Clinical trial site feasibility questionnaire template

Bond Health template · bondtrials.com/templates/feasibility-questionnaire · Last updated 2026-10-25

Sponsors and CROs send a feasibility questionnaire before they shortlist a site, and many cover the same ground in a different order. This template puts those questions in one place so your site can answer once, keep the answers current, and copy them into each sponsor's form. It includes a worksheet for patient counts drawn from your EHR, because a count with its method attached is easier to believe than an estimate.

What is this feasibility questionnaire for?

A feasibility questionnaire is how a sponsor or CRO decides whether your site can run a study and enroll for it. In a 2024 ACRP blog post, one site leader put these forms at anywhere from 10 to 40 pages. Sites are typically not compensated for feasibility work, according to a 2024 paper by an industry task force of sites, site networks, sponsors and CROs. The same paper cites an estimate, extrapolated from oncology survey data, that the burden and inefficiency of site feasibility cost the industry $1.6 billion.

- **11%** of sites in a typical trial enroll no patients
- **37%** of sites enroll fewer patients than planned
- **$1.6B** estimated industry-wide cost of feasibility inefficiency, extrapolated from oncology

The sponsor's caution has a basis. Those site-performance figures come from a Tufts CSDD analysis of more than 150 studies and nearly 16,000 sites, released in January 2013. The questionnaire is the sponsor's first attempt to tell the sites that will enroll from the ones that will not.

Use this template as your site's master answer file. Fill it in once per therapeutic area, update it each quarter, and paste from it when a sponsor's form arrives. The guide to how sponsors choose sites explains what happens to your answers after you send them.

How should your site use the template?

Step 1: Fill in the standing sections once

Site profile, staff, experience, equipment and timelines change slowly. Complete them now and have the site director review them.

Step 2: Run the patient count for each protocol

The patient population section depends on the protocol's criteria. Rerun the EHR query for each synopsis and record the query date.

Step 3: Check competing studies

List every open or planned study at your site that draws on the same patients, including investigator-initiated work.

Step 4: Have the PI review it

The sponsor will hold the principal investigator to the enrollment estimate. The PI should see the count, the method and the projection before the form goes out.

Step 5: Keep a dated copy

Save each completed response with the date and the sponsor's version. When the study starts, compare actual enrollment against what you projected.

Answer with data, not adjectives: Replace "large patient population" with a count, a query date and a method. Replace "experienced staff" with named roles and the studies each person has run. If you do not know a number, say so and say how you would get it. A sponsor can plan around an honest gap. It cannot plan around a guess.

What goes in the site profile, staff and experience sections?

These answers change slowly, so they can be reused across sponsors. Replace the bracketed text with your own details.

Section A. Site profile

Site name and address

[Site name], [street address], [city, state, ZIP]

Site type

Options: Independent research site / Site network member / Academic medical center / Hospital or health system / Physician practice / FQHC or community health center

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Principal investigator

[Name, credentials, specialty, board certification]

Primary contact for this study

[Name, role, email, phone]

IRB of record

If a local IRB is required, give its meeting schedule and usual turnaround.

Options: Central IRB accepted / Local IRB required / Either, depending on the sponsor

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Electronic systems in use

EHR vendor, CTMS, eRegulatory or eISF, eSource. Note which sponsor systems your staff already use.

Patient catchment

Clinics, referral partners and counties your site draws from.

Section B. Staff

Investigators

PI and each sub-investigator: [name], [specialty], [studies as PI or sub-investigator in the past three years], [GCP training date].

Study coordinators

Number of coordinators, time each devotes to research, and current study load per coordinator.

Regulatory, data entry and pharmacy support

Named roles, and whether each is in-house or shared.

Languages spoken by consenting staff

Languages in which staff can hold the consent discussion without an interpreter.

Staffing changes expected during the study

Planned hires, departures or leave.

Section C. Experience

Studies in this therapeutic area, past three years

For each: phase, indication, sponsor or CRO, enrollment commitment, patients randomized, status.

Enrollment against commitment for closed studies

Randomized versus committed for each study that closed in the past three years. Give a reason next to any shortfall.

Screen failure rate on similar studies

Screen failures divided by patients screened, with the top reasons.

Audit and inspection history

FDA inspections and sponsor audits, with outcomes and any Form FDA 483 observations.

Sponsors weigh this history for a reason: sites with a track record of successful enrollment are more likely to meet their targets. Systems count too. Florence's 2024 State of Technology Enabled Clinical Trials report, as cited in WCG's 2024 site survey report, found that 43% of sponsors view a site's adoption of the sponsor's software as a key selection criterion, so list the sponsor platforms your staff already know.

How should you report the patient population?

A diagnosis-code count is not a count of eligible patients. The worksheet below turns one into the other in steps, so the sponsor can see which inclusion and exclusion criteria you applied and which you could not check in the chart.

EHR patient-count worksheet

Step	Criteria applied	Data source	Patients remaining
Diagnosis	[ICD-10-CM codes or problem-list terms for the condition]	Problem list, encounter diagnoses	[n]
Active at your site	Seen at [site] within [lookback window]	Encounters	[n]
Age and sex	[Protocol age range and sex criteria]	Demographics	[n]
Key labs and measures	[Lab thresholds, vitals or scores the protocol requires]	Lab results, vitals, flowsheets	[n]
Prior and current therapy	[Required or excluded medications and washout periods]	Medication lists, orders	[n]

Step	Criteria applied	Data source	Patients remaining
Major exclusions	[Conditions or events that exclude]	Problem list, notes, reports	[n]
Chart-reviewed sample	[n] charts reviewed by [role]; [n] held up	Coordinator review	[n]

Record the query date, the lookback window and who ran the query. Criteria the chart cannot answer, such as willingness to follow the visit schedule, belong in the pre-screening call, not the count.

Section D. Patient population

Query date and method

[Date], [who ran it], [EHR report, data warehouse or screening software]

Final count from the worksheet

Criteria you could not check in the EHR

List them. These are checked at pre-screening or screening.

Demographic breakdown of the final count

By race, ethnicity, sex and age group, where the data allows. Note fields that are often blank.

New patients per month who meet the key criteria

From new diagnoses or referrals over a recent period. State the period.

Projected randomizations per month

Apply your historical consent and screen failure rates to the final count and to new patients per month, over the planned enrollment period. Show the arithmetic.

Recruitment sources beyond the EHR

Referral partners, registries, community outreach, IRB-approved advertising.

Do not commit the eligible pool: The final count is patients who might qualify, not patients who will enroll. Convert it to an enrollment estimate last, using your own screen failure and consent rates, and show that step. The guide to pre-screening vs screening explains where the pool shrinks.

What should you report on competing studies, equipment and timelines?

Section E. Competing studies

Open studies that draw on the same patients

[Sponsor or protocol], [phase], [status], [where the criteria overlap]

Planned studies now in start-up

Same details as above.

How you would prioritize referrals

Which study gets first referral when a patient qualifies for more than one.

Section F. Facilities and equipment

- ☐ Dedicated exam rooms for research visits
- ☐ Locked, access-controlled storage for investigational product
- ☐ Temperature-monitored refrigerator and freezer with alarms and logs
- ☐ Ultra-low temperature freezer, if the protocol requires one
- ☐ Refrigerated centrifuge
- ☐ Investigational pharmacy or pharmacist oversight
- ☐ ECG machine with calibration records
- ☐ On-site or contracted imaging: [modalities]
- ☐ Staff trained to ship biological samples as dangerous goods
- ☐ Remote monitoring access to the EHR or eSource

Other protocol-specific equipment

[List, with calibration or maintenance dates]

Section G. Start-up timelines

Budget and contract review

Median days from receipt to signature on recent studies, and who reviews: the site, the institution, or both.

IRB review

Central IRB reliance steps, or local IRB meeting frequency and median days to approval.

Earliest site initiation visit

[Date staff can attend]

Activation to first patient screened

Median days on recent studies.

Blackout dates

Holidays, staff leave or audits during the projected enrollment period.

Published start-up benchmarks to check your answers against

Measure	Published benchmark	What to report
Activation to first patient screened	Median 20 days; top quartile 8 days, bottom quartile 34 days, in a CRIO analysis for SASI published July 2026	Your median across recent studies
Start-up at independent sites and physician practices	60% reported starting studies in under 60 days in WCG's 2024 site survey	Your median from contract receipt to activation
Start-up at academic medical centers, community hospitals and health systems	77% reported start-up longer than 60 days in the same survey	The same measure, split into budget, contract and IRB

If your numbers are slower than these, give the reason next to them. A sponsor trusts an explained delay more than an unexplained one.

What should the budget section ask?

Some questionnaires ask about budget expectations before a draft budget exists. State your standard fees and terms now so the negotiation starts from your numbers.

Section H. Budget expectations

Start-up fee

[Amount], non-refundable, invoiced at [contract signature or activation]

IRB fees

Initial review, continuing review and amendments, if not paid directly by the sponsor.

Pharmacy fees

Set-up, dispensing and close-out.

Per-patient visit costs

From your research rate sheet for the procedures in the schedule of assessments.

Screen failure reimbursement

A fee per screen failure, or the ratio of screen failures paid per randomized patient.

Pre-screening and recruitment costs

Chart review, patient outreach, advertising and any recruitment vendor fees.

Coordinator time outside visits

Feasibility, start-up, monitoring visits, query resolution and close-out.

Overhead or indirect rate

[Rate], applied to [which costs]

Payment terms

Invoice frequency and the days to payment you require.

Holdback

The share withheld until database lock, if any, and whether you accept it.

Why terms matter as much as fees: In WCG's 2024 survey of 852 sites worldwide, budgets and contracts were the leading contributor to delayed study start-up, affecting 69% of respondents. Putting your terms in writing at feasibility gives the contract team a starting point.

Does any of this need IRB approval?

Completing the questionnaire itself generally does not: it describes your site, not a study procedure, and no patient is contacted. Two activities around it need care, and your IRB and privacy office have the final word on both.

- **Running the EHR count.** Reviewing records to judge whether a study is feasible is usually handled under the HIPAA provision for reviews preparatory to research. The covered entity must obtain the researcher's representation that the review is solely to prepare a research protocol or for similar purposes preparatory to research, that no protected health information will be removed from the covered entity, and that the information is necessary for the research. Send the sponsor aggregate counts only, and follow your privacy office's rules on who may run queries.
- **Contacting patients to test interest.** That is recruitment, not feasibility. FDA's recruiting guidance (issued January 1998 and posted on its website as of October 2026) treats direct advertising for study subjects as the start of the informed consent and subject selection process, and says advertisements should be reviewed and approved by the IRB. Wait until the study, its recruitment materials and any outreach scripts are approved.

The guide to IRB and HIPAA rules for patient outreach covers the outreach side in detail.

Where does Bond fit?

Bond Health does not fill in feasibility questionnaires. It helps with the part that depends on chart review: the patient count. Identify reads structured and unstructured EHR records against a study's inclusion and exclusion criteria, ranks candidates, and shows the chart evidence behind each criterion decision. A coordinator can check a sample of those decisions before the site reports a number, which is the chart-reviewed step in the worksheet above. Full EHR integration usually takes 48 hours, depending on the EHR, IT review and interface method.

Once a study is awarded and its recruitment materials are IRB-approved, the same candidate list can feed Engage for outreach and scheduling, so outreach starts from patients already screened against the criteria. See Bond for research sites, or browse the other templates.

Sources

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