|  |  |  |
| --- | --- | --- |
| Name\* | Click or tap here to enter text. | |
| Position/Job Title\* | Click or tap here to enter text. | |
| Company's Name\* | Click or tap here to enter text. | |
| Address | Click or tap here to enter text. | |
| Phone No.\* | Click or tap here to enter text. | |
| Email address\* | Click or tap here to enter text. | |
| Role in the Project\* | Choose an item. | Click or tap here to enter text. |
| Project Title\* | Click or tap here to enter text. | |
| Project Period\* | Click or tap here to enter text. | Click or tap here to enter text. |
| Investigational Product (IP)\* | Choose an item. | Click or tap here to enter text. |
| Study Phase | Choose an item. | |
| Availability of Study Document\* | Choose an item. | Click or tap here to enter text. |
| Case Report Form (CRF) | Choose an item. | Click or tap here to enter text. |
| Number of Subject | Click or tap here to enter text. | |
| Site Number / Site Location | Click or tap here to enter text. |  |
| Principal Investigator | Click or tap here to enter text. | |
| Other Information | Click or tap here to enter text. | |

\* Mandatory

| **SERVICES** | | | | | | |  | **By Sponsor** | **By Investigator** | **Not Applicable** | **Note** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | | | | | | |  |  |  |  |  |
| **STUDY PREPARATION** |  | 1 | Study Documents | | | |  |  |  |  |  |
|  | a. | | Protocol  (Study design / concept shall be provided by Client) | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | | **Please choose:**  Paper Case Report Form (CRF) | Choose an item. |  |  |  |  | Click or tap here to enter text. |
| Electronic Case Report Form (e-CRF) |
|  | b. | | Informed Consent Form (ICF) | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  | c. | | Subject Diary | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  | d. | | Questionnaire (Please specify document name) | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  | e. | | Document Translation  (Please specify document name) | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  | f. | | Other Documents  (i.e., Data Management Plan, Study Concept Sheet, Study Manual, etc.) |  |  |  |  |  | Click or tap here to enter text. |
|  | g. | | Statistical Analysis Plan (SAP) | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  | h. | | Investigator Product (IP) Label Review & Translation |  |  |  |  |  | Click or tap here to enter text. |
|  |  | | | | | | | | | |
|  | 2 | Site and Investigator Feasibility and Selection / Site Qualification and preparation | | | | | | | | |
|  |  | a. | | Site and Investigator Feasibility & Selection |  |  |  |  |  | Click or tap here to enter text. |
|  |  | b. | | Project Feasibility |  |  |  |  |  | Click or tap here to enter text. |
|  |  | c. | | Site and Investigator Qualification |  |  |  |  |  | Click or tap here to enter text. |
|  |  | d. | | Site Contracting (including Addendum, if any) |  |  |  |  |  | Click or tap here to enter text. |
|  |  | e. | | Site Preparation |  |  |  |  |  |  |
|  |  |  | | * Site Set-up |  |  |  |  |  | Click or tap here to enter text. |
|  |  |  | | * Site logistic preparation |  |  |  |  |  | Click or tap here to enter text. |
|  | | | | | | | | | | |
|  | 3 | Clinical Trial Submission | | | | | | | | |
|  |  | a. | | Clinical Trial Approval/Notification from Regulatory | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | b. | | Ethical Approval from Ethics Committee (EC) |  |  |  |  |  | Click or tap here to enter text. |
|  | c. | | Material Transfer Agreement (MTA) Submission |  |  |  |  |  | Click or tap here to enter text. |
|  | d. | | Import License | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  | e. | | Amendment Submission to Regulatory |  |  |  |  |  | Click or tap here to enter text. |
|  | f. | | Progress Report to Regulatory |  |  |  |  |  | Click or tap here to enter text. |
|  | g. | | Approval Renewal Submission to Regulatory |  |  |  |  |  | Click or tap here to enter text. |
|  | h. | | Clinical Study Report (CSR) Submission to Regulatory |  |  |  |  |  | Click or tap here to enter text. |
|  | i. | | SAE/SUSAR Reporting to Regulatory |  |  |  |  |  | Click or tap here to enter text. |
|  | j. | | Amendment Submission to EC |  |  |  |  |  | Click or tap here to enter text. |
|  | k. | | Progress Report to EC |  |  |  |  |  | Click or tap here to enter text. |
|  | l. | | Clearance Renewal Submission to EC |  |  |  |  |  | Click or tap here to enter text. |
|  | m. | | Clinical Study Report (CSR) Submission to EC |  |  |  |  |  | Click or tap here to enter text. |
|  | n. | | SAE/SUSAR Reporting to EC |  |  |  |  |  | Click or tap here to enter text. |
|  |  |  |  | |  |  |  |  |  |  |  |
| **STUDY CONDUCT** |  | 4 | Study Meetings | | | | | | | | |
|  |  | a. | | Kick-off Meeting Coordination | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | b. | | Investigator Meeting Coordination | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | c. | | Progress Meetings | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | d. | | Final Study Meeting Coordination | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | e. | | Other Meetings (Please specify) | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  |  | |  |  |  |  |  |  |  |
|  | 5 | Study Monitoring & Management | | | | | | | | |
|  |  | a. | | Site Initiation Visit (SIV) | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | b. | | On-Site-Monitoring Visit (OMV) |  |  |  |  |  | Click or tap here to enter text. |
|  |  | c. | | Remote Monitoring |  |  |  |  |  | Click or tap here to enter text. |
|  |  | d. | | Close Out Visit (COV) | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | e. | | Progress Reporting | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | f. | | Newsletter Update | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | g. | | Trial Master File (TMF) Management | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  |  | |  |  |  |  |  |  |  |
|  | 6 | Investigational Product (IP) Management | | | | | | | | |
|  |  | a. | | Coordination of IP availability and Storage | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | b. | | Coordination to collect used/unused IP and supplies from Trial sites | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  |  | |  |  |  |  |  |  |  |
|  | 7 | Site Management | | | | | | | | |
|  |  | a. | | Investigator and study team management, fee arrangement & administration | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | b. | | Study Coordinator | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | c. | | Site Staff Provision (i.e., Nutritionist, Data Entry Staff, Recruiter, etc.) (Please specify the role) |  |  |  |  |  | Click or tap here to enter text. |
|  |  | d. | | Subject Recruitment |  |  |  |  |  | Click or tap here to enter text. |
|  |  | e. | | Training (Good Clinical Practice, Protocol, Manuscript Writing, and other trainings) |  |  |  |  |  | Click or tap here to enter text. |
|  |  | f. | | Advertisement |  |  |  |  |  | Click or tap here to enter text. |
|  |  |  | |  |  |  |  |  |  |  |
|  | 8 | Site Audit & Inspection | | | | | | | | |
|  |  | a. | | CRO assistance on Regulatory inspection |  |  |  |  |  | Click or tap here to enter text. |
|  |  | b. | | On-site Audit |  |  |  |  |  | Click or tap here to enter text. |
|  |  |  |  | |  |  |  |  |  |  |  |
| **POT STUDY CONDUCT** |  | 9 | Data Management, Analysis & Report | | | | | | | | |
|  |  | a. | | Data management (data entry, collection, data query) |  |  |  |  |  | Click or tap here to enter text. |
|  |  | b. | | Statistical Data Analysis | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | c. | | Clinical study report | Choose an item. |  |  |  |  | Click or tap here to enter text. |
|  |  | d. | | Manuscript, please specify journal name | Choose an item. |  |  |  |  | Journal name:  Click or tap here to enter text. |
|  |  |  |  | |  |  |  |  |  |  |  |
| **LABORATORY** |  | 10 | | Laboratory Services (by Prodia Laboratory) | | | | | | | |
|  |  | a. | | Laboratory Testing |  |  |  |  |  | Click or tap here to enter text. |
|  |  | b. | | Sample Handling |  |  |  |  |  | Click or tap here to enter text. |
|  |  | c. | | Sample Storage |  |  |  |  |  | Click or tap here to enter text. |