|  |  |
| --- | --- |
| 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. |