CHECK LIST OF PRODIA THE CRO SERVICES

Date :
Name of Sponsor :
PIC of Sponsor :
Investigational Product : Drug ☐ Vaccine/Infus ☐ Food Supplement/Milk ☐ Device ☐
Sites No. / Name of Site : Site(s) /
Principle Investigator :

SERVICES	PRODIA	SPONSOR
1 STUDY DOCUMENTS		
a Protocol Development / Amandement / Review *)	☐	☐
b Case Report Form (CRF) Development / Review *)	☐	☐
c Informed Consent Form (ICF) Development / Review *)	☐	☐
d Translation of ICF and Subject Information	☐	☐
e Other Patient Documents (Patient Diary, Patient Visit Card) Development / Review *)	☐	☐
*) please do strikethrough if not applicable		
2 ETHICS COMMITTEE AND REGULATORY AUTHORITY SUBMISSION		
I Ethics Committee		
a. Clinical Study Approval	☐	☐
b. Renewal / Amendment	☐	☐
c. Serious Adverse Event Reporting	☐	☐
d. Annual Reporting	☐	☐
e. Final Study Reporting	☐	☐
II Regulatory Authority		
a. Clinical Study Approval / Notification *)	☐	☐
b. Renewal / Amendment	☐	☐
c. Investigational Product Import Permit	☐	☐
d. Serious Adverse Event Reporting	☐	☐
e. Annual Reporting	☐	☐
f. Final Study Reporting	☐	☐
*) please do strikethrough if not applicable		
3 FEASIBILITY AND SELECTION		
a Project feasibility	☐	☐
b Site feasibility and selection	☐	☐
c Investigator feasibility and selection	☐	☐
4 STUDY COORDINATOR	☐	☐
5 GCP TRAINING		
(GCP training for Investigators, CRAs, Study Coordinators)	☐	☐
6 INVESTIGATIONAL PRODUCT		
a Packaging, labeling, storage and delivery	☐	☐
b Randomization and Blinding	☐	☐
c Translation of Investigational Brochure	☐	☐
d Service of Investigational Product (Handling and Keeping)	☐	☐
e Delivery of Investigational Product to Clinical Study Sites	☐	☐
f Drug Accountability	☐	☐

	SERVICES	PRODIA	SPONSOR
		☐	☐
7	**SUBJECT RECRUITMENT**		
a	Subject recruitment planning	☐	☐
b	Publication : posters, brochure, *etc.*	☐	☐
8	**STUDY MANAGEMENT**		
a	Set up Agreement with Clinical Study Site / Investigators *)	☐	☐
b	Set up Arrangement of Investigator and study team payment	☐	☐
c	Set up Arrangement of Subject Fee	☐	☐
d	Set up Logistic Clinical Study Site	☐	☐
e	Set up Investigator Meeting	☐	☐
f	GCP Overview for Investigators, CRAs or Study Coordinators	☐	☐
g	Set up Initiation Meeting	☐	☐
h	Study Documents (Trial Related Documents, Lab., CRF) Printing / Distribution *)	☐	☐
i	Set up Study Close Out	☐	☐
j	Set up Final Study Meeting	☐	☐
k	Archiving	☐	☐
9	**CENTRAL LABORATORY SERVICES**		
a	Routine safety test	☐	☐
b	Biomolecular testing	☐	☐
c	Other specific testings	☐	☐
d	Sample handling, storage and shipping	☐	☐
10	**MONITORING** (Source Data Verification (SDV), Query Management, Updated Trial Requirements, Subjects Tracking,Collected CRF back to sponsor, Monitoring Visit Report, Evaluate Screening and Enrollment Subject, Drug Accountability)	☐	☐
11	**BIOMETRIC**		
a	Data management (data entry and collection, data query)	☐	☐
b	Data analysis and reporting	☐	☐
c	Final study report English / Indonesia *)	☐	☐
d	Study publication / Medical article review	☐	☐
12	**SITE AUDIT AND QUALITY ASSURANCE**	☐	☐
13	**BA/BE SERVICES**	☐	☐