Protocol Concept Sheet (PCS)

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

Principal Investigator Contact Information	
Investigator's Name	
Investigator's Title	
Institution/Organization	
Office Address	
Phone	
Fax	
Email	
Curriculum Vitae (CV)	☐ CV attached, initialed and dated within prior 2 years CV date: N/A ☐

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Complete the form below electronically and attach specified documentation.

Study Specifications(1)	
Sponsor/Budget (in the case of undecided, describe a plan)	
Potential conflict of interest (COI): follow COI rule of JSMO	◯ not present ◯ present (described in JSMO format)
Approval of IRB	◯ Yes ◯ No
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:

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Study Specifications(2)	
Sample Size	Number of patients to be evaluated across all arms/cohorts:
	Number of patients within above total to receive drug/device:

Regulatory & Institutional Review Board/Committee Review Process (IRB, EC, etc.)	
Board/Committee Review *As required per local regulations	What type of board approval will be required for this study? Choose an item.
	If 'Other', please specify:
	How often does the review board or committee meet? Choose an item. Comments:
Regulatory Authority	Will this study be submitted to a Regulatory Authority? ◯ No ◯ Yes
	◯ PMDA ◯ FDA ◯ EMA
Other comments related to approval requirements	

Timelines	
Abstract or Manuscript Journal Submission or CSR	Approximate target month/year:
For retrospective or in vitro studies, summarize timelines	

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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

◯ See attached Synopsis

- Abstaract
- Background, study rationale and unmet medical need
- Study population (detailed description of therapeutic area, patient type, setting, type of procedure if applicable, etc.)
- Hypothesis
- Study objective(s) (list as many as apply)
- Timelines (including all phases of a multi-phase study)
- 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.)
- Clinical laboratory or other assessments
- Brief description of any disease state or quality of life measures that will be measured
- Inclusion and exclusion criteria
- Treatment (dose and administration)
- Duration of treatment
- Reference therapy (dose and administration)
- Concomitant and prohibited medications
- Outcomes/endpoints (primary, secondary, exploratory)
- Statistical analyses/assumptions（Describe presence or absence of advice of the statistician as well)
- Schedule of assessments
- Flow diagram (if available)
- Informed consent
- Study assessment
- SAE reporting