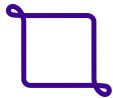


## Guide for Sites, Sponsors, CROs:



Do not rely on **feasibility questionnaires** to finalize protocol design, rather, Sponsors and CROs should **get feedback from sites** using stakeholder engagement meetings and consulting opportunities.



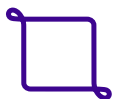
Sponsors/CROs should utilize pre-existing site profile and capability information (as described in the full whitepaper) for site identification in the study development process, relying on sites to provide protocol-specific information later.

- **Use a system** that provides up-to-date site data to speed up the process and reduce the site workload.
- **Share** within your organization; sites often receive similar questions from multiple stakeholders in the same organization.



Ensure all critical path items are complete (or drafted) **before** starting the protocol-specific assessment phase of Site Feasibility.

- Refer to the Site Feasibility Checklist provided here
- Final documents are required for sites to assess their ability to meet protocol requirements **accurately** and for their feasibility assessment to be valid.
- The impact/risk of starting protocol-specific site feasibility with sites before essential items have been shared includes delayed start-up, inaccurate submissions from sites, and site dropout.



Share this guide and checklist with other stakeholders engaged in your current feasibility processes to align on expectations. These resources were created by a diverse group of stakeholders at sites, sponsors and CROs.



# List of Required Materials to Initiate Site Feasibility

The Site Feasibility Task Force, part of the Site Enablement League (SEL), released “*Redefining Feasibility in Clinical Trials: Collaborative Approaches for Improved Site Selection*” (at [researchrevolution.com](https://www.researchrevolution.com)) which includes the following guide and checklist for sites, sponsors, and CROs to improve their site feasibility process. By sharing specific information before protocol-specific feasibility, the process becomes more efficient, leading to smoother study startup and reduced timelines for all. Read the full report for in-depth analysis of problems, real world examples, and practical tools.

## Documents

- Finalized Protocol
- Lab Manuals (Draft or Final)
- Pharmacy manual (Draft or Final)
- Imaging manual / requirements (Draft or Final)
- Non-redacted FDA approval letter (for IDE, IND studies)
- Finalized CRFs
- eCRF completion guidelines
- Central lab shipping requirements
- Equipment List (Draft or Final)
- Budget template (Draft or Final)
- NCT Number

## Communications

- Site Point of Contact Email & Phone Number
- Sponsor Point of Contact Email & Phone Number
- CRO Point of Contact Email & Phone Number
- Communication Plan
- Operational manuals

## Tools Disclosed

- List of all vendors and system being used
- EDC
- Regulatory
- Source
- Recruitment
- Consent
- Inventory Management
- Other: \_\_\_\_\_

## Miscellaneous

- Pilot/early phase data
- Projected timeline for all parties



Scan to give feedback on this checklist:

