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: Choose an item.
	Number of Cohorts: Choose an item.
	Randomized ◯ Yes ◯ No
	Stratified ◯ Yes ◯ No If 'Yes", please specify type of stratification:
	Type of control group: Choose an item. If 'Other', please specify:
	Blinded ◯ Yes ◯ No If 'Yes", please specify type of blind:
Patient Population (e.g., Cancer unknown primary with X gene mutation)	
Number of Sites/Countries	Geographic scope: Choose an item.
	Total No. Sites: Total No Countries:
	List All Planned Countries:
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)

- Abstaract
- 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)