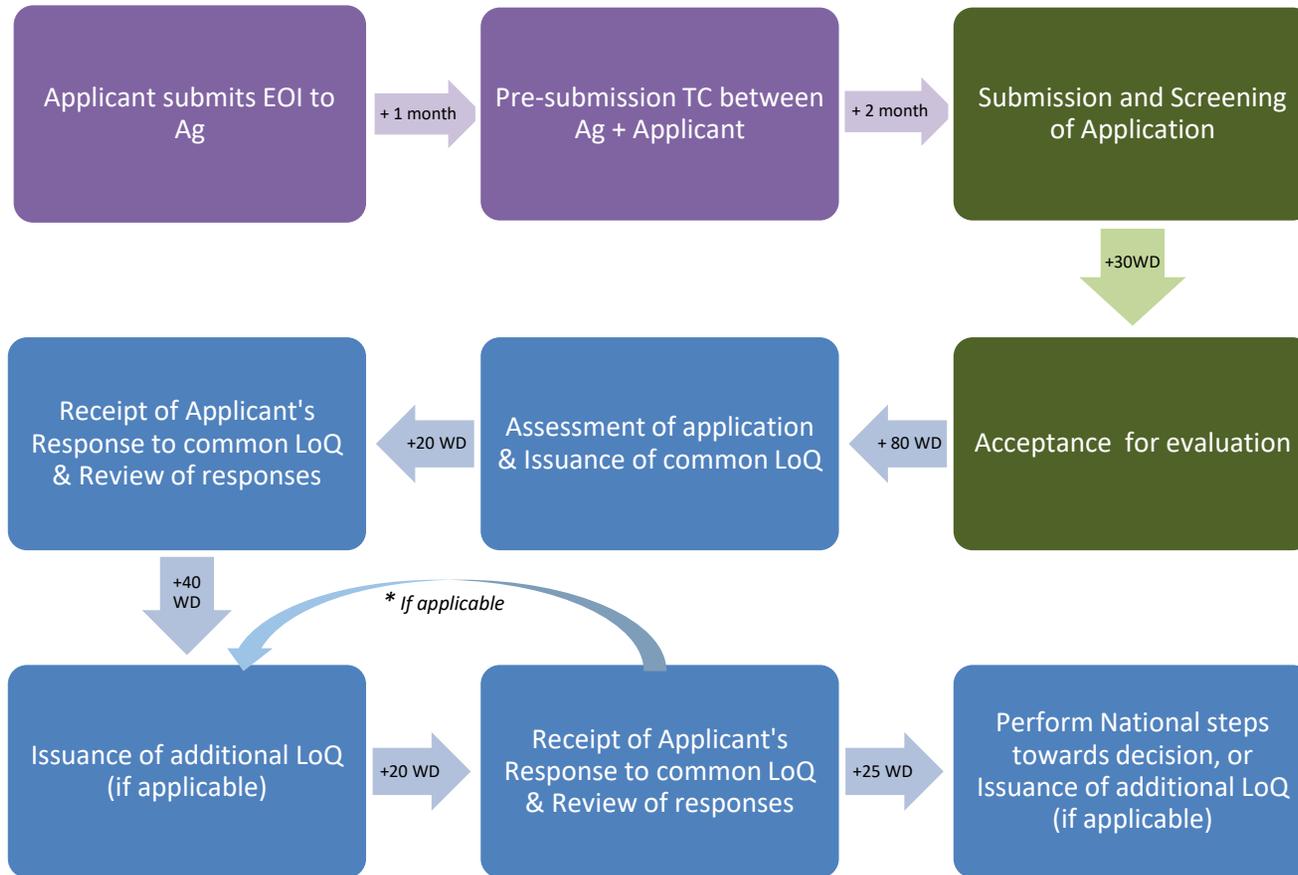


Operational Procedures

Stage	Process
Prior to application submission	<ol style="list-style-type: none"> 1. Applicant to inform both agencies on interest to participate in the pilot via submission of Expression of Interest (EOI) form through the following: <ul style="list-style-type: none"> • NPRA: Hardcopy submission (Cover Letter* & EOI) addressed to the Director of NPRA • HSA: Softcopy submission (Cover Letter* & EOI) addressed to HSA_TP_Enquiry@hsa.gov.sg <p><i>*Note: Cover letter should contain general expression of interest in the pilot</i></p> 2. All applicants who had submitted EOI will be notified by the Agencies if their application is shortlisted for the pilot. 3. For shortlisted applications, a tele-conference meeting between the applicant and both agencies will be held to address any concerns/ queries the applicant has. Differences, if any, in the dossiers to be submitted to both Agencies (as declared in the EOI form) should also be highlighted to the Agencies during the teleconference. The applicant will also be required to confirm that the minimum submission requirements can be met. <p><i>*Note: Tele-conference is to be conducted at least 2 months before the planned submission date.</i></p> 4. After the tele-conference, the applicant will be notified if their application is confirmed for participation in the pilot, and to proceed with submission.
Screening	<ol style="list-style-type: none"> 1. Application is to be submitted online via PRISM or QUEST 3+ accordingly. 2. Any pending issues discussed during the tele-conference should be addressed, if requested by Agencies. 3. A letter declaring that all aspects of the technical dossier, other than those declared in the EOI, are identical between that submitted to HSA and NPRA. 4. Complete submission, including the drug master file (DMF), if any, should be received by both agencies within the same week following application submission.
Evaluation	<ol style="list-style-type: none"> 1. Companies to respond to both agencies within the same week of the deadlines set for each correspondence. 2. A maximum of five rounds of correspondence (queries) will be allowed. 3. Once the technical evaluation is completed, each agency will proceed with their respective national procedures towards the final regulatory decision.

Timelines of the Steps in the Worksharing Process



Processes **prior to screening** – Boxed in purple
 Processes **during screening** – Boxed in green
 Processes **after acceptance for evaluation** – Boxed in blue

TC: Teleconference
 EOI: Expression of Interest
 Ag: Agency
 LoQ: List of Queries
 WD: Working Day

**Queries will be capped to a maximum of 5 rounds*