

PSG DCRB: Protocol Feasibility Assessment

Feasibility is assessed by the PI in consultation representatives of all departments that may be required to provide supportive services in the conduct of this study
(e.g. Diagnostic laboratories, nursing services, other specialty services such as radiodiagnosis etc.).

DCRB will coordinate the feasibility assessment when contacted by the Sponsor for non-investigator initiated trials.

Study title	
Reviewer(s)	
Date of Review	
Disease focus (ICD-10 classification)	

Sponsor / CRO

Has your previous experience with this sponsor/CRO been satisfactory?
If you have had no previous experience with this CRO/Sponsor, have you checked the sponsor/CRO's reputation with colleagues?

Population:

Do you have access to the right patient population?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Will you need to recruit patients from external sources?	Yes <input type="checkbox"/> No <input type="checkbox"/>
If so, will the sponsor provide funding?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Is the proposed enrollment period realistic?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Will enrollment compete with other studies seeking the same patients?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Are inclusion/exclusion criteria reasonable to meet enrollment? (Consider the likely screen failure ratio and the number of screen failures for which the sponsor will pay)	Yes <input type="checkbox"/> No <input type="checkbox"/>
Total duration of the study (including screening, recruitment and follow-up):	_____ weeks/months/years
Total number of visits each patient will make:	_____ visits.

How are the above visits scheduled? (Use table below)

Visit number	Exact time point	Estimated duration of visit

Factors impeding enrollment (check any that apply)	
<input type="checkbox"/> Age	
<input type="checkbox"/> Duration of participation	
<input type="checkbox"/> Timing/frequency of visits	
<input type="checkbox"/> Frequency of dosing	
<input type="checkbox"/> Procedural discomfort/inconvenience (frequent/painful/laborious documentation/complex dosing schedule etc.)	
<input type="checkbox"/> Phase III protocol (drug may become commercially available while study is still underway)	
<input type="checkbox"/> Other, (specify)	
Are vulnerable populations involved, e.g. children, impaired adults with special consent issues?	Yes <input type="checkbox"/> No <input type="checkbox"/>
Are visits	scheduled <input type="checkbox"/> or opportunistic <input type="checkbox"/> ?

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Estimate of total enrollment:	_____	persons
Estimate of enrollment per month:	_____	persons
Estimate the screen to failure ratio:	_____	persons
Are Clinic patients eligible for the protocol?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Will recruitment require a special drive/advertisement for volunteers?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Will sponsor provide resources/plan of action for enrollment?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
What resources will the sponsor provide towards screening (as per the plan of action) for enrollment?		
Are frequent/severe Adverse events expected? (How ill is the population)	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Protocol:

Circle Phase of Study: I II III IV Other		
Is the protocol well designed?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Is the study question important?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Does protocol (objectives, procedures, safety considerations) agree with clinical judgment?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Can protocol be adequately integrated with routine standards of care?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Special considerations for IRB submissions:	•	
Will the patient benefit from this study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If 'YES', then, what are the compensation, and benefit sharing provisions in place? Please provide details.		
Does the protocol provide resources that benefit the Institution?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If 'YES', then, does the protocol provide resources that benefit the Institution? (Academically [training]/ infrastructure/ equipment/ reagents/ kits). Please provide details.		
Will co-ordination with other departments/services be required for study visits or procedures?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Can other services (e.g. lab, radiology) meet the protocol requirements?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Is necessary equipment available?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If Inpatient study, will floor staff need to be involved?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
If yes, then estimate nurse (or floor staff)/patient ratio.		
Are patient compliance problems likely? (Will intensive monitoring with post-cards and phone-calls be required?)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Are case report forms complex?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Is there a large number of case report forms per subject?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Are drug or device storage/accountability requirements complicated?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
List pharmacy/storage needs:	•	
Will the drug be available for patients at the end of the study? (This can impact patient satisfaction)	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Resources:

Can the protocol be completed within regular office hours?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
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	Does the sponsor expect to audit this study (time-consuming)?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Will electronic or remote data retrieval systems be used?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	If so, will sponsor provide training?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Will sponsor's site monitors visit frequently? (Frequent visits will consume staff time but may help to minimize the number of data queries.)	Yes <input type="checkbox"/>	No <input type="checkbox"/>
	Will the monitor need to meet with the PI at every visit?	Yes <input type="checkbox"/>	No <input type="checkbox"/>

Study design:

Outcome- endpoints (primary and secondary):

To be answered by the reviewer(s):

- Appropriateness of study: Study addresses drug/condition of interest? Yes No
 (Is the study question important? Is the protocol well designed?)
- Is adequate staff available to complete this study? Yes No
- Do staffs have adequate time available to incorporate this protocol? Yes No
- Can we undertake and successfully perform this protocol? Yes No
- Is the IRB likely to consider the protocol favorably? (Is the protocol ethical?) Yes No

Special Items to include in budget negotiation:

Questions / Comments for sponsor:

- Is the protocol in final form? If not, how many amendments can be expected before it is in final form? Yes No
- Is the sponsor willing to consider suggestions or modifications if you do not think the protocol is feasible as written? Yes No

Recommendation

- Pursue protocol
- Pursue with conditions (explain below) e.g., "only if sponsor pays non-refundable start-up costs."
- Do not pursue protocol (explain below) e.g., "sponsor's enrollment goal is unrealistic in proposed time frame."