N. CLINICAL TRIAL AMENDMENT UNDER REGULATORY RELIANCE

The CTA Amendment is granted to Sponsor, Clinical Research Organization and/or Principal Investigator once the proposed changes to the protocol and other related documents on the conduct of clinical trial has been approved.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Sponsors, Contract Research Organizations (CROs), Principal Investigators and Importers of Pharmaceutical Products
Fees to be Paid	:	AO 50 s. 2001 Php 1,000.00 + 1% LRF

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO No. 2020-0010: Regulations on the Conduct of Clinical Trials for Investigational Products Initial Clinical Trial & Import License Application Requirements 1. Cover Letter (FDA-CRS Form 2.0) 2. Application Form (Appendix D1) 3. Original Version, corresponding amendments/s and rationale in a tabulated format 4. Supporting Data 5. Proof of Payment	Applicant Company

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. E-mail submission: Submits the application for preassessment through clinicalresearch@fda.gov.ph.	1. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the preassessment, issue the Document Tracking Number (DTN), and instructs the client to proceed with the payment. If the application did not satisfactorily pass the pre-assessment, advises	None	Day 1 1 working day	CRS Administrative Staff

	appointment schedule, inform the client of the deficiency/ies.			
2. For accepted applications, pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to Clinical Research Section through clinicalresearch@fda.gov.ph	2. Upon receipt of the proof of payment, the application will be encoded/update in the database.	AO 50 s. 2001 Php 1,000.00 + 1% LRF	Day 1 1 working day	CRS Administrative Staff
	3. Decks/Assigns the application to an evaluator.	None	Day 1 1 working day	Food-Drug Regulation Officer (FDRO) III
If an electronic notice of deficiencies (ENOD) was issued by the evaluator, submits complete compliance documents to the evaluator	4. Evaluates the application according to requirements and prescribed standards *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication	None	Day 2-11 10 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III (Senior Evaluator)
	5. Assignment of Scientific Advisory Committee (SAC) **The decision to assign to SAC is based upon the complexity of the amendments.*	None	Day 2 1 working day	FDRO I/II/III

	6. SAC Review	None	Day 3-11 9 working days	Scientific Advisory Committee (SAC)
	7. Reviews the evaluated application bearing the recommendation of the evaluator.	None	Day 12 -13 2 working days	Clinical Research Section Supervisor
	8. Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD)	None	Day 14 1 working day	PRSDD Chief
	9. Signs and approves the final decision	None	Day 14 1 working day (per batch of applications)	CDRR Director
	10. Encodes/Updates the Database and Endorses the final output document to the FDAC Releasing Section	None	Day 15 1 working day (per batch of applications)	CDRR-CRR Unit Personnel
3. Receives the letter	11. Releases the letter to the client	None	Day 215 1 working day (per batch of applications)	FDAC Releasing Section Personnel
TOTAL: Service is covered under Administrative Order No. 2020-0010.		**PHP 1,010.00**	**15 Working Days**	