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**Feasibility**

**Questionnaire**

**FQ Format #: CFQ000**

**Version #: 01**

**Date: Dec 13, 2019**

|  |
| --- |
| General Information |

 Name of the investigator

|  |  |  |
| --- | --- | --- |
| First Name |  | Last Name |

 Investigator’s qualification Therapeutic area

|  |  |  |
| --- | --- | --- |
| MBBS, MD, BDS, etc. |  | Cardiology, Oncology, Neurology etc. |

 Email Contact number

|  |  |  |
| --- | --- | --- |
|  |  |  |

|  |
| --- |
| Professional Details of Investigator |

 Medical Experience Clinical Experience

|  |  |  |
| --- | --- | --- |
| Years, Months |  | Years, Months |

 How many trials has Investigator conducted till now?

|  |
| --- |
| Number |

|  |
| --- |
| Clinical Trial Details |

 **Previous clinical trial details**

|  |  |  |
| --- | --- | --- |
| Trial title |  | Patient population details |
|  |  |  |
|  |  |
| Number of patients to be randomized |  | Number of patients recruited |
|  |  |  |
| Period of recruitment |  | Status of the trial |
|  |  | Ongoing, Completed, Terminated |

|  |
| --- |
| General Questionnaire |

 Is the investigator a member of site’s IRB or ethics committee?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

 Is the investigator trained in current good clinical practices (cGCP)?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

 Any honors & awards for the investigator?

|  |
| --- |
|  |

 Publications & any other memberships

|  |
| --- |
|  |

|  |
| --- |
| Site Study Coordinator Details |

 Name of the study coordinator (CRC)

|  |  |  |
| --- | --- | --- |
| First Name |  | Last Name |

 Clinical research experience

|  |
| --- |
| Years, Months |

 Email Contact number

|  |  |  |
| --- | --- | --- |
|  |  |  |

 Given other work load and requirements of this study, do you think the CRC will have time to manage this study?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

 Does CRC have good clinical practice (GCP) training and certifications? If yes, specify the details.

|  |
| --- |
|  |
|  |

|  |
| --- |
| Site Details |

 Site name

|  |
| --- |
|  |

 Site address

|  |
| --- |
|  |

 What are the therapeutic areas your site deals with?

|  |
| --- |
|  |

 How many clinical trials were conducted at your site till now?

|  |
| --- |
| Number |

 How many staff does your site have?

|  |
| --- |
| Number |

 How many of the site staff are GCP trained?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| All of them |  | None of them |  | Some of them |  |

What type of equipment does your site have?

|  |
| --- |
| MRI, CT, ECG, TMT, Ultrasound, etc. |

 Do you have access to a pathological laboratory to perform tests?

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Do not have access to lab |  | Have access to in-house lab  |  | Have access to external lab |  |

 What type of storage facility do you have at your site?

|  |
| --- |
| Records storage room, Secure drug storage facility, Separate documentation facility etc.  |

 Does your site use Electronic Medical Records (EMR)?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

 Do you have Standard Operating Procedures (SOPs) for management of site operations?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

 Does your site have any affiliations/accreditations?

|  |
| --- |
|  |

 How does your site recruit patients (ex: advertisements, referred by someone, etc.)?

|  |
| --- |
|  |

|  |
| --- |
| Timelines & Contract Related Questions |

 What is the time period for agreement / contract with your site?

|  |
| --- |
| Month/s and Day/s |

What contracts are needed other than a clinical trial agreement with both the site and investigator?

|  |
| --- |
|  |

 What is the name of the IRB/IEC you will use?

|  |
| --- |
|  |

 How often does IRB meet for study review?

|  |
| --- |
|  |

 How long does it typically take from submission to receipt of approval letter?

|  |
| --- |
|  |

|  |
| --- |
| Project Based Questions |

 Does investigator have required time and resources to conduct this study?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

 How many clinical trials are currently active at your site?

|  |
| --- |
|  |

How many patients with (*specify the disease conditions related to study here, e.g. AML, diabetes etc.)* visit your site every month?

|  |
| --- |
|  |

What is the standard of care (SoC) for the treatment of (*specify the disease conditions related to study here, e.g. AML, diabetes etc.)* in your country?

|  |
| --- |
|  |

What challenges and risks, if any, do you see for this study? What can you do or recommend managing them?

|  |
| --- |
|  |

Do you have access to all the necessary laboratories and equipment’s that are required in this study?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

 If No, then how do you manage?

|  |
| --- |
|  |

 Do you foresee monthly study visits negatively impacting patient recruitment/retention?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

 If yes, how do you think you can manage?

|  |
| --- |
|  |

Based on Inclusion & Exclusion criteria, how many patients do you expect to recruit per month?

|  |
| --- |
| Number |

 **Questions related to IRB/EC**

 How much time do you expect it will take to get IRB approval for this trial?

|  |
| --- |
| Month/s and Day/s |

 What are the IRB requirements for this study?

|  |
| --- |
|  |

**Question related to clinical trials in non-English speaking regions**

Will you need the informed consent form in a language other than English?

|  |  |  |  |
| --- | --- | --- | --- |
| Yes |  | No |  |

What are the languages would you need ICF and other patients’ documents translated into?

|  |
| --- |
|  |

|  |
| --- |
| More questions that may help in building a great feasibility questionnaire |

 Just pick and add

 Site related questions

* Type of practice or institution: University Hospital, Community Hospital, Group
* How many active patients does your [site/department] have (visits within the past 12 months)?
* How many physicians at your site treat patients with the (*specify the disease conditions related to study here, e.g. AML, diabetes etc.)*?
* How many clinical research studies are currently active at your site?
* How many physicians at your site are currently working as principal investigator in clinical trials?

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 Investigator related questions

* Do you want to conduct this study? Why?
* What percent of your work time do you devote to clinical research?
* What human subject’s protection (HSP) and good clinical practice (GCP) training and certifications do you have?
* Are you affiliated with a site network or SMO?
* How many clinical research studies have you conducted in the past three years?
* What percent of your previous studies has been industry-sponsored?
* What percent of your previous studies did you participate in as principal investigator?
* Do you have experience with this type of study? (e.g., gene therapy)
* How many clinical research studies have you conducted in the past three years on related conditions?
* Do you consider yourself a key opinion leader? Explain.

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 Subject Enrollment

* How many subjects did the investigator enroll in any study in the past 12 months?
* How many subjects did the investigator enroll in studies of the (*specify the disease conditions related to study here, e.g. AML, diabetes etc.)* in the past 3 years?
* How many studies at the site will be enrolling subjects with the (*specify the disease conditions related to study here, e.g. AML, diabetes etc.)* during (time period)?
* How many active patients does the investigator have (visited in the past 12 months)?
	+ Of these, how many were / are newly diagnosed with (*specify the disease conditions related to study here, e.g. AML, diabetes etc.)*?
	+ Of these, how many meet the eligibility criteria provided in the study summary?
* Based on the study summary, how many subjects do you expect to enroll from the investigator's practice in [*specify time period*]?
* How many additional subjects do you expect to enroll from elsewhere in your site?
* How many additional subjects do you expect to enroll from outside your site?
* How many patients do you expect to screen for each enrollment?
* Will this study appeal to your patients? If no, why?
* Do you have a different database you can use to identify potential subjects for this study?
* What is your process for contacting potential subjects and bringing them into your site?
* How will you identify potential subjects for this study?
* Are you willing to submit a blinded list of at least non potential subjects (who have expressed interest in the study)?
* Do you have access to potential subjects in a hospital/living facility? If so, is traveling to the facility a problem?

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 Study Coordinator(s)

* How many actively enrolling studies do your CRCs typically manage?
* How many study nurses/coordinators (CRCs) will participate in this study?
* Who will the primary study coordinator be?
* What are the qualifications (CCRC, RN, PA, MD, etc.) does he/she have?
* What human subject’s protection (HSP) and good clinical practice (GCP) training and certifications does he/she have?
* What percent of work time does he/she spend on clinical research?
* Does the CRC have time for this study?
* Does the CRC want to manage this study?
* How many studies with EDC does this person have experience in?
* Does he/she have a computer with high-speed Internet access for EDC?
* Does he/she have experience with electronic subject diaries? Describe.
* Who would the other key members of the study team be, and what would their roles be?

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 Capabilities & Resources

* Does the (investigator/team member) have adequate experience with (*Specify assessment / procedure / assessment / test*)
* Who will perform (*Specify assessment / procedure / assessment / test*)?
* Do you have access to (equipment, pharmacy, lab, dry ice, secure storage, etc.) with adequate capacity (during the required hours)?
* Do you actively use clinical research standard operating procedures (SOPs)?
* How many sub investigators will enroll subjects? Describe.
* Can you use a central laboratory?
* Do you have a local laboratory? What is its name?
* What is your site’s access to public transportation?
* Is parking readily available? At what price?
* What waiting areas are available for family members and during long visits?
* What food and beverage services are available? During what hours?
* Do you have a pharmacist to prepare study drug?
* Do you have a sub investigator who can do blinded assessments?
* What is the brand and model of the equipment?
* Can you administer study drug during (required hours)?
* Do you have a dedicated, analog, direct-dial fax line?
* Do you provide Internet access to site monitors with laptops, without special login or?
* configuration requirements?
* How many satellite sites will participate? Describe.

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 Site Initiation

* How long does it typically take your site to start a study of this type (from receipt of final protocol to site initiation visit)?
* Does your site pursue IRB/IEC approval at the same time as contract & budget completion?
* Will you use (the study's IRB/IEC) for this study?
* If not, what is the name of the IRB/IEC you will use?
	+ How often does it meet?
	+ How long does it typically take from submission to receipt of approval letter?
	+ Are there additional approvals or review committees?
	+ Names & approval times?
* Can you use our standard clinical trial agreement template (with negotiated? modifications, if any)?
* What contracts are needed other than a clinical trial agreement with both the site and investigator?
* Can you attend a site qualification visit (period)?
* Can the investigator and CRC attend the investigator meeting on (dates)?

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 Other

* Has your (site/investigator) been inspected by the FDA or similar regulatory agency in the past five years?
	+ What was the outcome?
	+ Provide copy of 483 or equivalent document.
* What challenges and risks, if any, do you see for this study? If so, how will you address them? How can we, the sponsor, address them?
	+ Study design
	+ Subject recruiting, screening & enrollment
	+ Subject adherence & retention
	+ IRB and other approvals
	+ Contract & budget
	+ Additional comments or questions.
* Which, if any, of the answers above are uncertain?
* Who completed this questionnaire?
* Role and contact information (if not above)
* Has your [site/investigator] been audited by sponsors in the past five years? When and if yes, what was the result?
* Do you want to participate in the PK sampling part of this study?
* Do you have experience with PK sampling?
* Do the investigator and CRC speak English?
* Do you have a 24/7 contact available for subjects?

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