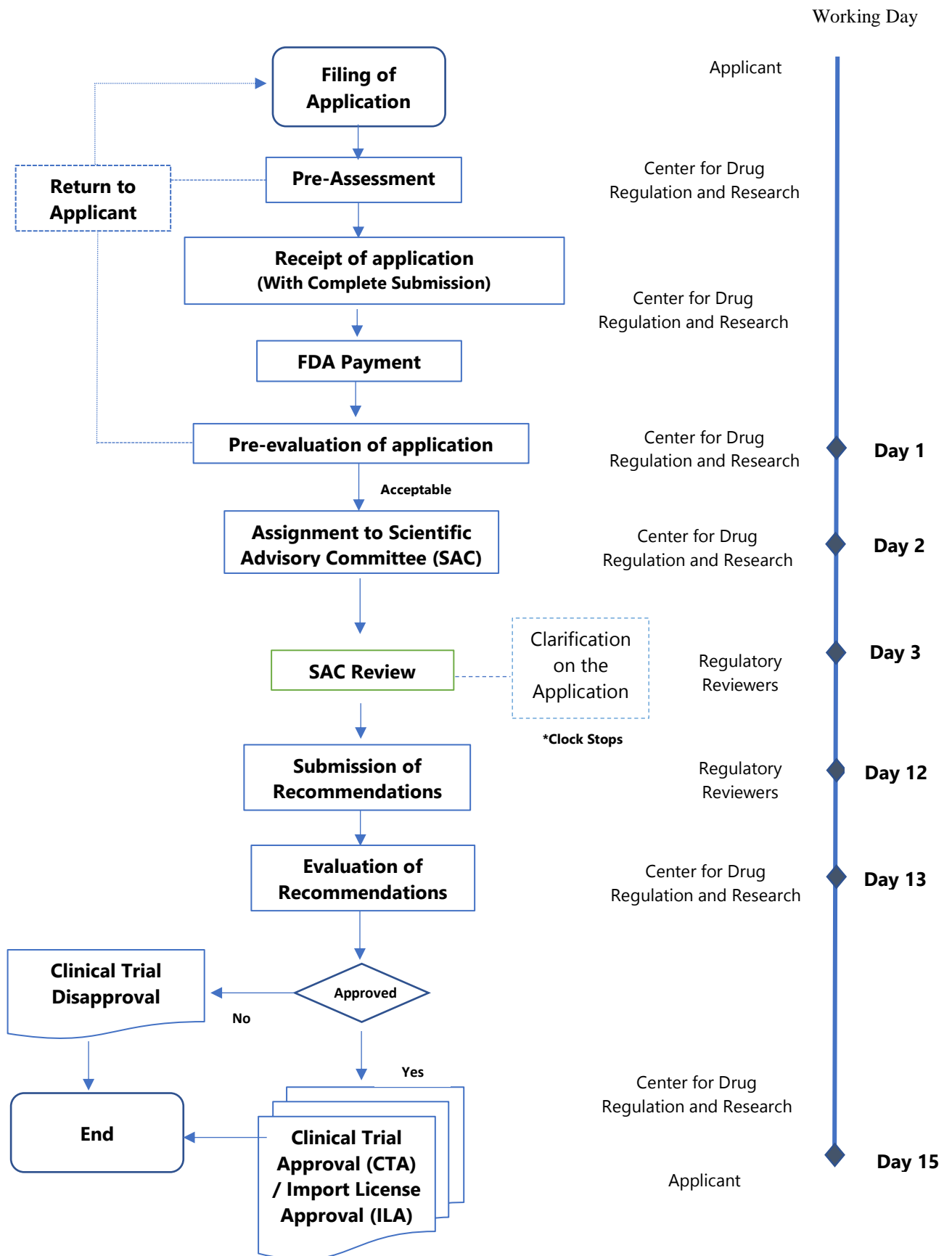


Annex D

Abridged Clinical Trial Amendment Approval Process Flow Chart *[Amendments with Scientific Advisory Committee Review]*



**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.*