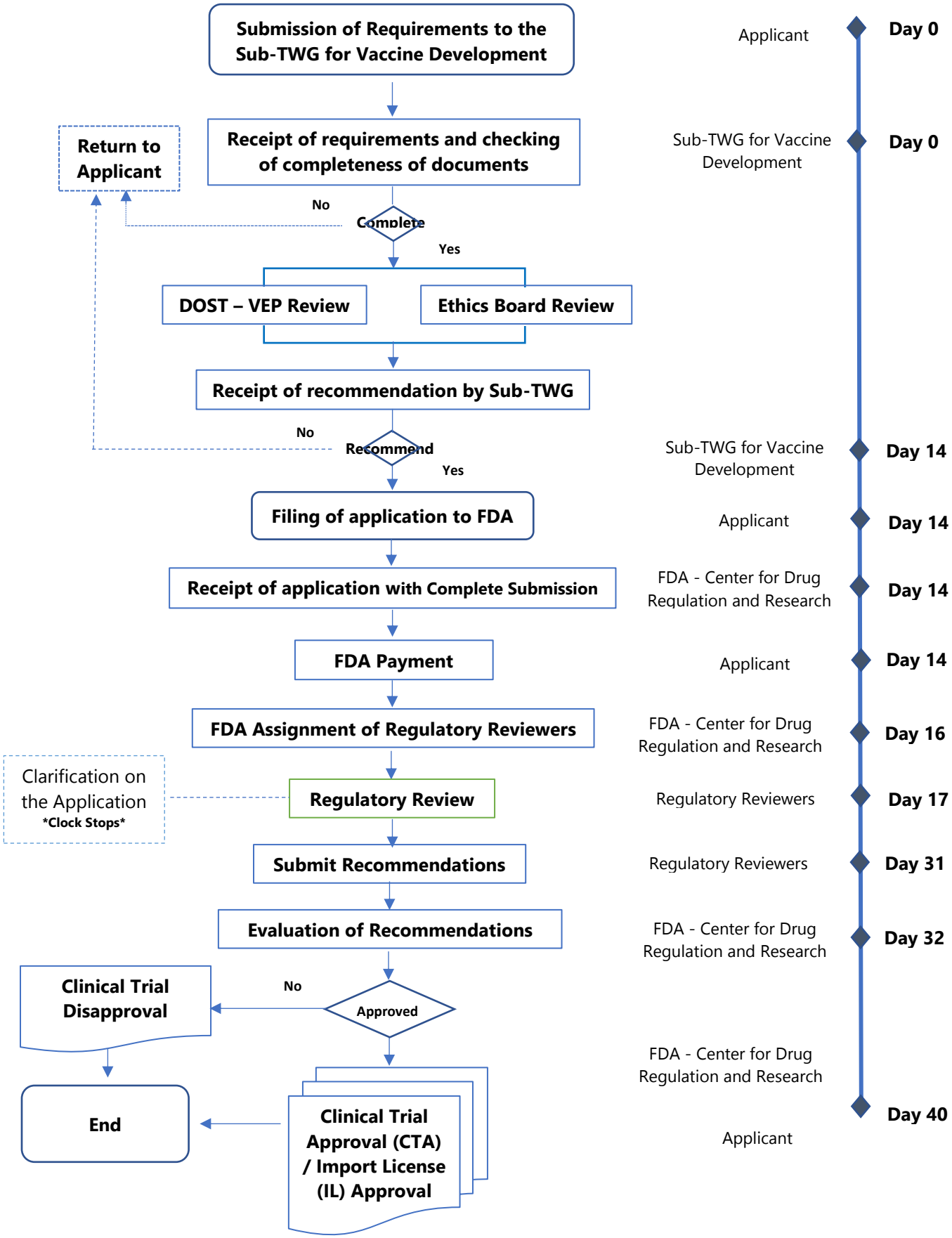
Covid-19 Vaccine Clinical Trial Approval Process Flow Chart



**If the regulatory reviewers request for supplementary information from the applicant, the clock stops on the day the request is sent via email. Review will commence on the day the response is received.*

***Applicants are advised to coordinate with Department of Health (DOH) for reportorial requirements.*

ANNEX 1

A. Submission of requirements to the Sub-TWG for Vaccine Development

The following documentary requirements are forwarded to the DOST-PCHRD through email, VEPsubmissions@pchrd.dost.gov.ph:

a. Letter of intent to conduct clinical trial addressed to Sub-TWG Chair and DOST Undersecretary for R&D, Dr. Rowena Cristina Guevara
b. Investigational Product (IP) and Ancillary Supplies Information (Appendix C4)
c. Clinical Trial Protocol and Protocol Amendments where applicable
d. Informed Consent Form, Assent Form if applicable, in English and Filipino version
e. Investigator's Brochure (IB)

B. Filing of application to the Philippine Food and Drug Administration

The Sponsor and/or CRO shall submit the COVID-19 clinical trial application to the FDA through email at clinicalresearch@fda.gov.ph with the following documentary requirements as per the A.O. No. 2020 - 0010. After the initial evaluation, a clinical trial application may be assigned to a regulatory reviewer wherein sixty thousand pesos (PhP 60,000.00) will be charged to the applicant:

a. Proof of recommendation from the VEP and Ethics Board to proceed to filing of application to FDA
b. Table of Contents for Clinical Trial Application (Appendix C1)
c. Cover Letter for Application (Appendix C2)
d. Accomplished Clinical Trial Application Form (Appendix C3)
e. Investigational Products and Ancillary Supplies Information (Appendix C4)
f. Accomplished Import License Application Form (Appendix C5), if the Investigational Product/s and Ancillary Supplies are to be imported into the Philippines
g. Letter of Authorization, if the applicant is not the Sponsor (Appendix C6)
h. Clinical Trial Protocol and Protocol amendments where applicable
i. GCP Certificate and Curriculum Vitae for Investigators of each trial site
j. Informed Consent Form, Assent Form (if applicable), in English and Filipino Version
k. Investigator's Brochure (IB)
l. Pharmaceutical Data (ASEAN Common Technical Dossier should be followed and GMP Certificate and shipping condition for IP should be submitted)
m. Labeling Materials (i.e., primary and/or secondary packaging) for Investigational Product
n. Proof of Payment (PhP 2,525.00)

Also, COVID-19 vaccine trial should follow the zoning guidelines issued by the Sub-TWG on Vaccine Development.