K. CLINICAL TRIAL APPROVAL (CTA) AND IMPORT LICENSE APPROVAL (ILA) [INITIAL]

The CTA is granted to Sponsor, Clinical Research Organization and/or Principal Investigator to conduct a clinical trial of an investigational drug product. On the other hand, the IL is granted to Sponsor, Clinical Research Organization and/or Principal Investigator to allow importation of investigational product and ancillary supplies necessary for the conduct of clinical trial.

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 & FDA Circular No. 2012-007-A Protocol for MR/Post Marketing Surveillance: Php 2,500.00 + 1% LRF Fee for External Regulatory Reviewers: Php 60,000.00 Importation Clearance for Clinical Study: Php 500.00/importation + 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. Table of Contents for Clinical Trial Application 2. Cover Letter for Application 3. Clinical Trial Application Form 4. Investigational Product and Ancillary Supplies Information 5. Import License Application 6. Proof of payment 7. Letter of Authorization 8. Clinical Trial Protocol and amendment(s), where applicable 9. GCP Certificate and Curriculum vitae (CV) for investigators of each trial site 10. Informed Consent Form/Assent Form	Applicant Company

11. Investigator's Brochure 12. Pharmaceutical Data 13. GMP Certificate from NRA and/or evidence of GMP compliance 14. Shipping condition for IP and trial related materials 15. Labelling Materials of the Investigational product 16. Acknowledgement Receipt/Approval of the Research Ethics Committee (REC)	

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
2. E-mail submission: Submits the application for pre-assessment through fdac.letters.cdrr@fda.gov.ph For COVID-19-related applications, send through clinicalresearch@fda.gov.ph	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number (DTN).	None		CDRR *Personnel*

3. For accepted applications, pays the required fee through any of the following: • FDA Cashier • BANCNET • Landbank OnColl Sends proof of payment to the FDAC.	3. Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	Day 1 1 working day	FDA Cashier/ Landbank FDAC *Personnel*
	4. Receives the application from FDAC and encodes/updates the database	None	Day 2 1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	5. Decks/Assigns the application to the assigned evaluator	None	Day 2 1 working day	CDRR Director/ CRR Unit *Personnel*
	6. Evaluates the application for completeness and scientific worth *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication (5 working days to respond to the queries)	None	Day 3-4 2 working days	*Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/ FDRO III*
	7. Assigns regulatory reviewer /issuance of regulatory permit	None	Day 4 1 working day	*FDRO I/II/III*

	8. Forwards documents (Protocol and other documents) to External Regulatory Reviewer *Submit the Acknowledgement Receipt of the Regulatory Reviewer within three (3) calendar days after the receipt of the Regulatory Reviewer (both COVID and Non-COVID Clinical Trials) *Submit the Proof of Payment to the Regulatory Reviewer within 14 calendar days for Non-COVID Clinical Trials and 6 calendar days for COVID Clinical Trials	Fee for External Regulatory Reviewers: Php 60,000.00 (direct to External reviewers) FDA Circular 2012-007-A	Day 5 1 working day	*FDRO I/II/III*
	9. Reviews Pharmaceutical data requirements and Import License application	None	Day 6-35 30 working days	*FDRO I/II/III*
If an electronic notice of deficiencies (E-NOD) was issued by the external regulatory reviewer, submits complete compliance documents to the evaluator	10. Assesses the application through the FDA CT Assessment Form *Any clarifications/ deficiencies will be communicated to the clients through electronic communication (30 calendar days to respond to the queries) *This constitutes a stop clock on the processing time (based on AO 2020-0010, Section VI, Paragraph 5.6 and FDA Circular No. 2020-0029-1)		Day 6-35 30 working days	*External Regulatory reviewer* *[St. Luke's Medical Center (SLMC), University of the Philippines – National Institutes of Health (UP-NIH), Philippine Heart Center (PHC)]*

	11. Reviews the assessment from the Regulatory reviewer	None	Day 36-37 2 working days	*FDRO I/II/III*
	12. Reviews the evaluated application bearing the recommendation of the evaluator	None	Day 37 1 working day	*Clinical Research Section Supervisor*
	13. Prints the final response and transmittal, and forwards it to the Product Research and Standards Development Division (PRSDD) Chief	None	Day 38 1 working day	*FDRO I/II/III*
	14. Checks and recommends the decision of the evaluator/s by affixing initial/signature	None	Day 38 1 working day (per batch of applications)	*PRSDD Chief*
	15. Signs and approves the final decision	None	Day 39 1 working day (per batch of	*CDRR Director*
	16. Encodes/Updates the Database and Endorses the final output document to the AFS Releasing Section	None	Day 40 1 working day (per batch of applications)	*CDRR-CRR Unit* *Personnel*
4. Receives the documents	17. Releases the appropriate CT response and IL to the client	None	Day 40 1 working day	*AFS Releasing Section*
TOTAL: Service is covered under Administrative Order No. 2020-0010.		**PHP 63,035.00**	**40 Working days** ***For COVID-19 related Clinical Trials: 20 working days**	