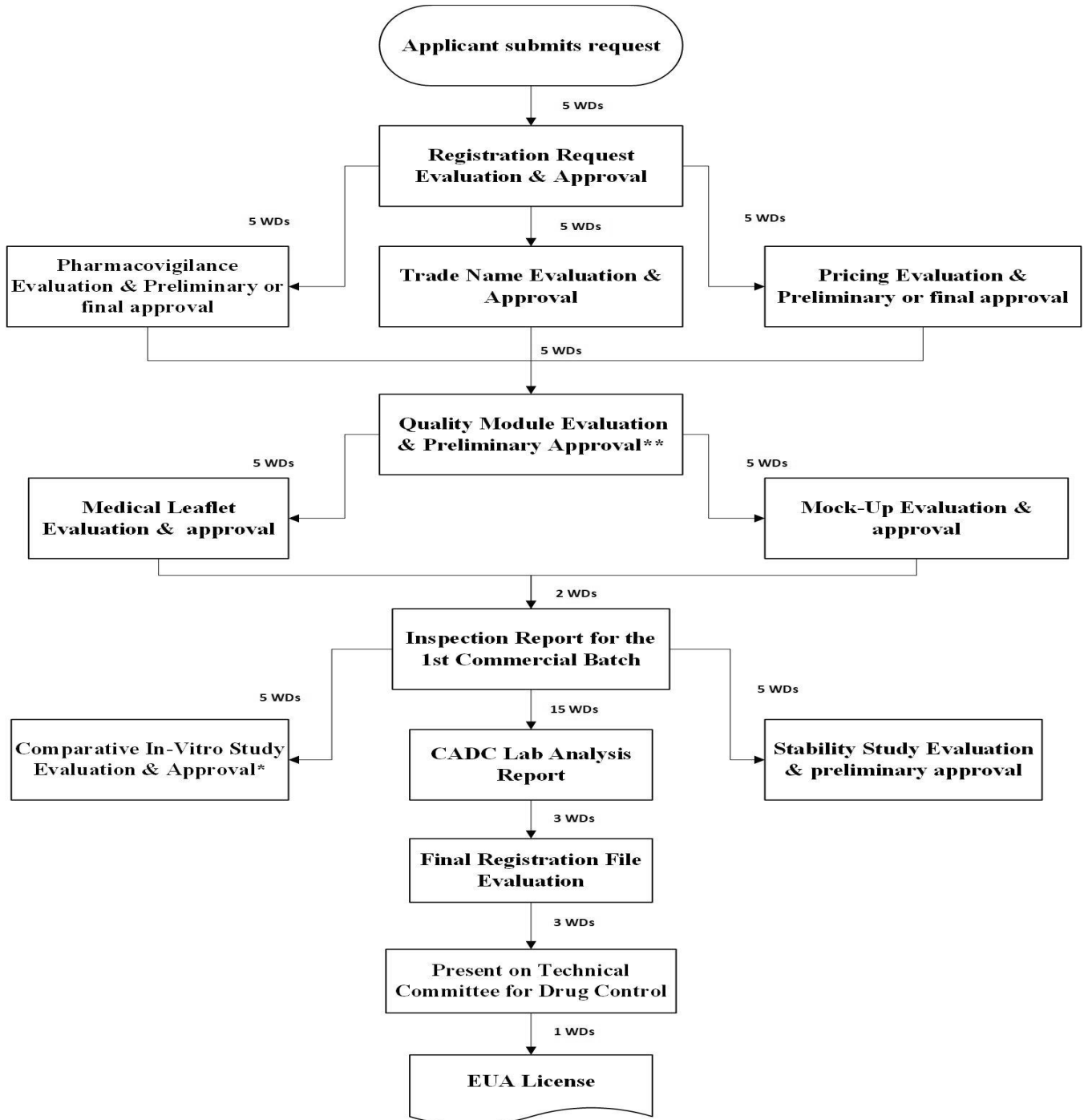


## Emergency Use Approval (EUA) Flowchart with assessment timelines



- Assessment timelines start from receiving complete files from applicants

\*Bioequivalence study approval is a condition for the commercial batch release (if applicable)

\*\*If the time of release of the batches intersected by the zero or 3rd or 6th month of the accelerated stability studies, the batches will not be released till EDA approves the stability data for the intersected time interval.