

Protocol Concept Sheet (PCS)

THIS FORM MUST BE COMPLETED ELECTRONICALLY (DUE TO THE INCLUSION OF DROP-DOWN FIELDS)

Complete the form below electronically and attach specified documentation.

Study Specifications(1)			
Title of Proposal/Protocol			
Study Drug/Device			
Study Type (e.g. Phase, in vitro, registry, etc.)	Please specify study type:	If 'Other', please specify:	
Design	Number of Arms:		
	Number of Cohorts:		
	Randomized	Yes No	
	Stratified	Yes No	
	If 'Yes", please specify type of stratification:		
	Type of control group: If 'Other', please specify:		
Patient Population (e.g., Cancer unknown primary with X gene mutation)	Blinded		
	Yes No		
	If 'Yes", please specify type of blind:		
Number of Sites/Countries	Geographic scope:		
	Total No. Sites:	Total No Countries:	
	List <u>All Planned</u> Countries: <div style="text-align: center;">_____</div>		
Sample Size	Number of patients to be evaluated across all arms/cohorts:		
	Number of patients within above total to receive drug/device:		
Sponsor/Budget (in the case of undecided, describe a plan)			
Approval of IRB (at the time of application)	Yes	No	

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Study Synopsis

Requestor must either attach Study Synopsis or, to the extent relevant, add the details in text form below. See details below *up to 500 - 1000 words (excluding references)

- Abstract
- Background, study rationale and unmet medical need
- Study objective(s) (list as many as apply)
- Methodology/sequence of procedure
 - Screening period (if retrospective/prospective data evaluation, describe the process for screening charts for eligibility)
 - Treatment period (if using drug on-formulary for a retrospective/prospective data evaluation, please specify standard of care followed)
 - Follow-up period (if retrospective/prospective data evaluation, specify any part of patient care post-treatment or procedure for which data will be collected from the charts, including in a post-op area or post-48 hours, etc.)
- Inclusion and exclusion criteria
- Treatment (dose and administration)
- Statistical analyses/assumptions (Describe presence or absence of advice of the statistician as well)