Recommendations: Best Practice Guide for Feasibility

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) 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: