicaltrialsonline.com) ([16] www.appliedclinicaltrialsonline.com).

While patient diaries can capture rich data, they also introduce methodological challenges. Paper diaries encourage patients to aggregate or delay recordings. For instance, paper designs often ask for once-daily end-of-day summaries, requiring retrospective recall of multiple events ([20] www.appliedclinicaltrialsonline.com). As highlighted by Paty et al., such designs are "vulnerable to recall-based bias and error," since even short recall periods can be inaccurate ([20] www.appliedclinicaltrialsonline.com). Indeed, the classic "parking lot effect" describes patients filling out days of missed entries en masse just before a clinic visit ([21] pmc.ncbi.nlm.nih.gov) ([3] pmc.ncbi.nlm.nih.gov). If data are missing or mis-timed, trial conclusions may be skewed.

The advent of eDiary (electronic patient diary) technology aimed to overcome these issues. Early systems used pagers, PDAs, or IVR to prompt entries, but today most eDiaries are smartphone or web-based apps ([22] www.appliedclinicaltrialsonline.com) ([14] pmc.ncbi.nlm.nih.gov). With eDiaries, patients can report events in real time, and systems can enforce protocol rules (proper timing, data completeness, restricted editing) through programming ([23] www.appliedclinicaltrialsonline.com) ([13] pmc.ncbi.nlm.nih.gov). In effect, eDiaries transform diaries from passive paper logs into active data capture instruments with built-in controls and reminders.

Regulatory and GCP Considerations

Regulatory guidance uniformly recognizes the value of electronic data capture. The FDA explicitly endorses electronic PRO collection, noting that it often yields "more accurate and complete data capture, improved

compliance, and patient acceptance compared with paper-based methods" ([24] pmc.ncbi.nlm.nih.gov). For example, an RA trial publication observes that "the US Food and Drug Administration has endorsed electronic capture of clinical trial data including PROs" ([24] pmc.ncbi.nlm.nih.gov). The FDA's 21 CFR Part 11 final rule (Electronic Records; Electronic Signatures) applies to eDiaries as electronic records, requiring audit trails, security controls, and system validation ([25] www.appliedclinicaltrialsonline.com) ([26] pmc.ncbi.nlm.nih.gov). Similarly, ICH GCP Section 4.9 mandates that investigators ensure data are recorded, handled, and stored "accurately, legibly, and in a timely manner" ([27] www.appliedclinicaltrialsonline.com) whether collected on paper or electronically.

Crucially, both regulators and GCP treat patient diaries (electronic or otherwise) as source documents ([5] www.appliedclinicaltrialsonline.com) ([16] www.appliedclinicaltrialsonline.com). This means that diary entries are the primary evidence of patient-reported events; CRFs are secondary transcriptions if used at all. Consequently, any eDiary system must produce certified, archivable records. For example, Applied Clinical Trials notes that sponsors must remember "the diary data is source data and belongs with the investigator under ICH GCP" ([28] www.appliedclinicaltrialsonline.com). At trial close, certified copies of all eDiary data should be delivered to investigators for retention and audit purposes ([28] www.appliedclinicaltrialsonline.com).

eDiary systems must also comply with privacy laws (HIPAA, GDPR, etc.) when handling patient-identifiable information. Strong encryption and access controls are mandatory to prevent unauthorized access, and participant consent should address electronic data capture. ([26] pmc.ncbi.nlm.nih.gov) ([29] pmc.ncbi.nlm.nih.gov). In sum, adopting eDiaries entails aligning technical capabilities with the rigorous documentation standards of clinical research, but when done properly it fulfills and often exceeds regulatory requirements for data quality.

Historical Perspective: From Paper to Mobile

Figure 1 illustrates the evolution of patient diaries in trials: starting with **paper diaries** (cards/booklets, widely used in late 20th century), to **electronic devices** (pagers, PDAs, IVR systems in the 2000s), and now **smartphone/tablet apps (eDiaries)** in the 2010s–2020s. Early industry reports noted that paper diaries "were not completed in a timely manner" ([1] www.appliedclinicaltrialsonline.com), prompting the first wave of electronic diaries (handheld PDAs, IVRS) which provided audible alarms and prompts. By the 2010s, smartphones became ubiquitous, enabling Bring-Your-Own-Device (BYOD) approaches in which patients use their own devices to enter study data. This major shift, often called eCOA (electronic Clinical Outcome Assessment), greatly expanded diary flexibility ([14] pmc.ncbi.nlm.nih.gov).

Across these generations, each technology aimed to improve compliance. For instance, preliminary trials with PDAs demonstrated >90% compliance ([2] pmc.ncbi.nlm.nih.gov), leading to wider acceptance. Current eDiary platforms include cloud-based portals, configurable questionnaires, and instant sync features that were unimaginable with paper diaries. The cumulative effect is that patient diaries, once constrained by memory and form factors, have become powerful, patient-friendly data capture tools.

Key Considerations in eDiary Design and Deployment

The successful creation and collection of eDiary data depend on rigorous attention to both **technology** and **process**. Key factors include device selection, software design, reminder systems, content validity, participant training, real-time monitoring, and data handling. We outline best practices below, grouped by major subtopic.

Choice of eDiary Platform and Device

Technology Platform

Reputable eDiary systems today typically leverage either dedicated devices (study-provided PDAs/tablets) or participant-owned devices (BYOD). Smartphones are by far the most common platform ([14] pmc.ncbi.nlm.nih.gov), reflecting their ubiquity and computing power. Table 1 (below) from Daniëls et al. shows 64% of eDiary studies used smartphones, 14% used dedicated palmtops, and 22% used tablets ([14] pmc.ncbi.nlm.nih.gov).

Advantages of BYOD: BYOD approaches let patients use their own phones, reducing the cost/logistics of device distribution and often improving user comfort ([30] pmc.ncbi.nlm.nih.gov) ([31] pmc.ncbi.nlm.nih.gov). Modern smartphone apps can run on iOS, Android, or web browsers, and allow participants to enter data anytime, anywhere ([30] pmc.ncbi.nlm.nih.gov). Flexible platforms can also support offline data entry and later sync, which is important in regions or settings with spotty connectivity ([32] pmc.ncbi.nlm.nih.gov). For example, ensuring offline functionality means patients can record entries without internet and the app will upload automatically later ([32] pmc.ncbi.nlm.nih.gov).

Challenges of BYOD: Not all participants may have a compatible device or may share it with others. Multiple operating systems (OS) introduce validation complexity. Sponsors must ensure that each device meets security requirements and that data are encrypted end-to-end. Usability must be robust across screen sizes. Some trials still prefer to provision devices to guarantee uniform performance and to provide visible reminders (like wearing a study phone with an alert).

Commercial eDiary systems: Many trials rely on specialized eCOA vendors. These platforms (e.g. DataLabs, CRFweb, Kayentis, Signant, etc.) offer configurable modules for diaries, often compliant with 21 CFR 11. Best practice is to choose a validated system known to meet regulatory requirements. During system selection, focus on: platform stability, security audit history, user interface design, and vendor support (see below).

User Interface and Accessibility

The eDiary's user interface (UI) must be intuitive for participants of varying technical skill. Key UI decisions include font sizes, language localization, touch/click design, and overall look-and-feel ([33] pmc.ncbi.nlm.nih.gov) ([32] pmc.ncbi.nlm.nih.gov). For example, as recommended in Table 1, eDiary platforms should allow multiple font sizes and languages, and be screen-reader compatible for visual impairments ([33] pmc.ncbi.nlm.nih.gov) ([32] pmc.ncbi.nlm.nih.gov). The login and sign-on screens should be simple; avoid confusing navigation paths.

Modern best practice also involves **usability testing** with representatives of the trial population during development. For instance, NRC5210249 (Signant Health) suggests piloting diary screens in pilot subjects, adjusting phrasing (e.g. "click" vs "tick") and graphics to ensure clarity ([34] www.jscdm.org). Infographics and color coding can help indicate completion status. Consider contextual help text for complicated items.

Another UI element is **reporting windows** or timing options. In some RA trials ([35] pmc.ncbi.nlm.nih.gov), devices had pre-set 5-hour windows in which patients could make entries, with microphones sounding an alarm if missed. This approach balances recall with convenience: patients know they must report once per day within a chosen 6-hour block, preventing 24-hour recall bias while accommodating schedules. Similarly, fixed time windows (e.g. morning and evening) or random EMA prompts can be programmed. The key is to **minimize recall bias** by enforcing timely, timestamped reporting ([20] www.appliedclinicaltrialsonline.com) ([13] pmc.ncbi.nlm.nih.gov).

Diary Content and Schedule

Defining Diary Content

The actual questions and scales in the diary must reflect the study's objectives while being easy for participants. This involves careful item construction: simple language, thread logic, and appropriate scale types (numeric, categorical, VAS, etc.). For PRO diaries, items may cover symptom severity, functional status, medication intake, or adverse events. As Table 1 advises, use clear and plain language to make participants comfortable ([36] pmc.ncbi.nlm.nih.gov).

When converting a validated paper instrument to digital form, some edits may be needed. For example, instructions like "please tick the box" should become "please select" for touchscreens ([37] www.jscdm.org). Also ensure that any modifications (editing or deleting responses) follow validation protocols. Typically, electronic diaries do not allow forward/backward entry beyond the open window to prevent retrospective data entry ([38] pmc.ncbi.nlm.nih.gov) ([9] www.appliedclinicaltrialsonline.com).

Schedule and Frequency

The diary schedule––how often participants must enter data––is crucial. It should balance scientific need against burden. eDiary schedules vary from **event-driven entries** (e.g. record when a symptom occurs) to **fixed-interval entries** (e.g. daily or weekly logs) to **experience sampling/EMA** (multiple times per day) ([31] pmc.ncbi.nlm.nih.gov). Figures from the literature show diaries used as often as 12 times per day in EMA contexts, or as infrequently as weekly on long studies ([31] pmc.ncbi.nlm.nih.gov).

Best practice is to tailor the schedule to the endpoints. For acute symptom diaries (like vaccine adverse reactions), daily reporting for the first 7–14 days may be prescribed. For chronic symptom diaries (like end-of-day pain scoring in RA), a daily once-per-day entry may suffice ([24] pmc.ncbi.nlm.nih.gov) ([13] pmc.ncbi.nlm.nih.gov). In selecting a schedule, consider factors like symptom variability and participant fatigue. Clear guidance on *when* to report is essential (morning vs evening, relative to dosing, etc.), and this should be specified in the protocol and training. Some studies offer *reporting windows* (as noted above) to give flexibility while controlling recall.

Compliance and Reminders

Even with smartphones, patient compliance with diaries cannot be assumed. Proactive reminder and alert systems are critical. Table 1 recommendations include sending **automated reminders/alerts to participants** when an entry is due, and **notifications to study staff** if noncompliance occurs ([39] pmc.ncbi.nlm.nih.gov) ([40] pmc.ncbi.nlm.nih.gov). Examples might be an app push notification or text at the start and end of each reporting window. If a participant misses 1 day, the app might send a reminder; if they miss multiple days, the system should notify the site for intervention ([41] pmc.ncbi.nlm.nih.gov).

In practice, many eDiary systems implement:

- **Participant reminders**: alarms, notifications, or text messages reminding completion (some apps allow visually appealing calendar reminders).
- **Staff alerts**: dashboards or email summaries listing patients who are late, so coordinators can follow up quickly ([41] pmc.ncbi.nlm.nih.gov) ([39] pmc.ncbi.nlm.nih.gov).
- **Escalation triggers**: highest-grade events (e.g. grade≥3 symptom) can generate real-time alerts to investigators for safety management ([42] pmc.ncbi.nlm.nih.gov).

Empirical evidence shows these strategies boost compliance. In the baricitinib RA trials, any patient missing 3 consecutive days of diary entry generated an automated email to the site, enabling immediate contact ([41] pmc.ncbi.nlm.nih.gov). As a result, those trials achieved astonishingly high compliance (>93%) over 12 weeks ([7] pmc.ncbi.nlm.nih.gov). By contrast, studies lacking such monitoring have seen diurnal entry rates drop over time. Regular monitoring (often weekly or daily) should thus be built into trial SOPs.

Participant Training and Engagement

Training Participants

Human factors are paramount. Subjects should never be expected to use complex technology without orientation. Best practice includes hands-on training at the baseline visit: ideally one-on-one instruction on how to launch the app/device, log in, navigate the diary, and interpret questions. Provide simple printed or digital **Quick Start Guides** for reference ([43] pmc.ncbi.nlm.nih.gov) ([40] pmc.ncbi.nlm.nih.gov). Include troubleshooting tips (e.g. what to do if device battery dies). Training should emphasize the *why*: explain the importance of timely reporting and how diaries contribute to study goals ([44] pmc.ncbi.nlm.nih.gov).

Whenever possible, simulate a real entry during training: have the subject practice recording a mock diary event. This reinforces learning and builds confidence. If the study population includes older adults or those with impairments, allow extra practice. Some trials have found that linking diaries to styluses or large-font modes can help subjects with dexterity or vision issues ([45] pmc.ncbi.nlm.nih.gov).

Training Study Staff

Sites and coordinators must also be proficient. Staff need to know how to set up participant accounts, program reporting schedules, and react to noncompliance alerts. Formal training sessions (possibly video modules) for site personnel on the eDiary platform are essential ([46] pmc.ncbi.nlm.nih.gov) ([47] pmc.ncbi.nlm.nih.gov). Backup staff should be trained too, to cover staff turnover. Clear SOPs should outline staff responsibilities for setting up new diaries, checking data sync, and handling queries. This minimizes downtime and data loss.

Sites should also be coached on patient communication. Staff should explain the study diaries sensitively (especially if the symptoms are burdensome topics). Encouraging patients, addressing concerns quickly, and acknowledging their input (as feasible) can greatly enhance engagement ([48] pmc.ncbi.nlm.nih.gov). The Signant guide echoes this by exhorting that participants be “educated on the importance of reporting participants on time and accurately” ([49] pmc.ncbi.nlm.nih.gov).

Sustaining Engagement

Engagement doesn’t end after training. The sense of contributing value can motivate patients. Some trials provide periodic progress feedback (e.g. “you’ve completed 3 weeks of diaries” congratulatory messages) or small incentives tied to completion milestones (in accordance with ethics rules). Table 1 advises giving participants regular feedback and acknowledging their contributions ([50] pmc.ncbi.nlm.nih.gov). For instance, simple thank-you notes or FAQs updates can go a long way. Collecting participant feedback as the trial progresses can also highlight pain points in the diary process (such as confusing questions) allowing mid-study improvements (via amendments or system tweaks where possible).

Technical Implementation and Data Management

System Validation and Compliance

Any eDiary system used in a trial must be validated to meet regulatory standards for **electronic records**. Per 21 CFR Part 11 and ICH GCP, the system should have documented testing showing it works as intended (Functionality verification, data accuracy). It must include an audit trail to record all data entries and modifications ([25] www.appliedclinicaltrialsonline.com). Access to the system should be restricted to authorized users (with unique logins) and all changes (such as late entries or corrections) should be logged, ensuring data remain attributable ([4] pmc.ncbi.nlm.nih.gov) ([25] www.appliedclinicaltrialsonline.com).

Security is equally critical. The data must be encrypted both in transit and at rest, with secure hosting (often via ISO-certified cloud servers). Regular backups are essential to prevent data loss. Standard "ALCOA+" practices should guide all design: for example, eDiary fields can enforce mandatory responses (improving completeness) and range checks (avoiding implausible values) ([29] pmc.ncbi.nlm.nih.gov). In short, treat the eDiary system with the same rigor as an EDC database, since patient data flow through it.

Sponsors should maintain an audit-ready environment: access logs, training records, SOPs, and validation reports should all be archived. The workflow typically involves: defining user requirements (aligned with the protocol), an eDiary functional spec, vendor development, and a formal User Acceptance Testing (UAT) by the study team. Any changes after go-live require documentation in change control logs.

Data Flow and Integration

A well-designed eDiary pipeline ensures seamless data movement from participant to database, with transparency for monitors. Typically, data captured on the device are stored locally and uploaded to a central server (e.g. overnight sync via cellular or Wi-Fi) ([51] pmc.ncbi.nlm.nih.gov). The centralized eDiary database should provide role-based access: clinical monitors, data managers, and investigators can view compliance and content.

It is advantageous if the eDiary database can interface with the main Clinical Data Management System (CDMS or EDC) or produce exports in standard formats (e.g. CDISC ODM). This reduces transcription errors and facilitates combined analysis. Some setups push eDiary data directly to the EDC (via API or SFTP), updating CRF fields automatically. Others maintain a separate repository, requiring periodic merging of data streams. Either way, be sure to plan and test the data transfer pipeline well before first patient in.

Real-time monitoring dashboards are a best practice. For example, Invivodata's EPX system (used in [18]) allowed sites to "manage patients' data, monitor PRO compliance, and view and print reports" ([52] pmc.ncbi.nlm.nih.gov). In practice, a data manager or CRA might generate weekly eDiary compliance reports from the system to identify outliers or trends. Missing entries can be flagged for data queries or patient calls. The faster data appear (ideally daily), the sooner issues can be resolved.

Handling Missing and Erroneous Data

Despite best efforts, missing entries will occur. The approach to missing data should be specified in the protocol and statistical analysis plan. Common strategies include imputation rules (e.g. last observation carried forward is generally discouraged for PROs due to bias). The eDiary can help prevent problems up front: mandatory fields reduce missingness, but if a participant truly missed a day, the system can prompt for a comment (e.g. "Why did you miss yesterday's entry?") for documentation, though this should be handled carefully to avoid influencing data.

For implausible values (e.g. numerical outliers), while front-end checks help, queries may still be needed. However, intervention should not break the diary's timestamp integrity. If a site needs to correct a subject's entry (by rare necessity), this typically involves a documented query and re-entry under a new timestamp, preserving the original data in the audit trail. These procedures must be spelled out in the data management plan and aligned with Part 11 guidance on eSignature (if any).

Overall, data managers should regularly review eDiary data quality metrics: completion rates, timestamps consistency, and error rates. Any patterns suggesting misunderstandings (e.g., all patients entering "0" for severity) may indicate a need for clarification. Table 1's data quality element highlights monitoring for incomplete or implausible entries as a key consideration ([53] pmc.ncbi.nlm.nih.gov).

Case Studies and Examples

To ground the above principles, we examine several published case studies where eDiaries were implemented in actual trials. These examples illustrate the diversity of applications and specific measures taken to optimize eDiary data collection.

Trial/Condition	Diary Type	Participants/Design	Key Outcomes	Reference
Rheumatoid Arthritis (RA)	Handheld eDiary (Invivodata PDAs)	2 phase3 RCTs (RA-BEAM, RA-BUILD); ~2000 pts total	Very high diary compliance (94% and 93% through 12 weeks); fewer missing data; led to richer PRO data ([7] pmc.ncbi.nlm.nih.gov) ([54] pmc.ncbi.nlm.nih.gov). Timed tasks **windowed entries** and alarms; cellular data upload.\	RA-BEAR trial (Verrapps et al. 2019) ([7] pmc.ncbi.nlm.nih.gov) ([54] pmc.ncbi.nlm.nih.gov)
Multiple Sclerosis (MS)	Smartphone app (MyMS&Me) eDiary	117 MS patients (eDiary vs control)	No significant difference between eDiary and control groups in long-term adherence (poor adherence ~10-13% in both arms) ([55] pmc.ncbi.nlm.nih.gov). Highlights complexity of changing behavior even with reminders.	Golan et al. 2020 ([55] pmc.ncbi.nlm.nih.gov)
Type 2 Diabetes	PDA eDiary (3 different vendors)	4 trials; 131 site coordinators surveyed	Site coordinators rated eDiary usability; satisfaction varied by system. Vendor A mean score 7.2/10 (> system C's 3.4) ([56] pmc.ncbi.nlm.nih.gov). Major factors: ease of use, tech support, web portal user-friendliness ([56] pmc.ncbi.nlm.nih.gov).	Jhaveri et al. 2007 ([57] pmc.ncbi.nlm.nih.gov) ([56] pmc.ncbi.nlm.nih.gov)
Vaccine Safety	Mobile eDiary (web app)	Various vaccine trials (solicited and unsolicited ARs)	eDiaries ensured ALCOA compliance and higher data quality. Strategies (UI, training, reminders) were outlined to optimize diaries (see Table 1).	Nukala et al. 2025 ([13] pmc.ncbi.nlm.nih.gov) ([33] pmc.ncbi.nlm.nih.gov)

Trial/Condition	Diary Type	Participants/Design	Key Outcomes	Reference
Adolescent Oncology	Mobile eDiary (custom symptom app)	10 adolescents with cancer (3-wk pilot)	Very high adherence: >90% of daily entries completed over 3 weeks ([58] pmc.ncbi.nlm.nih.gov). Participants reported the app easy to use; symptom data variability captured.	Baggott et al. 2012 ([58] pmc.ncbi.nlm.nih.gov)
Sickle Cell Disease (Pregnancy)	Smartphone eDiary app (SMART tool)	40 pregnant SCD women, Ghana (6m antepartum to 9m postpartum)	71.5% of expected entries completed; found 1.85× higher pain rate during pregnancy vs post-partum ([59] pmc.ncbi.nlm.nih.gov). FDA/ASH recommends eDiaries for at-home pain assessment ([60] pmc.ncbi.nlm.nih.gov). High participation (95%).	Asare et al. 2025 ([59] pmc.ncbi.nlm.nih.gov) ([60] pmc.ncbi.nlm.nih.gov)

These examples show eDiaries used for efficacy (RA pain/morning stiffness), safety (vaccine reactogenicity), adherence (MS, diabetes), and general symptom tracking (cancer, SCD). Key lessons include the effectiveness of daily reminders and tight monitoring in the RA trials ([7] pmc.ncbi.nlm.nih.gov) ([51] pmc.ncbi.nlm.nih.gov), the critical role of vendor quality (as in the diabetes study ([56] pmc.ncbi.nlm.nih.gov)), and the ability of eDiaries to capture data that would otherwise be missed (e.g. home-managed SCD pain ([61] pmc.ncbi.nlm.nih.gov)). They underscore that context matters: while one trial achieved >90% compliance, another only 71.5%, suggesting that population, duration, and training all influence adherence.

Best Practices and Recommendations

Drawing from the literature and the above cases, we summarize best practices in key areas.

System and Protocol Design

- **Embed eDiary in Protocol from the Start:** Address diaries in the protocol writing phase (see Table 1). Define exactly *what* must be captured (symptom list, scales), *when* (time points, windows), and *how* (device, format). Include feasibility considerations (e.g., patient ability to use tech), and adapt eligibility criteria to require patients willing and able to use the device ([23] www.appliedclinicaltrialsonline.com) ([62] www.jscdm.org). The protocol should specify eDiary data handling responsibilities.
- **User Requirements Specification (URS):** Develop a detailed URS for the eDiary system based on the protocol. This includes data flow, security, user roles, and any specialized functions (e.g. branching questions). Collaborate with IT/developers to map the protocol's "what, how, when" into technical requirements ([23] www.appliedclinicaltrialsonline.com) ([63] www.appliedclinicaltrialsonline.com).
- **Questionnaire Development:** Choose validated PRO instruments or develop symptom lists carefully. For new questionnaires, conduct cognitive interviews (to ensure patients interpret items correctly) and pilot the eDiary version to confirm equivalence with paper if translating an existing scale ([13] pmc.ncbi.nlm.nih.gov) ([34] www.jscdm.org). Use plain language and consistent formatting.

Training and Support

- **Initial Training:** Provide comprehensive training for participants and staff. For participants, cover device usage, login, navigation, and address the importance of honest, timely reporting. Table 1 notes the value of hands-on tutorials and FAQs ([49] pmc.ncbi.nlm.nih.gov). For staff, cover the backend (account setup, monitoring portal, troubleshooting). Repeat training for any staff turnover.
- **Quick Reference Materials:** Give participants an easy-to-use guide (paper or electronic) summarizing steps for using the diary. Include screenshots or pictures for visual aid. Study staff should have SOPs and quick-check guides as well ([43] pmc.ncbi.nlm.nih.gov) ([47] pmc.ncbi.nlm.nih.gov).
- **Ongoing Helpdesk:** Ensure participants can get timely technical support. This could be a hotline, email, or in-app help. The diabetes site survey particularly highlighted that rapid resolution of technical issues (and helpful support staff) was strongly correlated with overall satisfaction ([56] pmc.ncbi.nlm.nih.gov). Don't underestimate this: delayed fixes can lead to prolonged noncompliance.

Engagement and Motivation

- **Communicate Importance:** Emphasize to participants how their data will help. At enrollment, explain that the eDiary data directly informs safety/efficacy evaluations. This heightens the sense of contribution.
- **Reminders:** As noted, schedule automated reminders in the app (with alerts or push notifications) to prompt entries at the correct time, reducing human error. If possible, allow participants to set personal reminder preferences (alert tone, vibration).
- **Follow-Up:** Promptly contact participants who fall behind. Many eDiary platforms can send automatic alerts to staff if a threshold of missed entries is exceeded ([41] pmc.ncbi.nlm.nih.gov). Protocols should define when and how sites reach out (e.g. after 3 missed days, call the patient).
- **Feedback:** Provide occasional feedback (e.g., "You're doing great! 80% of entries complete.") or a summary of their entered data if not interfering with blinding. This can foster commitment ([50] pmc.ncbi.nlm.nih.gov).
- **Appropriate Compensation:** Depending on the IRB's judgment, consider incremental compensation tied to eDiary completion milestones (in line with ethical guidelines). This is often effective in longer trials.

Technical Features

- **Offline Capability:** Ensure the app works offline, storing responses locally with a timestamp, then syncing when online. This is critical in areas with intermittent internet ([32] pmc.ncbi.nlm.nih.gov). Test these functions exhaustively.
- **Multi-Platform Compatibility:** The application should run on all targeted devices (Android, iOS, tablets). Implement responsive design. If supplying devices, verify each hardware model thoroughly (battery life, storage limits).
- **Security Measures:** Data must be encrypted in-transit and at-rest. The app should lock automatically after inactivity, requiring re-login. Access controls should prevent co-enrollment and identify duplicitous entries.
- **Audit Trails:** All data entries, edits, and even deleted questions should be logged. The system should record user ID, timestamp, and nature of change. These logs must be reviewable by monitors/auditors if required.

Site Oversight

- **Real-Time Monitoring:** Provide sites (investigator teams and CRAs) with web-based dashboards to review compliance daily. Include flags for missing entries, and optionally high-severity entries (e.g., grade 3+ adverse events). Ideally, sites can drill down to individual diary entry details via secure login ([41] pmc.ncbi.nlm.nih.gov) ([13] pmc.ncbi.nlm.nih.gov).

- **Intervention Plan:** Define in the Monitor Plan how often eDiary data will be reviewed (e.g. weekly). Sites should have SOPs for contacting participants after missed entries or data anomalies. Continuous oversight is key for quality.
- **Accountability:** Remind investigators that eDiary data are source documents that must be archived with the trial master file ([5] www.appliedclinicaltrialsonline.com). Ensure that certified copies of all eDiary data are sent to the site at study close.

Data Management

- **Data Cleaning:** Like any electronic data, eDiary entries may require cleaning (e.g. resolving contradictory answers). The process should preserve original responses. Implement database edit checks where sensible (e.g. implausible numeric range triggers query) ([53] pmc.ncbi.nlm.nih.gov).
- **Metadata Logging:** Ensure date/time of start and submission of each diary are stored (as per Table 1 recommendations). This allows auditability of "how timely" each entry was ([64] pmc.ncbi.nlm.nih.gov).
- **Integration:** Plan for eDiary data export and merging. Use standard data models (CDISC ODM/SDTM if possible) to facilitate analysis. Avoid manual transcription from eDiary to CRF; instead, prefer automated transfers to minimize error.
- **Compliance Reporting:** Generate regular (weekly or monthly) reports on completion rates, entry timeliness, and missingness. Use these to inform data monitoring committees or sponsor on the need for corrective action.
- **Privacy and Consent:** Data flows must comply with consent. If diaries include sensitive information, ensure HIPAA agreement covers it. If diary data are collected cross-border, comply with GDPR/PDPA/etc. Many eDiary vendors have built-in attestations for these regulations.

Data Analysis and Evidence

eDiary data are usually analyzed as part of the primary or secondary endpoints. Because entries are time-stamped, one can examine patterns (e.g. diurnal symptom variation) or compute summary metrics (e.g. number of headache episodes over 14 days). Importantly, compliance itself can be a secondary endpoint. Studies often report rates like "days completed/expected". In the baricitinib RA study, compliance through 12 weeks exceeded 93% ([7] pmc.ncbi.nlm.nih.gov), which implies very little missingness bias.

In contrast, any analysis plan must anticipate missing data. Analyses should include intent-to-treat vs per-protocol comparisons, and sensitivity analyses if missingness is substantial. The rich timestamp data can sometimes be used to impute missing values (e.g., linear interpolation for PRO daily scores), but imputation must be justified and documented. All imputation rules and numbers of missed days should be reported in publications, per CONSORT extensions for eCOA.

When reporting eDiary results, investigators often emphasize improved data fidelity. For example, in diabetes trials eDiaries yielded 100% error-free returns vs 51% for paper ([65] pmc.ncbi.nlm.nih.gov), and in the RA study daily diaries allowed gatekeeping of data quality. Such evidence should be cited to bolster sponsors' decisions to invest in eDiaries: reducing missing data and entry errors translates to more statistical power and reliability.

Challenges and Limitations

While eDiaries offer many benefits, they are not without challenges:

- **Technology Barriers:** Not all patients are tech-savvy or have access to devices. Older adults or low-income populations may struggle with smartphones. Special accommodations (larger fonts, stylus pointer, in-person support) may be needed ([32] pmc.ncbi.nlm.nih.gov) ([66] pmc.ncbi.nlm.nih.gov).

- **Internet Access:** Reliance on connectivity can be problematic in remote settings, though offline mode mitigates this. Still, delayed sync can complicate real-time monitoring.
- **Data Overload:** Continuous eDiary data produce large datasets. Data management resources must scale accordingly. Sponsors should ensure enough bandwidth for data handling and storage.
- **Regulatory Complexity:** Even though eDiaries fit within current regulations, sponsors must maintain vigilance. Guidance does evolve (e.g., FDA's updated framework on decentralized trials) ([67] www.reuters.com). Keeping up with new FDA/EMA/PMDA recommendations on eCOA and DHT (digital health technology) safety is necessary.
- **Patient Burden:** Ironically, diaries themselves can be burdensome. Asking a patient with arthritis to tap out long entries every day may be onerous. Incomplete diaries over time can happen despite reminders. Trial design should consider the maximum feasible diary burden.
- **Privacy Concerns:** Some participants may worry about electronic tracking. Clear consent language and robust security assurances help. Also, eDiaries may inadvertently collect metadata (GPS/time) which should be handled carefully.
- **False Security:** High compliance does not guarantee accuracy of content. While eDiaries timestamp entries, participants could still enter inaccurate symptom ratings (intentional or not). Hence, diary data still require clinical interpretation.
- **System Failures:** Like any tech, device/app malfunctions happen. Sponsors should have a contingency plan (e.g., switch to paper backup). In [18], if a PDA malfunctioned its data were extracted before replacement ([68] pmc.ncbi.nlm.nih.gov) – a model approach.

Future Directions

The field of eDiary data capture continues to evolve. Emerging trends include:

- **Wearables and Passive Data:** Integration of wearable sensors (e.g. activity trackers, smartwatches) with diaries could enrich datasets. For example, a patient might concurrently log pain in an eDiary while a wearable measures sleep. Best practices on combining active diaries with passive sensors are being developed.
- **AI and Natural Language:** Text-based diaries or voice diaries could use NLP to interpret responses. This could reduce user fatigue (participants speak their entries). However, this raises new validation and accuracy issues.
- **Decentralized Trials:** As remote trials become common, eDiaries will be central. Future guidance will likely emphasize BYOD approaches and remote monitoring integration, especially post-pandemic. Regulatory bodies are showing interest in digital tools for endpoints, which may lead to updated guidance on ePRO and eDiary.
- **Standardization:** The CDISC ePRO standard and the Transcelerate PhUSE CRDM consortium are working on formats for eDiary data exchange ([12] www.jscdm.org). Adoption of FHIR and other interoperability standards will simplify multi-vendor data collection.
- **Enhanced Usability:** Continuous improvement in app design (gamification, adaptive questionnaires) may improve engagement. For example, using progress bars or mini-rewards for daily completion has been piloted in some studies.
- **Data Security:** As cybersecurity threats evolve, future eDiary platforms will need to implement cutting-edge encryption and possibly blockchain-like audit trails.

Conclusion

Collecting clinical trial data via patient eDiaries offers compelling advantages, but realizing these gains demands rigorous best practices. Electronic diaries that are thoughtfully designed (simple UI, robust reminders, clear protocols), validated (meeting Part 11/GCP requirements) and well-supported (training, monitoring) yield higher data quality, greater adherence, and richer endpoints than traditional diaries ([1] www.appliedclinicaltrialsonline.com) ([7] pmc.ncbi.nlm.nih.gov). The published case studies above demonstrate

record compliance and data completeness when these practices are followed ([7] pmc.ncbi.nlm.nih.gov) ([58] pmc.ncbi.nlm.nih.gov).

Sponsors and investigators should start eDiary planning early, working with experienced vendors and clinical data managers to align system capabilities with protocol needs. Attention to ALCOA principles ensures regulatory compliance and scientific credibility. Moreover, patient-centric considerations (usability, engagement) must guide the eDiary design, as ultimately patients are the users. When executed properly, eDiaries can transform the patient experience in trials and empower investigators with high-resolution data that drives robust conclusions on safety and efficacy ([13] pmc.ncbi.nlm.nih.gov) ([60] pmc.ncbi.nlm.nih.gov).

Looking forward, eDiaries are poised to integrate with wearables, telehealth, and advanced analytics, further embedding patient voice in real time into drug development. As the FDA and other regulators continue to support digital health innovations, adherence to best practices in eDiary data creation and collection will remain crucial. By following the comprehensive guidelines and examples outlined in this report—with training, monitoring, and technology aligned to patient needs—clinical trials can fully leverage eDiaries to enhance data integrity and trial efficiency ([6] pmc.ncbi.nlm.nih.gov) ([25] www.appliedclinicaltrialsonline.com).

Tables

Feature	Paper Diaries	Electronic Diaries (eDiary)
Compliance	Low, often <20% timely entries ([1] www.appliedclinicaltrialsonline.com); subject to "parking lot" fabrication ([2] pmc.ncbi.nlm.nih.gov) ([3] pmc.ncbi.nlm.nih.gov).	High (often >90%) with alarms/reminders ([7] pmc.ncbi.nlm.nih.gov) ([1] www.appliedclinicaltrialsonline.com).
Recall Bias	High; retrospective, end-of-day recall leads to inaccuracies ([23] www.appliedclinicaltrialsonline.com).	Low; time-stamped real-time entries minimize recall error ([13] pmc.ncbi.nlm.nih.gov) ([16] www.appliedclinicaltrialsonline.com).
Data Integrity	Vulnerable; missing or falsified data are common ([1] www.appliedclinicaltrialsonline.com) ([2] pmc.ncbi.nlm.nih.gov).	Robust; built-in validation, edit checks, full audit trail ([4] pmc.ncbi.nlm.nih.gov) ([51] pmc.ncbi.nlm.nih.gov).
Timeliness	Delayed; data seen only after site visits (arm data lag) ([69] www.appliedclinicaltrialsonline.com).	Real-time or near-real-time; automatic uploads allow daily monitoring ([51] pmc.ncbi.nlm.nih.gov) ([16] www.appliedclinicaltrialsonline.com).
Patient Burden	Moderate; carrying paper booklets is cumbersome. Often disliked by patients ([70] www.appliedclinicaltrialsonline.com).	Generally low; use of phones/apps is convenient for most, can include user-friendly UI ([30] pmc.ncbi.nlm.nih.gov) ([32] pmc.ncbi.nlm.nih.gov).
Customization	Static content; difficult to modify mid-study.	Highly flexible: dynamic question routing, multimedia, languages, offline support ([33] pmc.ncbi.nlm.nih.gov) ([32] pmc.ncbi.nlm.nih.gov).
Regulatory Compliance	No audit trail; prone to error, limited oversight. FDA/ICH guidelines apply to source docs ([16] www.appliedclinicaltrialsonline.com).	Inherently compliant: supports 21 CFR Part 11 (timestamping, security, audit trails, validation) ([4] pmc.ncbi.nlm.nih.gov) ([25] www.appliedclinicaltrialsonline.com).
Cost	Low tech cost (printing); labor costs for data entry and monitoring are high.	Higher upfront cost (software/dev), but saves on data entry and query work. Costs drop as volume scales ([6] pmc.ncbi.nlm.nih.gov).

Table 1. Comparison of paper diaries vs electronic diaries ([1] www.appliedclinicaltrialsonline.com) ([4] pmc.ncbi.nlm.nih.gov) ([7] pmc.ncbi.nlm.nih.gov) ([25] www.appliedclinicaltrialsonline.com).

Strategy Element	Recommendations (Best Practices)
eDiary Platform (UI)	User-friendly interface (clear layout, large fonts) ([33] pmc.ncbi.nlm.nih.gov); multi-language/localization; offline mode; accessible support ([33] pmc.ncbi.nlm.nih.gov) ([32] pmc.ncbi.nlm.nih.gov).
Training	Hands-on participant training (tutorials, practice entries) ([44] pmc.ncbi.nlm.nih.gov); train staff on account setup, monitoring, troubleshooting ([44] pmc.ncbi.nlm.nih.gov) ([47] pmc.ncbi.nlm.nih.gov).
Reminders & Alerts	Automated participant reminders for diary completion ([39] pmc.ncbi.nlm.nih.gov); notifications to staff for noncompliance and severe events ([39] pmc.ncbi.nlm.nih.gov).
Data Quality	Real-time monitoring of data completeness/consistency; built-in range checks and mandatory fields ([29] pmc.ncbi.nlm.nih.gov) ([53] pmc.ncbi.nlm.nih.gov); enforce ALCOA.
Diary Content	Use plain language, comprehensive items (for solicitations) ([36] pmc.ncbi.nlm.nih.gov); adjust UI for older/disabled (e.g. larger fonts) ([36] pmc.ncbi.nlm.nih.gov).
Timing/Windows	Define clear reporting windows (balance recall vs burden) ([71] pmc.ncbi.nlm.nih.gov); e.g. fixed 5–6 hr windows chosen by patient ([35] pmc.ncbi.nlm.nih.gov).
Timestamps/Traceability	Record date/time of start and completion of each entry ([64] pmc.ncbi.nlm.nih.gov); ensure logs show any edits.
Security/Privacy	Strong encryption, user authentication ([72] pmc.ncbi.nlm.nih.gov); comply with HIPAA/GDPR; restrict data access.
Patient Engagement	Provide feedback/acknowledgement to participant ([50] pmc.ncbi.nlm.nih.gov); address concerns; collect usability feedback.
Support	24/7 technical helpdesk; proactive site follow-up for issues; backup devices if failure.

Table 2. Strategies for optimizing eDiary use in clinical trials ([33] pmc.ncbi.nlm.nih.gov) ([50] pmc.ncbi.nlm.nih.gov). These recommendations are based on expert opinion and trial experiences (Nukala et al. 2025, *Jour. Med. Internet Res.*).

References: All statements above are drawn from peer-reviewed sources and regulatory guidance. Citations (e.g. [36], [18], [74]) indicate specific examples or data: FDA/ICH guidelines and recent studies demonstrate the points made ([4] pmc.ncbi.nlm.nih.gov) ([7] pmc.ncbi.nlm.nih.gov) ([1] www.appliedclinicaltrialsonline.com) ([25] www.appliedclinicaltrialsonline.com).

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