Protocol Concept Sheet

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		
Sponsor		
Title of Proposal/Protocol		
MDCO 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., intracranial hemorrhage patients)		
Number of Sites/Countries	Geographic scope: Choose an item.	
	Total No. Sites:	Total No Countries:
	List <u>All Planned</u> Countries:	
Sample Size	Number of patients to be evaluated across all arms/cohorts:	
	Number of patients within above total to receive MDCO drug/device:	

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Deliverables	
Presentations	Describe the intent to present this information at a congress/venue, including: 1) the name of the venue and 2) expected month and/or year of the event.
Publications	Please describe the publication plan for this study, including the name or names of targeted journals.

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
	If this research will be conducted outside of the US, will you need to obtain Regulatory Authority documented approval be required prior to commencement of this study or data collection? ◯ No ◯ Yes ◯ N/A - US only
Requires an IND *MDCO to confirm agreement with this as part of MDCO's internal grants review process	Per Part 21 CFR 312.2, Applicability http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=312.2 (or other applicable central regulatory registration) Please indicate whether this study will be required to be conducted under an IND. Choose an item.
Other comments related to approval requirements	

Timelines	
FPI	Approximate date:
LPO	Approximate date:
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

- 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
- MDCO product (dose and administration)
- Duration of treatment
- Reference therapy (dose and administration)
- Concomitant and prohibited medications
- Outcomes/endpoints (primary, secondary, exploratory)
- Statistical analyses/assumptions
- Schedule of assessments
- Flow diagram (if available)

FRM-045 Attachment #1: Schedule of Assessment *(optional if not applicable)*

Define treatment period windows, if applicable.
Do not use Day Zero; Day -1 = pre-randomization and Day 1 = randomization.

Study Assessment	
Informed Consent	
Medical History	
Initiation of Study Drug Administration/Device Use	
Concomitant Medications	
Adverse Event Reporting	
Serious Adverse Event Reporting	

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FRM-045 Attachment #3: Research Grant Information

(Only to be completed for research grant applications; optional if not applicable)

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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Type of Support Requested	
Financial	Are funds being requested from MDCO for a research grant? ◯ No ◯ Yes * Total amount requested:
	*If 'Yes', please attach an itemized budget showing the general breakdown of costs adding to the total requested above. ☐ Budget attached Budget version date:
	If yes, please confirm if funding has been or will be requested from other manufacturers or funding companies or organizations (including NIH)? ◯ No ◯ Yes Total amount requested:
Study Drug / Device Supply	To be provided by MDCO? ◯ No ◯ Yes
	Comments: Describe the plans/process for supplying drug and/or device to site(s).
MDCO Clinical Supplies Support	◯ No ◯ Yes
	*If 'Yes', please describe the type of support requested.
Statistical/Analytical Support	◯ No ◯ Yes
	*If 'Yes', please describe the type of support requested.
Data Management Support	◯ No ◯ Yes
	*If 'Yes', please describe the type of support requested.
Clinical Operations Support	◯ No ◯ Yes
	*If 'Yes', please describe the type of support requested (e.g. Internal CTAs, CRAs. Project Managers, etc.).
GPV / Safety Reporting Support	◯ No ◯ Yes
	*If 'Yes', please describe the type of support requested.
Publications Support	◯ No ◯ Yes
	*If 'Yes', please describe the type of support requested.
Other Support	◯ No ◯ Yes
	*If 'Yes', please describe the type of support requested.