

Protocol Feasibility Checklist-Pharmaceutical Industry Sponsored Study

1. Sponsor/Clinical Research Organization (CRO)

<input type="checkbox"/>	Has your previous experience with this sponsor/CRO been satisfactory?
<input type="checkbox"/>	If you have had no previous experience with this sponsor/CRO, have you checked the sponsor/CRO's reputation with colleagues?

2. Population

<input type="checkbox"/>	Do you have access to the right patient population?
<input type="checkbox"/>	Will you need to recruit patients from external sources? If so, will sponsor provide funding?
<input type="checkbox"/>	Is the proposed enrollment goal realistic?
<input type="checkbox"/>	Is the proposed enrollment period realistic?
<input type="checkbox"/>	Will enrollment compete with other studies seeking the same patients?
<input type="checkbox"/>	Are inclusion/exclusion criteria overly restrictive? (Consider the likely screen failure ratio and the number of screen failures for which the sponsor will pay.)
<input type="checkbox"/>	Do you expect a significant number of adverse events? (How ill is this population?)

3. Protocol

<input type="checkbox"/>	Is the protocol well designed?
<input type="checkbox"/>	Is the study question important?
<input type="checkbox"/>	Will the subjects benefit from participating in the study?
<input type="checkbox"/>	Will coordination with other departments/services be required for study visits or procedures (PK studies)?
<input type="checkbox"/>	Is the study unusually long in duration?
<input type="checkbox"/>	Are patient compliance problems likely? If so, will it be necessary to monitor subjects' compliance with time-consuming phone calls or postcards?
<input type="checkbox"/>	Are case report forms complex?
<input type="checkbox"/>	Are there a large number of case report forms per subject?
<input type="checkbox"/>	Will the drug be available for patients at the end of the study? (This can impact patient satisfaction.)

4. Procedures

<input type="checkbox"/>	Are procedures frequent?
<input type="checkbox"/>	Are procedures difficult, e.g., pre-medication before cycles, etc.?
<input type="checkbox"/>	Are subject questionnaires used? If so, does this require staff time for transcription or interpretation?
<input type="checkbox"/>	Is the dosing schedule complex?

5. Staff

<input type="checkbox"/>	If needed, is training available from the sponsor?
<input type="checkbox"/>	Is the workload manageable?
<input type="checkbox"/>	Does the PI have adequate time to devote to the protocol?
<input type="checkbox"/>	Is projected query turnaround time workable?

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6. Other

<input type="checkbox"/>	Is adequate clinic and office space available?
<input type="checkbox"/>	Does the sponsor expect this study to be audited by the FDA? (FDA audits take staff time.)
<input type="checkbox"/>	Does the sponsor expect to audit this study (also time-consuming)?
<input type="checkbox"/>	Will electronic or remote data retrieval systems be used? If so, will sponsor provide training?
<input type="checkbox"/>	Will sponsor's site monitor visit frequently? (Frequent visits will consume staff time but may help to minimize the number of data queries.)
<input type="checkbox"/>	Will the monitor need to meet with the PI at every visit?