Date:

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| **Trial Representative(s):** | **CTMS Support Representative(s):** |

***\* CTMS Required Field (cannot configure without this information) \*\* CTMS Required Field (will accept temporary place holder)***

| ***Field*** | ***Approved Value*** | ***Instructions*** |
| --- | --- | --- |
| **\* Protocol Acronym** |  | ***Requirements:*** Must begin with alpha character, All capital ltrs, No spaces or dashes (use underscore), ***no more than 10 characters***, must match IVRS (Enrollment), ClinTrial, DCF Transfer, Trial Payments & Inform. |
| **\*\*Protocol #** |  | From Protocol or Synopsis (Prints on Conf. & F/U Ltrs, and the Trip Rpts) |
| **\*\* Description** |  | Full name of Protocol. Entered in the Description Field on Protocol Tab in CTMS. (Prints on Conf. & F/U Ltrs). |
| **Primary End Points** |  | From Protocol or Synopsis |
| **\* Project #** |  | From EPM |
| **\* Mega Trials Protocol** | Choose an item. | Specify if this is a Mega Trials Protocol |
| **PhlexEView Protocol** | Choose an item. | Specify if this protocol will be using the PhlexEView eTMF |
| **\* Program** |  | Corresponds to Therapeutic Area (CARDIOVASCULAR, ONCOLOGY etc.) |
| **\* Product** |  | Name of Drug or Device (Prints on Trip Rpt) |
| **\* Product Type** | Choose an item. | Compound, Device or Not Applicable |
| **\* Indication** |  | Condition being studied *(Limited to one Indication)* |
| **Discipline** |  | Therapeutic Area *(May track a secondary Discipline)* |
| **\* Phase** | Choose an item. | I, II, III, IV, Registry, or Not Applicable |
| **Population** |  | Age group of subjects in study (Adult, Pediatric, etc) |
| **\* Protocol Type** | Choose an item. | Feasibility, Market Support, Network, New Indication, New Info, Not Specified |
| **\* Application Type** | Choose an item. | IND, IDE or Other |
| \* **Application Sub-Type** | Choose an item. | Government, Industry, Investigator, Professional/Society Foundation |
| **\* Region Names** |  | Regions are Protocol Specific |
| **\* Total # of Planned Sites** |  | # of sites for ENTIRE Protocol |
| **\* Total # of Planned Subjects** |  | # of subjects for ENTIRE Protocol |
| **# of DCRI Sites** |  | # of sites to be managed/coordinated by DCRI |
| **# of DCRI Subjects** |  | # of subjects that will be enrolled at DCRI Sites |
| **# Planned SSVs** |  | # of Planned Site Selection Visits by DCRI |
| **# Planned SIVs** |  | # of Planned Site Initiation Visits by DCRI |
| **# Planned PMVs** |  | # of Planned Periodic Monitoring Visits by DCRI |
| **# Planned COVs** |  | # of Planned Close Out Visits by DCRI |
| **# Planned Remote** |  | # of Planned Remote Visits by DCRI |
| **# Planned Booster** |  | # of Planned Booster Visits by DCRI |
| **# Planned Unblinded** |  | # of Planned Unblinded Visits by DCRI |
| **# Planned Other Visits** |  | # of Planned Other Visits by DCRI |
| **Total # Planned Visits** |  | Total # of Planned Visits by DCRI |
|  | ***DCRI Services*** |  |
| **Site Management** | Choose an item. | Is DCRI contracted for Site Management? (Yes /No) |
| **Enrollment** | Choose an item. | Is DCRI capturing Enrollment in CTMS? (Yes /No) |
| **Enrollment Information** | Rando Import  Manual  Subject ID Concatenation Rules  **Screening ID**  **Randomization ID**  **Enrollment ID**  Notes: | If using IVRS, check Enrollment and check Rando.  ***Note****: If using IVRS, PL must contact Clinical Data Management Services (CDMS) Group to arrange import of enrollment to the central enrollment table.*  ***Note****: If using Manual Enrollment, one or any combination can be checked – this will determine what the Subject ID will consist of.*  ***(The order of the numbers will always be:***  ***Screening ID:Randomization ID:Enrollment ID)*** |
| **Site Monitoring** | Choose an item. | Is DCRI contracted for Site Monitoring? (Yes/No) |
| **Trip Report Functionality** | Choose an item. | Will Study Team use Trip Report Functionality? (Yes/ No) |
| **Trip Report**  **Information** | DCRI Trip Rpt Template  Custom Trip Rpt Template (*Study Team to Provide*)  Trial Specific Confirmation & F/U Letter  Templates (*Study Team to Provide*)  ICFs  CRFs  Unblinded  ISF  ISF PDF Report Display  **ISF Document** Choose an item.  **ISF Safety** Choose an item.  **ISF Training** Choose an item.  Notes: | ***Note:*** *If requesting a “custom Trip Rpt. Template”, the PL and AD must approve.*  ***The Format of the standard CTMS Trip Report PDF******can not be changed****.*  **ICFs & CRFs** (*must be checked if you wish to include functionality in your trip reports*)  **Unblinded** (*check if study will be using the blinded/unblinded functionality*)  **ISF** (must be checked if you wish to include the ISF functionality – Activity Plan must also indicate where you want Documents/Training/Safety Letters to display (Site Only, TR Only or Both)) |
| **Clinical Monitoring Plan (CMP) Monitoring Visit Frequency** | Minimum # of weeks  Maximum # of weeks | Minimum & Maximum number of weeks between periodic monitoring visits. |
| **TR Completion Metrics** | **SSV:** VC to TRS  TRS to TRA  VC to TRA  **SIV:** VC to TRS  TRS to TRA  VC to TRA  **PMV:** VC to TRS  TRS to TRA  VC to TRA  **COV:** VC to TRS  TRS to TRA  VC to TRA  **REMOTE:** VC to TRS  TRS to TRA  VC to TRA  **BOOSTER:** VC to TRS  TRS to TRA  VC to TRA  **UNBLINDED:** VC to TRS  TRS to TRA  VC to TRA  **OTHER:** VC to TRS  TRS to TRA  VC to TRA | Business days between Visit Complete to Trip Report Submitted (VC to TRS), Trip Report Submitted to Trip Report Approved (TRS to TRA) and Visit Complete to Trip Report Approved (VC to TRA) and for each visit type.  **VC to TRA** and **TRS to TRA** should total **VC to TRA** for each visit. |
| **Monitoring Interval/Units** | **Interval**  **Units** | Number for Expected Interval of Monitoring Visits  Days, Weeks, Months, Years |
| **DATA REFERENCE ONLY** | |  |
| **Biomarkers Trial** | Choose an item. | Is this a Biomarkers Trial? (Yes/No) |
| **Contracts** | Choose an item. | Is DCRI negotiating Contracts? (Yes/No) |
| **Safety** | Choose an item. | Is DCRI contracted for Safety? (Yes/No) |
| **Site Payments** | Choose an item. | Is DCRI contracted for Site payments (Yes/No) |
| **Inpatient Trial** | Choose an item. | Is this an Inpatient Study (Yes/ No) |
| **Outpatient Trial** | Choose an item. | Is this an Outpatient Study (Yes/ No) |
| **Data Management** | Choose an item. | Is DCRI contracted for Data Management? (Yes/No) |
| **Data Management**  **Information** | EDC ClinTrial | If Yes to Data Management, check either EDC or ClinTrial. |

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|  | ***External Partners (Sponsor, Vendors, CROs etc.)*** | | | | | | | |
| **Name**  ***Info listed here will be added under “Accounts” at Protocol Level in CTMS*** | | **Account Type** | **Role(s)** | **Address** | **City** | **State** | **Zip** | **Country** |
|  | | Choose an item. | Sponsor - Required |  |  |  |  |  |
|  | | Choose an item. | Choose an item. |  |  |  |  |  |
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|  | | Choose an item. | Choose an item. |  |  |  |  |  |

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| ***Vendor Information for Sending Reg Pack, Starter Box, Drug and Device Shipment*** | | |
| **Service(s)** (*Milestone used)* | **Vendor Name** *(Company Name)* | **Vendor Email** *(email of person -or group- to be notified)* |
| Send Reg Pack |  |  |
| Send Starter Box |  |  |
| Send Drug IP |  |  |
| Send Device IP |  |  |

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| ***DCRI & External Personnel requiring access to CTMS protocol:*** | | | | | | | |
| **Last Name** | **First Name** | **Role** | **User ID** | **Email** | **Phone** | **Trip Report Approver** | **Unblinded CRA** |
|  |  | Choose an item. |  |  |  |  |  |
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**Additional Requirements/Comments: (Additional information that cannot be documented in other sections of this form. This area also may be used to explain nonstandard protocol details.)**

***Activity Plan(s)*** *(attached)*

**The Activity Plan(s) for this study consists of the Milestones, Documents, Training and Other Requirements that will be tracked in**

**CTMS for *ALL* sites.**

***Note:* The difference between tracking the IRB approval letter DOCUMENT and the IRB approval MILESTONE.**

***Document* – *IRB Approval Letter* (metrics pull from here – All Protocols must track this Document)**

***Milestone* – *IRB Approval* (can track here as well, but should be entered in both places)**