MEDICAL SCHOOL
UNIVERSITY OF MICHIGAN

Planning Questionnaire for Externally Sponsored Clinical Trials

The purpose of this questionnaire is to obtain information from the sponsor in order to facilitate and accelerate the process of study submission. Please complete this questionnaire prior to the pre-site selection visit (PSV) or call. If a PSV is not required, please complete the form and submit with the full regulatory start-up package.

Study Number: _____

Study Title: | |

STUDY TARGETS

Study Length *(in months)*	Accrual Length *(in months)*	Total Sites	Total Accrual	U-M Accrual

Comments: | |

STUDY PROGRESS

Active Sites (#)	Current Accrual	Activation Date of Initial Site	Initial Visit Date of First Patient	Final Visit Date of Last Patient
		☐ Projected ☐ Actual	☐ Projected ☐ Actual	Projected

Projected Number of Data Locks & Interim Analysis? | |

Projected Database Closure & Site Termination? *(ex.: six months after last patient off-study)* | |

Is there an amendment in progress? ☐ Yes ☐ No

If yes, please provided the projected date of release? | |

If yes, can sites enroll under the current protocol if approved prior to receipt of the new amendment? ☐ Yes ☐ No

Comments: | |

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STUDY DOCUMENT

In addition to the regulatory start-up documents (i.e., protocol, informed consent, investigator brochure, etc.), the following documents are required for submission. If they are not received in a timely manner, protocol activation may be delayed. Please indicate the status of availability for the following documents, if applicable.

Proposed study budget and contract	◯ N/A	◯ Yes	◯ No, available by:	
Laboratory Manual	◯ N/A	◯ Yes	◯ No, available by:	
Pharmacy Manual	◯ N/A	◯ Yes	◯ No, available by:	
EKG Manual	◯ N/A	◯ Yes	◯ No, available by:	
IVRS/IWRS Manual	◯ N/A	◯ Yes	◯ No, available by:	
Study Reference Manuals	◯ N/A	◯ Yes	◯ No, available by:	
Case Report Forms (CRFs)	◯ N/A	◯ Yes	◯ No, available by:	
CRF Completion Guidelines	◯ N/A	◯ Yes	◯ No, available by:	
Eligibility Checklist / Enrollment Form	◯ N/A	◯ Yes	◯ No, available by:	
Serious Adverse Event (SAE) Form	◯ N/A	◯ Yes	◯ No, available by:	
Contact List for CRO(s) and Vendor(s)	◯ N/A	◯ Yes	◯ No, available by:	
Contact List for Sponsor(s)	◯ N/A	◯ Yes	◯ No, available by:	
Subject Completed Questionnaires*	◯ N/A	◯ Yes	◯ No, available by:	
Subject Completed Oral Drug Diaries*	◯ N/A	◯ Yes	◯ No, available by:	

** requires approval by IRB*

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ADDITIONAL ITEMS FOR PLANNING

The following items will assist us in resource planning, budgeting, and coordinating across other internal units to ensure expedient approval and successful completion of the study.

Will any equipment be provided? *(ex: ECG machine, infusion pump, e-Diaries, etc.)* ☐ Yes ☐ No

If yes, list: ☐

Note: Please provide this equipment as soon as available. Inspection & approval by our Biomedical Engineering Unit (BEU) is required prior to IRB Approval.

Do any of the following require central review & results confirmation prior to enrollment? ☐ Lab ☐ Tissue ☐ Imaging

Is the site required to use central lab results to determine eligibility or subsequent dosing? ☐ Yes ☐ No ☐ Unknown

Is the study utilizing an IVRS/IWRS system? ☐ Yes ☐ No ☐ Unknown

If yes, indicate below all that apply:

☐ Drug Inventory ☐ Drug Assignments ☐ Patient Statuses ☐ Visit Confirmation Only

If used for patient statuses, indicate below all that apply:

☐ Screening ☐ Registration ☐ Randomization ☐ Other

If applicable, FDG PET Scan and/or MUGA required (as an additional committee approval will be needed)? ☐ Yes ☐ No ☐ Unknown

Will any scans (MRI, CT, PET, etc.) be considered "research" only, not standard of care (requires different internal radiology coordination)? ☐ Yes ☐ No ☐ Unknown

Will the study be using a central imaging vendor reviewer? ☐ Yes ☐ No ☐ Unknown

If yes, does the site need to pre-qualify with the imaging vendor? ☐ Yes ☐ No ☐ Unknown

If yes, what is involved in the pre-qualification process? *(Examples: phantom, standard-of-care de-identification transmission to vendor, etc.)* ☐

If yes, can site-initiation visit be held prior to qualification of site? ☐ Yes ☐ No ☐ Unknown

Will PK/PD/Genetic sample collection be required? ☐ Yes ☐ No ☐ Unknown

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Will special sample processing / additives / timeframe be required? ☐ Yes ☐ No ☐ Unknown

If yes, explain:

Will the study utilize an electronic data capture system (EDC)? ☐ Yes ☐ No ☐ Unknown

If yes, what is the EDC vendor?

Are serious adverse events reported via the EDC? ☐ Yes ☐ No ☐ Unknown

If yes, will some data entry be required only by the investigator? ☐ Yes ☐ No ☐ Unknown

If yes, indicate which SAE elements? ☐ Entire Report ☐ Grade ☐ Attribution

Will you need to monitor within two weeks of the first patient going on study? ☐ Yes ☐ No ☐ Unknown

Will the study at any point move into analytical risk-based monitoring? ☐ Yes ☐ No ☐ Unknown

How frequently do you anticipate intermediate "on-site" monitoring visits will be scheduled?

How frequently do you anticipate intermediate "remote" monitoring visits will be scheduled?

Will you use remote monitoring? ☐ Yes ☐ No ☐ Unknown

Will the sponsor have regularly scheduled teleconferences? ☐ Yes ☐ No ☐ Unknown

Is this study considered approved by the FDA? ☐ Yes ☐ No ☐ Unknown
(i.e., date of receipt of the IND by FDA is greater than 30 days or sponsor has received earlier notification by the FDA that studies may begin.)

Thank you for considering the University of Michigan for this important study.

www.clinicaltrials.med.umich.edu

Questions? Email CTSOgroup@umich.edu