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The Study-Ready EDC Buyer Kit

A practical procurement and launch framework for clinical trials, registries, ePRO and hybrid evidence programs.

THE DECISION

Move beyond feature checklists. Select a clinical data platform that can support the actual protocol, data flows, site workflows, inspection evidence and change control your study requires.

40-criterion vendor RFP | Evidence-led scoring | Data-flow map | 20 go-live gates | 60-day plan

FOR Clinical Operations • Data Management • RWE • Medical Affairs • Digital • Quality • Procurement

OCTOBER 2026 EDITION / Includes editable companion workbook

Educational decision-support tool. It does not establish regulatory compliance, system validation or suitability for any particular study.

01 / THE BUYER PROBLEM

Executive brief: buy for the study, not the demo

The most expensive EDC mistake is rarely a missing dashboard. It is discovering after contract signature that a seemingly small protocol requirement needs a workaround, a new integration, additional validation, or an operational process nobody owns.

A study-ready system is a combination of platform capability, configured workflows, reliable data transfers, trained people and retained evidence. All five must be assessed together. A polished demonstration proves very little unless it uses your protocol, site roles and data sources.

Why this matters in October 2026

- The European Medicines Agency states that ICH E6(R3) Principles and Annex 1 have applied in the EU since 23 July 2025, emphasizing quality by design and risk-proportionate conduct. [S1]
- ICH E6(R3) Annex 2 was adopted by ICH on 3 June 2026; its EU effective date is 15 January 2027. It addresses additional considerations for pragmatic and decentralized trials and real-world data sources. It is not yet in effect in the EU as of this edition. [S1, S2]
- FDA final guidance from September 2024 covers decentralized trial elements, while December 2023 final guidance addresses digital health technologies for remote data acquisition. [S3, S4]
- EMA guidance on computerized systems and electronic data provides a useful reference for sponsor oversight, data integrity, security, validation and user training. [S5]

BUYER TAKEAWAY

The question is not “Does the vendor have ePRO, APIs and audit trails?” It is “Can the vendor demonstrate the exact end-to-end workflow, show credible evidence, and explain who is accountable when something fails?”

What is inside

Guide: decision architecture, requirements, acceptance tests, evidence pack, RFP questions, launch gates and a 60-day plan.

Workbook: 40 scored requirements, three-vendor comparison, data-flow map, 20 release gates, implementation plan and source register.

02 / DECISION CONTEXT

Who should use this kit - and when

Use it before issuing an RFP, replacing an EDC, adding ePRO, setting up a registry, integrating external data, or launching a protocol amendment.

BUYER	CORE DECISION	PRIMARY OUTPUT
Clinical Operations	Will sites and participants complete required tasks with low friction?	Workflow acceptance scenarios
Data Management	Will records be complete, attributable, reviewable and exportable?	Data management / reconciliation map
Medical Affairs / RWE	Will the design capture evidence needed for endpoints and analyses?	Evidence and data-source mapping
QA / Regulatory	Can controls, vendor oversight and decisions be documented?	Supplier evidence and release gate
Digital / IT	Can systems integrate, secure data and support continuity?	Interface and architecture assessment
Procurement / Finance	What is the real total cost and exit risk?	Weighted vendor comparison

The six artifacts to agree before any demo

- **Study brief:** design, populations, geography, sites, subjects, duration and expected amendments.
- **Schedule of activities:** visits, windows, repeat events, deviations and participant follow-up.
- **Data inventory:** eCRF, ePRO, laboratory, imaging, device, EHR, safety and analysis outputs.
- **Critical-to-quality factors:** endpoints, safety, consent, blinding and data integrity risks.
- **Role map:** sponsor, investigator, monitor, participant, vendor, statistician and QA.
- **Release criteria:** what must be demonstrated before first participant data is collected.

03 / WORKFLOW MAP

Map the end-to-end study architecture

Treat each data source as a controlled journey from capture through validation, review, reconciliation, analysis and archiving.

LAYER	EXAMPLES	CONTROL QUESTION
Collection	Site eCRF, patient ePRO, eConsent, lab, DHT / wearable, EHR	Who enters or generates each data element?
Transport	Native capture, secure files, API, middleware	How are identity, timing and transfer failures handled?
Clinical operations	Queries, monitoring, protocol deviations, safety escalation	Who reviews exceptions and with what deadlines?
Data management	Edit checks, coding, reconciliation, audit trail, freeze / lock	Can changes and discrepancies be reconstructed?
Evidence output	Analysis exports, metadata, traceability, archive	Can the sponsor retrieve complete, usable records?

The eight questions to answer for every interface

- What is the system of record?
- What is the source identifier and mapping to participant / visit / event?
- What time zone and timestamp conventions apply?
- What data checks run before acceptance?
- What happens when transfer fails or repeats?
- How are corrections propagated and audited?
- How are source and destination counts reconciled?
- Who owns the interface at build, during study and at closeout?

WORKBOOK ACTION

Open DATA FLOW MAP. Start with the six illustrative rows and replace them with your study-specific sources, destinations, validations, reconciliation and owners.

04 / RISK-PROPORTIONATE REQUIREMENTS

Critical-to-quality: start with what can fail

Do not assign every feature the same importance. Identify what would compromise participant safety, endpoint reliability, informed consent, blinding or data integrity.

EXAMPLE FAILURE	CONSEQUENCE	CONTROL / ACCEPTANCE TEST
ePRO diary recorded outside the allowed visit window	Endpoint interpretability may be affected	Configure windows; test late entry and missing diary alerts
Safety event entered in EDC but not reconciled with safety system	Missed or delayed safety follow-up	Run mismatch scenario and review escalation log
Role permissions expose blinded treatment allocation	Potential trial integrity compromise	Test site, sponsor and emergency access profiles
Protocol amendment silently changes prior form values	Untraceable data modification	Compare versioned build and audit history
Device feed duplicates data after retry	Biased or incorrect derived metrics	Inject duplicate records and verify idempotency
Vendor export lacks essential metadata	Analysis or inspection limitations	Perform sample export and reconstruction test

Use a simple risk tier

- **Tier A - Critical:** failures could materially affect safety, rights, key endpoints or reliable records. Require documented demonstration and evidence; unresolved failures block go-live.
- **Tier B - Important:** operationally significant, but a controlled workaround may be acceptable.
- **Tier C - Convenience:** valuable but not decisive for suitability.

RULE OF THUMB

A requirement should be called “critical” because of its study consequence, not because it appears in a standard software feature list.

05 / PROCUREMENT

The 40-criterion vendor RFP

The companion workbook contains 40 requirements across eight domains. The matrix below shows the questions that should dominate evidence review.

DOMAIN	BUYER MUST SEE	RED FLAG
Study design	Protocol-to-form mapping, visits, amendments, role variation	Custom development for every protocol change
eCRF / data capture	Edit checks, query cycle, monitoring, freeze / lock	Only static form screenshots
Data integrity	Attribution, correction history, audit trail, retrieval	No usable audit-trail export
Safety / monitoring	AE/SAE workflows, deviation capture, reconciliation	Safety transfer treated as manual afterthought
ePRO / decentralized	Participant workflow, reminders, missing data, accessibility	Only mobile mockups; no exception handling
Interoperability	Real sample API/file transfers, error handling, export	"We have APIs" without documentation or tests
Security / audit	Access review, signatures where relevant, backup, vendor controls	Unclear roles or subcontractor boundaries
Delivery / operations	Validation evidence, UAT, SLAs, support, exit costs	No named implementation and escalation owner

Ask vendors to prove, not promise

For each priority requirement, request at least one of: a live scenario demonstration; a controlled configuration example; a validation/test artifact; a representative audit trail or export; an interface specification; an SOP / quality record; or a contractual commitment. Screenshots and roadmap statements should not score the same as demonstrated capabilities.

Never treat "21 CFR Part 11 compliant" as a universal product badge. Determine which electronic records/signatures are in scope and how applicable predicate-rule obligations and controls will be met. FDA guidance explains the scope and its limited enforcement-discretion approach. [S6]

06 / DECISION MODEL

A scoring method procurement can defend

The workbook scores three vendors against 40 study-specific criteria. It intentionally separates evidence coverage from feature fit.

SCORE	EVIDENCE STANDARD	INTERPRETATION
0	Failed demo or not supported	Not suitable without material change
1	Roadmap, workaround or major customization	High delivery and validation risk
2	Partially demonstrated with material limitations	Gap requiring decision / remediation
3	Demonstrated; minor documented constraints	Generally acceptable for this requirement
4	Demonstrated with objective evidence for exact workflow	Strongest support for this requirement

How the workbook calculates fit

- **Weighted points:** requirement weight (1-5) × vendor score (0-4) ÷ 4.
- **Weighted fit:** total earned points ÷ total possible points for assessed requirements.
- **Coverage:** requirements with numeric scores ÷ 40.
- **Critical gate:** a critical requirement scored below 3 is a failure; a blank critical score remains untested.

The workbook uses an 85% coverage threshold as a planning heuristic, not a regulatory benchmark. It will show HOLD if any critical requirement fails or remains untested, or if coverage is too low. Decision makers must still assess contracts, evidence quality, regulatory fit and residual risks.

ANTI-GAMING RULE

Do not allow a vendor to earn a high average by demonstrating only its strongest features. Keep missing requirements visibly untested and resolve every critical gap before making a procurement recommendation.

07 / DEMONSTRATION DESIGN

A realistic live-demo script

Give all shortlisted vendors the same short scenario. The goal is to observe behavior, not a sales presentation.

Illustrative study: 12-site, 180-participant, 12-month observational follow-up with site eCRFs, weekly patient diaries, central laboratory results and a safety event workflow. This is a fictional scenario for procurement testing.

STEP	REQUESTED DEMONSTRATION	ACCEPTANCE EVIDENCE
1	Configure two visit windows and a repeat unscheduled visit	Versioned configuration / visit behavior
2	Enter an out-of-range laboratory value	Edit check fires; query assigned
3	Change a field after initial entry	Old/new values, user, time and reason retained
4	Miss a participant diary for seven days	Missing-data report and escalation route
5	Import a duplicate laboratory file	Reject / de-duplicate; log and reconciliation
6	Record an SAE requiring safety follow-up	Escalation path and reconciliation evidence
7	Apply a protocol amendment	Controlled impact and revalidation plan
8	Export a locked test dataset	Record count, metadata and complete auditability

Three traps to avoid

- A vendor may demonstrate a generic feature that does not work in your configured study.
- A polished happy-path demo can hide how exceptions, corrections and failures are managed.
- A “supported” feature may depend on a paid third-party component, integration or custom change request.

WORKBOOK ACTION

Use RFP REQUIREMENTS to record each demonstration score and evidence ID; use VENDOR SCORECARD for decision support.

08 / DECENTRALIZED EVIDENCE

ePRO, remote data and hybrid trials

Participant-facing technology must be assessed as a clinical workflow, not merely an attractive app.

DESIGN AREA	QUESTIONS TO RESOLVE
Participant identity	How are identity, device sharing, proxy use and account recovery handled?
Schedule / reminders	What happens with late entries, travel, time zones and missed windows?
Usability / inclusion	Languages, accessibility, low-bandwidth operation and device compatibility?
Source and provenance	Which timestamp is authoritative? What data are retained if sync fails?
Safety escalation	Which participant responses trigger contact and who owns follow-up?
Data reconciliation	How are expected versus received diaries and device records compared?
Change / amendment	Can revised questions be versioned without corrupting earlier responses?
Privacy / security	What information appears in notifications and on shared devices?

Do not confuse convenience with fitness for purpose

FDA guidance on decentralized elements (September 2024) and remote DHT data acquisition (December 2023) is useful when planning remote activities and the collection of participant-generated data. Requirements should reflect the actual product, protocol, intended use, and applicable jurisdiction. [S3, S4]

ACCEPTANCE TEST

Simulate one participant with intermittent connectivity, a missed diary window, a device replacement and a potential safety signal. Observe the full path from participant action to site review and final data export.

09 / QUALITY EVIDENCE

Validation and inspection-readiness evidence

The platform may come with a vendor validation package, but the sponsor still needs evidence that the configured study and its integrations are suitable for intended use.

ARTIFACT	MINIMUM CONTENT / TEST
Requirements baseline	Approved functional and critical-to-quality requirements
Supplier assessment	Vendor quality, security, support, subcontractors and responsibilities
Risk assessment	Data integrity, participant safety, endpoints, blinding and failure modes
Traceability matrix	Requirements linked to build, tests, defects and approvals
Configuration specification	Forms, edit checks, visits, roles, signatures and interfaces
UAT and exception tests	Happy path, negative tests, corrections, failures and reprocessing
Access and training records	Authorized users, role approvals, site readiness and training
Audit trail review plan	Events captured, periodic review and escalation
Release and change record	Version, approvals, residual issues, rollback and amendment control
Archive / export test	Records retrievable with content, meaning and agreed metadata

Sponsor oversight is not a checkbox

Define who reviews vendor evidence, who accepts residual risks, who owns changes and who maintains records after the contract ends. The EMA computerized-systems guideline addresses areas including training, access control and system management. [S5]

DO NOT OVERCLAIM

No platform feature list, supplier certificate or workbook score by itself demonstrates compliance with ICH GCP, 21 CFR Part 11 or any applicable law. Compliance depends on context, configuration, procedures and execution.

10 / RELEASE AUTHORIZATION

Twenty go-live gates worth testing

A production release should be an evidence-backed decision. The companion workbook contains 20 editable gates and a live status summary.

CONTROL FAMILY	GATES TO CLOSE
Protocol and build	Approved protocol mapping; visits/windows; edit checks; randomization if applicable
Safety and integrity	AE/SAE escalation; reconciliation; audit trails; corrections; backup/restore
Access and consent	Role permissions; electronic signatures when applicable; participant workflows
Interfaces and data	Lab / DHT / EHR transfers; failed transfer handling; export and reconciliation
Validation and operations	Risk-based test pack; DMP; site training; support; supplier oversight
Release governance	Change control; rollback; approved release authorization

What a release decision should look like

- **GO:** all applicable critical gates passed, evidence is linked, residual risks approved and named owners are available for launch support.
- **HOLD:** any critical failure, missing evidence or untested workflow could materially affect participant rights, safety, key data or record integrity.
- **N/A:** documented reason why a gate does not apply; never use N/A to avoid a failed test.

WORKBOOK ACTION

In GO-LIVE GATES, enter Pass / Fail / N/A and an evidence reference. The release indicator will remain on hold if gates are untested or failed. It cannot replace authorized QA and sponsor sign-off.

11 / EXECUTION

A 60-day selection-to-launch workplan

This illustrative timeline assumes a relatively straightforward study and timely vendor access. Complex global trials, custom integrations or protocol changes may need materially longer.

WINDOW	PRIMARY OUTCOME	REVIEW GATE
Days 1-7	Study scope, CTQ factors, requirements and protocol mapping	Sponsor signs off on critical requirements
Days 6-20	Data-flow map, structured demos, vendor evidence and procurement review	Critical gaps resolved or explicitly rejected
Days 18-35	Configuration, roles, integrations and data management design	Build baseline approved
Days 28-45	Validation, site UAT, participant scenarios and defect closure	No unresolved critical test failures
Days 40-56	End-to-end rehearsal, export QC and go-live gate review	Documented release recommendation
Days 56-60	Controlled launch, monitoring and hypercare	Named support owners and metrics

Four metrics to monitor after launch

- **Critical data completeness:** expected versus received data for critical variables and visits.
- **Query cycle time:** time from issue to closure, with aging by site and severity.
- **Transfer reconciliation:** unmatched, failed or duplicate records per interface.
- **Participant / site burden:** ePRO completion, training issues and support tickets.

WORKBOOK ACTION

Assign named owners, dependencies, target dates and proof links in 60-DAY PLAN. Replace illustrative dates with a realistic plan tied to your protocol and vendor delivery commitments.

12 / PROCUREMENT JUDGMENT

Worked example: two vendors, different risks

Illustrative scenario only; figures are hypothetical and not vendor performance data.

	VENDOR ALPHA	VENDOR BETA
Demo story	Excellent eCRF / dashboard experience	Less polished UI; strong audit and integration tests
ePRO	Native; weak offline recovery demonstration	Partner integration; tested missed-data handling
Data exports	CSV export; metadata incomplete	Full test export and documented mappings
Safety reconciliation	Manual spreadsheet workaround	Demonstrated exception queue
Commercials	Low initial license; costly custom changes	Higher base price; fewer hidden integration fees
Critical gaps	2 failed, 1 untested	0 failed, 0 untested

What the committee should decide

Vendor Alpha may score highly on usability, but unresolved safety and export gaps create material risk. Vendor Beta may be more suitable for this specific protocol despite a less compelling demo. The correct decision depends on the study requirements, objective evidence, remediation feasibility, total cost and residual risk - not a single numerical ranking.

Three questions before signing

- Which critical-to-quality requirement is least convincingly evidenced?
- Which promised capability depends on a future release, subcontractor or paid customization?
- Can we retrieve all records and metadata if the vendor relationship ends?

COMMERCIAL LESSON

The cheapest license is not always the lowest-cost study. Rebuilds, amendments, site retraining, integrations, monitoring burden and delayed database lock can dominate the cost of the software itself.

13 / BUYER QUESTIONNAIRE

Ten vendor questions to copy into your RFP

These questions are designed to expose implementation risk and contractual ambiguity.

01	Can you configure our visit schedule, amendment and query process without custom code?
02	Which components are native, partner-supplied or planned? Name dependencies.
03	Show a correction and the corresponding audit trail, including original value.
04	Demonstrate a failed interface transfer, retry and reconciliation.
05	Show your validation evidence index and explain what sponsor testing remains.
06	How are site permissions, user delegation and training documented?
07	What is your approach to ePRO missingness, device changes and offline sync?
08	Which study amendments trigger fees, reconfiguration and revalidation?
09	What records, metadata and configuration can we export on termination?
10	Who owns critical incidents and how fast are they escalated and resolved?

RFP EVIDENCE REQUEST

For every answer, request a demonstration, document, sample artifact or binding contract clause. Record the evidence ID in the workbook. “Yes, supported” is not evidence.

14 / WHAT TO DO NEXT

Key takeaways and a practical next step

An EDC decision is a study-operating-model decision. Choose the platform that can support critical data, clinical workflows, sponsor oversight and the full lifecycle of evidence.

- Begin with the protocol and critical-to-quality factors, not a vendor feature list.
- Test exceptions - missed diaries, duplicate imports, corrections, SAE escalation and amendments.
- Separate assessed evidence from untested claims and roadmap commitments.
- Map each data handoff and define reconciliation ownership.
- Keep configuration and validation evidence connected to sponsor release decisions.
- Consider total lifecycle cost, including change requests, integrations, training and exit.
- Do not treat a vendor score as a regulatory compliance certification.

OPTIONAL NEXT STEP / 30-MINUTE STUDY DATA ARCHITECTURE REVIEW

Bring your protocol summary, current data-source list and two most important workflow risks. Nirmitee Health can help structure a study-specific requirements map and identify where EDC, ePRO, interoperability and validation planning need the most attention. The aim is to clarify the architecture and evidence needs before committing to implementation.

Where Clinera may be relevant

Clinera is a Nirmitee Health clinical data platform initiative spanning EDC and adjacent evidence workflows. It may be relevant to teams evaluating study build, site data capture, ePRO, registries or data operations. This kit is deliberately vendor-neutral: use the same evidence standards to evaluate Clinera or any alternative.

About Nirmitee Health

Nirmitee Health works at the intersection of Pharma and MedTech digital infrastructure, regulated product engineering, clinical data systems, interoperability, AI and evidence workflows.

This material is educational and does not replace study-specific regulatory, clinical, legal or quality review.

15 / REFERENCE NOTES

Official sources and regulatory context

Reviewed for the 21 October 2026 edition. Sources are linked for direct verification.

[S1] EMA - ICH E6 Good Clinical Practice

EU Principles and Annex 1 effective 23 July 2025; Annex 2 EU effective 15 January 2027.

<https://www.ema.europa.eu/en/scientific-guidelines/ich-e6-good-clinical-practice>

[S2] ICH - E6(R3) Annex 2 Step 4

Adopted by ICH on 3 June 2026; additional considerations for decentralized / pragmatic trials and RWD.

https://database.ich.org/sites/default/files/ICH_E6%28R3%29_Annex%202_Guideline_Step%204_2026_0603_0.pdf

[S3] FDA - Conducting Clinical Trials With Decentralized Elements

Final guidance, September 2024.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/conducting-clinical-trials-decentralized-elements>

[S4] FDA - Digital Health Technologies for Remote Data Acquisition

Final guidance, December 2023.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations>

[S5] EMA - Guideline on Computerised Systems and Electronic Data in Clinical Trials

Adopted 2023; computerized-system governance, data integrity and oversight.

https://www.ema.europa.eu/system/files/documents/regulatory-procedural-guideline/guideline_on_computerised_systems_and_electronic_data_in_clinical_trials_en.pdf

[S6] FDA - Part 11, Electronic Records; Electronic Signatures - Scope and Application

FDA guidance on scope, predicate rules and limited enforcement discretion.

<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/part-11-electronic-records-electronic-signatures-scope-and-application>

[S7] FDA - E6(R3) GCP final guidance listing

FDA guidance listing notes final E6(R3) GCP guidance issued September 2025.

<https://www.fda.gov/industry/phase-1-investigational-new-drug-ind-navigator/phase-1-ind-guidance-documents>

Regulatory status is jurisdiction-specific and can change. For example, ICH Annex 2 was adopted in June 2026 but is not effective in the EU until January 2027. FDA's December 2024 Annex 2 publication was a draft, not a final U.S. adoption at the time cited.