# Clinical Trial Feasibility Checklist: Protocol Assessment & Site Selection Criteria

Discover how the **Clinical Trial Feasibility Checklist** ensures study success by assessing protocol practicality and site readiness.

What if a clinical trial fails not because of a bad drug — but because it started at the wrong site?
What if months of planning collapse due to low patient enrollment or missing lab equipment?
These are exactly the risks that a well-structured **Clinical Trial Feasibility Checklist** aims to prevent.

The **Clinical Trial Feasibility Checklist** is a strategic tool used to evaluate whether a study can be conducted safely, ethically, and efficiently within real-world conditions. It helps sponsors and CROs assess protocol practicality, site capabilities, patient availability, regulatory readiness, and resource requirements—ensuring each trial is scientifically sound, operationally feasible, and set up for success before initiation.

A well-structured feasibility process examines the trial from two critical angles:

- **Protocol Assessment** — Is the study design realistic and executable?
- **Site Selection Criteria** — Do the chosen sites have the right experience, facilities, and patient population?

## LEVELS OF FEASIBILITY IN CLINICAL TRIALS

Feasibility in clinical research operates at multiple levels, each designed to ensure that a study is both scientifically valid and operationally achievable. Together, these levels form the backbone of effective trial planning:

## PROGRAM LEVEL FEASIBILITY:

Conducted early in the drug development phase to evaluate the *overall potential* of a therapeutic program. It looks at how common the disease is, where patients can be found, and whether the trial would make sense in different regions before starting multiple studies.

## STUDY LEVEL FEASIBILITY:

This looks at one specific clinical trial plan to see if it's practical and can actually work. It checks whether the study design, goals, and timelines make sense and if the procedures can be carried out smoothly in different locations and among real patients.

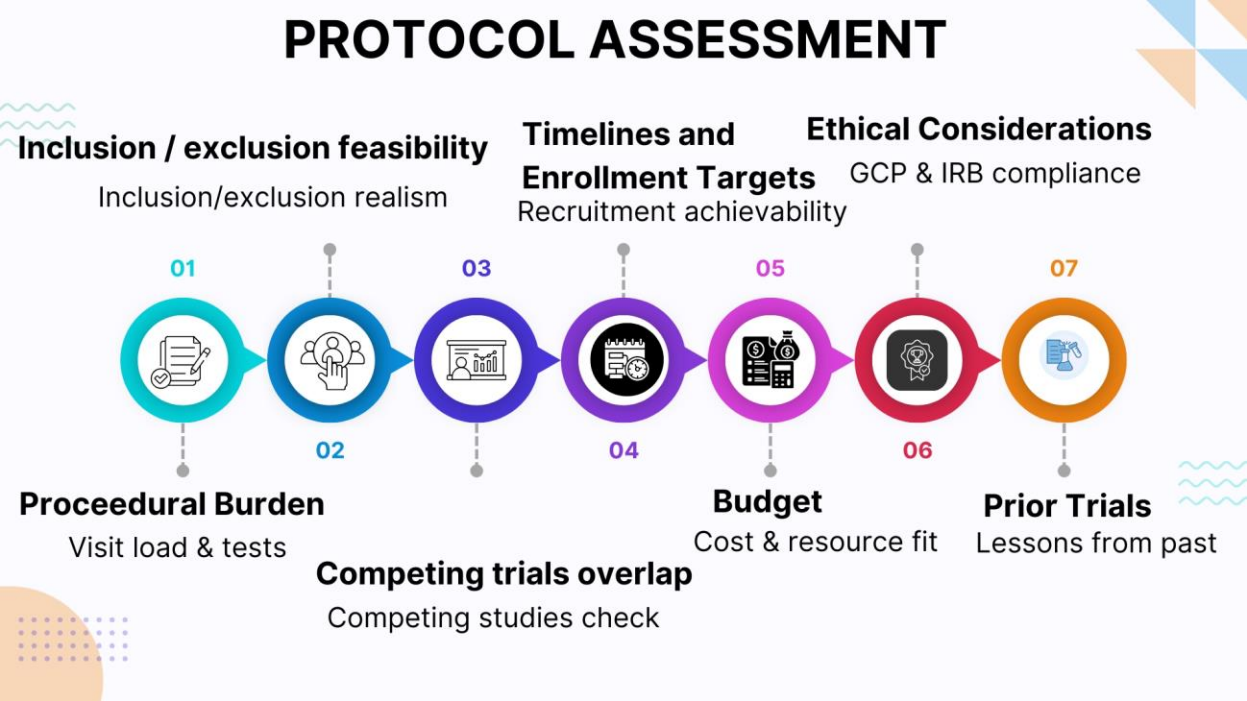
## SITE LEVEL FEASIBILITY:

This focuses on each hospital or research center where the trial will happen. It checks if the site has the right equipment, experienced doctors, trained staff, and enough suitable patients to run the study properly and follow all rules.

## PURPOSE OF CLINICAL TRIAL FEASIBILITY:

Clinical trial feasibility ensures that a study can work effectively in real-world settings before it begins. It checks if the design, sites, and patient availability are practical and achievable. This process helps identify potential risks or challenges early on. Ultimately, it ensures the trial runs safely, efficiently, and successfully.

# HOW THERE WILL BE A PROTOCOL ASSESSMENT




Before starting a clinical trial, the protocol must be carefully reviewed to see if it's practical for real-world conditions.

## PROCEEDURAL BURDEN:

Imagine a diabetes study that requires patients to visit the clinic every two days for blood glucose tests and undergo multiple labs scans each month. Many participants may drop out because of travel costs or time off work, and site staff may struggle to keep up with the workload. Simplifying visits (say, once a week) can make the trial more realistic and patient friendly.

The complexity of the protocol directly impacts site performance and patient participation. It evaluates the number of site visits, sample collections, and invasive procedures required throughout the study. A protocol with excessive or complicated procedures can increase staff workload, patient discomfort, and dropout rates. Simplifying visit schedules and reducing unnecessary tests can improve compliance and study efficiency.

## INCLUSION / EXCLUSION CRITERIA FEASIBILITY

Evaluate how strict the eligibility rules are (age, lab ranges, comorbidities) and the likely "screen failure rate." Overly restrictive criteria may result in very few eligible patients, making recruitment difficult. Feasibility means balancing scientific rigor with practical recruitability.

## COMPETING TRIALS OVERLAP

Check whether other studies in the same therapeutic area or near the same sites. If so, patient pools could be diluted, leading to lower enrollment per trial. Understanding the local trial landscape helps avoid conflicts and ensures adequate recruitment.

## TIMELINES & ENROLLMENT TARGETS

Examine whether the proposed schedule (site activation, patient enrollment, and last patient visit) is realistic. Aggressive targets may push sites to overextend, compromising data quality or timelines. A buffer and phased enrollment plan can reduce the risk of delay.

## BUDGET

Estimate cost per patient, reimbursements, training, lab costs, equipment needed, and logistics. If the budget is too tight, sites may cut corners or be unable to deliver what is required. Adequate financial planning supports site operations, staffing, and study demands.

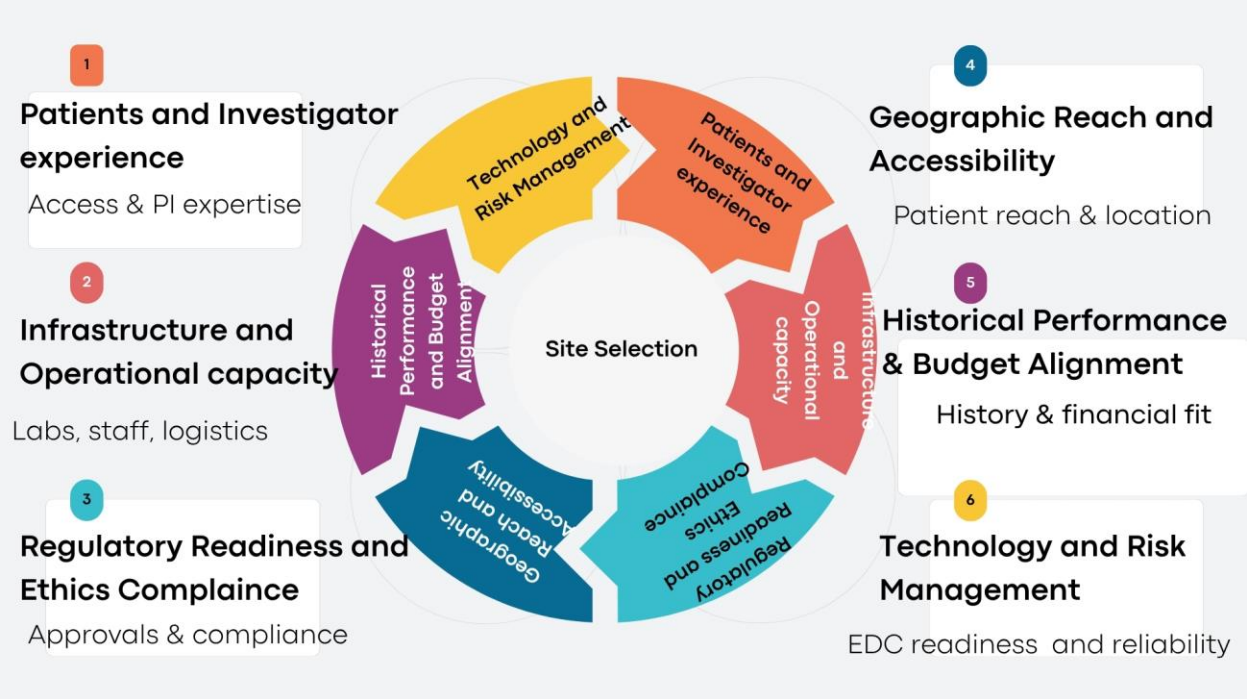
## ETHICAL CONSIDERATIONS

Determine what special approvals are required (e.g. for genetic testing, device trials, multi-center international trials). Multi-center or cross-border studies may face varied regulatory or ethics committee requirements. Early identification of these demands avoids delays in approval and site activation.

## PRIOR TRIALS

Review how similar protocols fared in past studies (enrollment rates, challenges, deviations). If prior versions had issues (slow recruitment, protocol deviations), these raise red flags. Learning from past data helps refine design and set realistic expectations.

## CHECKLIST FOR SITE SELECTION




Before starting a trial the site have been checked and analysed for the further proceedures,

- PATIENT POPULATION & INVESTIGATOR EXPERIENCE
  Sites are chosen based on access to the right patients and the investigator's proven expertise in handling similar trials.

- INFRASTRUCTURE & OPERATIONAL CAPACITY
  The site must have adequate labs, storage, and trained staff to manage study procedures efficiently and maintain data quality.

- REGULATORY READINESS & ETHICS COMPLIANCE
  Sites with prior ethics approvals, ICH-GCP awareness, and a history of regulatory compliance ensure smoother trial startup.

- GEOGRAPHIC REACH & ACCESSIBILITY
  Easily reachable sites encourage patient participation and reduce dropout rates, supporting better recruitment outcomes.

- HISTORICAL PERFORMANCE & BUDGET ALIGNMENT
  Past trial delivery, accurate data handling, and realistic cost planning indicate a site's reliability and sustainability.

- TECHNOLOGY & RISK MANAGEMENT
  Strong data systems, EDC readiness, and early identification of risks like staff turnover or competing trials ensure trial continuity.

## EVALUATION OF FEASIBILITY

### Site Feasibility Questionnaires / Site response Questionnaires (SFQs / SRQs)

These are structured, detailed forms that sponsors or CROs send to clinical trial sites. They ask about

- The site's patient population (how many eligible patients they see per month)
- Previous experience with trials, staff qualifications
- Available facilities, equipment, lab capacity, and data systems
- Operational capabilities, regulatory compliance history

### Decision Trees & Weighted Scoring Systems

**Decision Tree:**

- A visual “yes/no” logic flow that helps decide whether a site qualifies based on key checkpoints (for example: does the site have lab capabilities? → yes, proceed; no → disqualify).

  **RATING SCALE**
- Each criterion (e.g. recruitment potential, infrastructure, regulatory experience) is assigned a weight. Sites are scored on each criterion, and the total score helps rank them.

## MRCT Decision Tree

The **MRCT (Multi-Regional Clinical Trials) Decision Tree** is a framework developed to support multi-center, multi-country trials. It guides sponsors through critical checkpoints like capacity to enroll in diverse populations, site infrastructure, ethical and regulatory readiness, and recruitment potential.

## CHALLENGES IN THE CLINICAL FEASIBILITY CHECKLIST

### Protocol-Related Challenges

Complex study designs, excessive visits, or invasive procedures make protocols hard to execute. Overly strict eligibility criteria reduce patient recruitment. Unrealistic timelines and budgets strain site resources. Poor adaptation from prior trials leads to repeated issues.

### Site-Related Challenges

Sites may overestimate patient availability or lack trained staff. Limited infrastructure or competing studies slow enrollment. Regulatory delays and ethics approvals cause startup bottlenecks. Inconsistent performance or data quality affects trial reliability.

## Operational & Logistical Challenges

Inadequate funding, delayed payments, or poor coordination hinder site motivation. Weak data systems and communication gaps disrupt trial flow. Geographic inaccessibility reduces patient retention. High staff turnover increases error rates and monitoring needs.

## Ethical & Regulatory Challenges

Sites may struggle with GCP compliance or evolving local regulations. Multi-country studies face varied IRB/EC processes and documentation demands. Delays in approvals impact study timelines. Failure to maintain ethical standards can risk patient safety and study credibility.

# CONCLUSION

In simple terms, **clinical trial feasibility** is all about checking whether a study can actually work in the real world before it begins. It helps researchers find out if the plan, sites, and resources are practical, and if enough patients can safely take part. By identifying problems early—like complicated study designs, tight budgets, or limited staff—teams can save time, money, and effort later.

A well-planned feasibility process makes sure trials run smoothly, ethically, and efficiently. It builds confidence among sponsors, researchers, and patients that the study is realistic and valuable. In short, good feasibility means fewer surprises, faster progress, and more reliable results that help bring new treatments to people who need them most. To explore this topic in depth and gain hands-on knowledge of how real clinical trials are planned and managed enroll in PG Diploma in Clinical Research: Advance Your Career.

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