Central Administration Pharmaceutical Products
General Administration or Human Pharmaceuticals Registration

Notice to applicant

Flowchart for
Work flow of Issuing variation approvals for Variation Requests

Year 2024

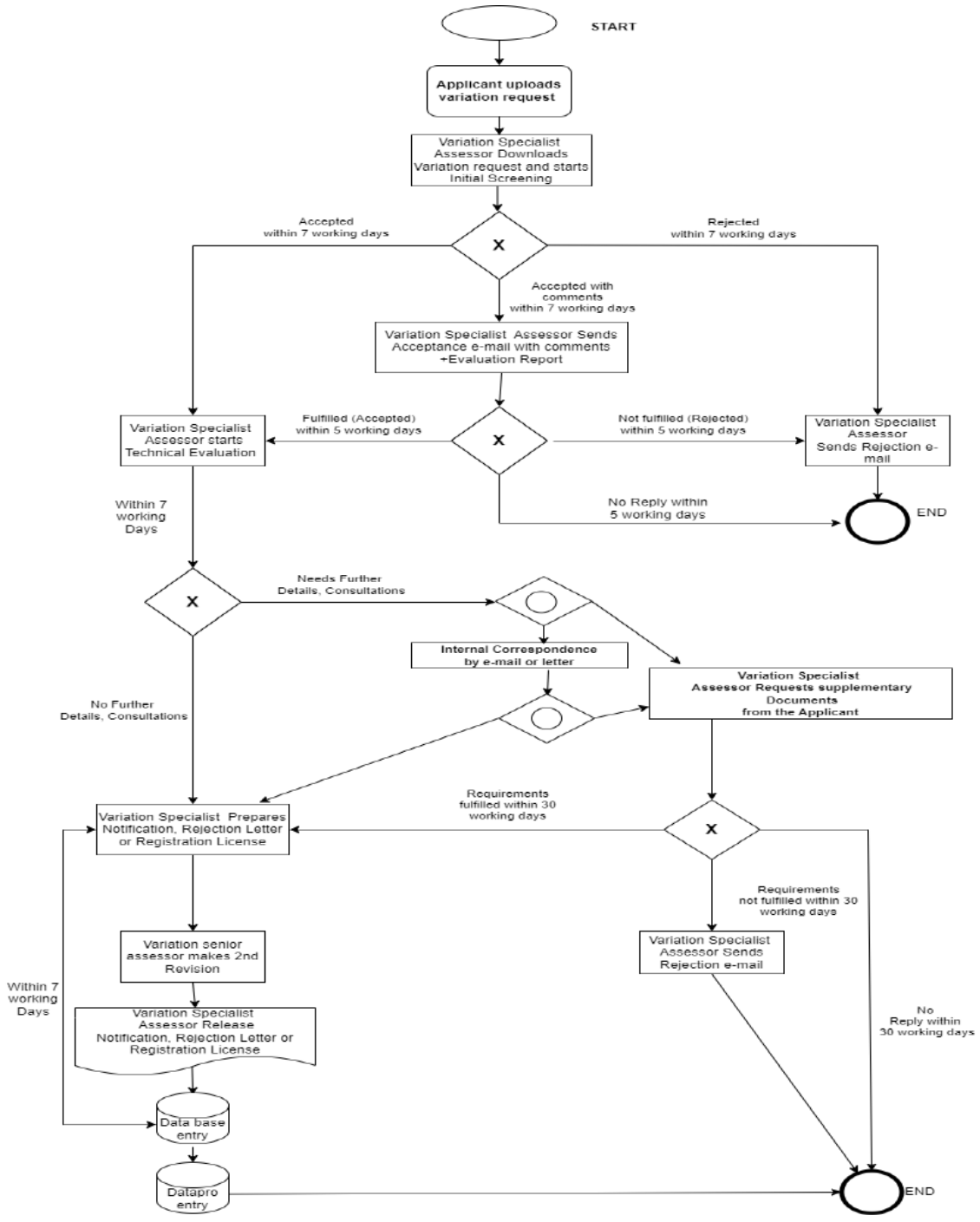
Code: EDREX:NP.CAPP.063
Version No: 3
Issue Date: 21/1/2024
Effective date (if needed): 21/1/2024

Flow chart of issuing variation approvals for Variation Requests Quality Procedure

1- For Local, Bulk & Under-license Pharmaceutical products Variation Requests

(Procedure Type PAC-A, PAC-N)

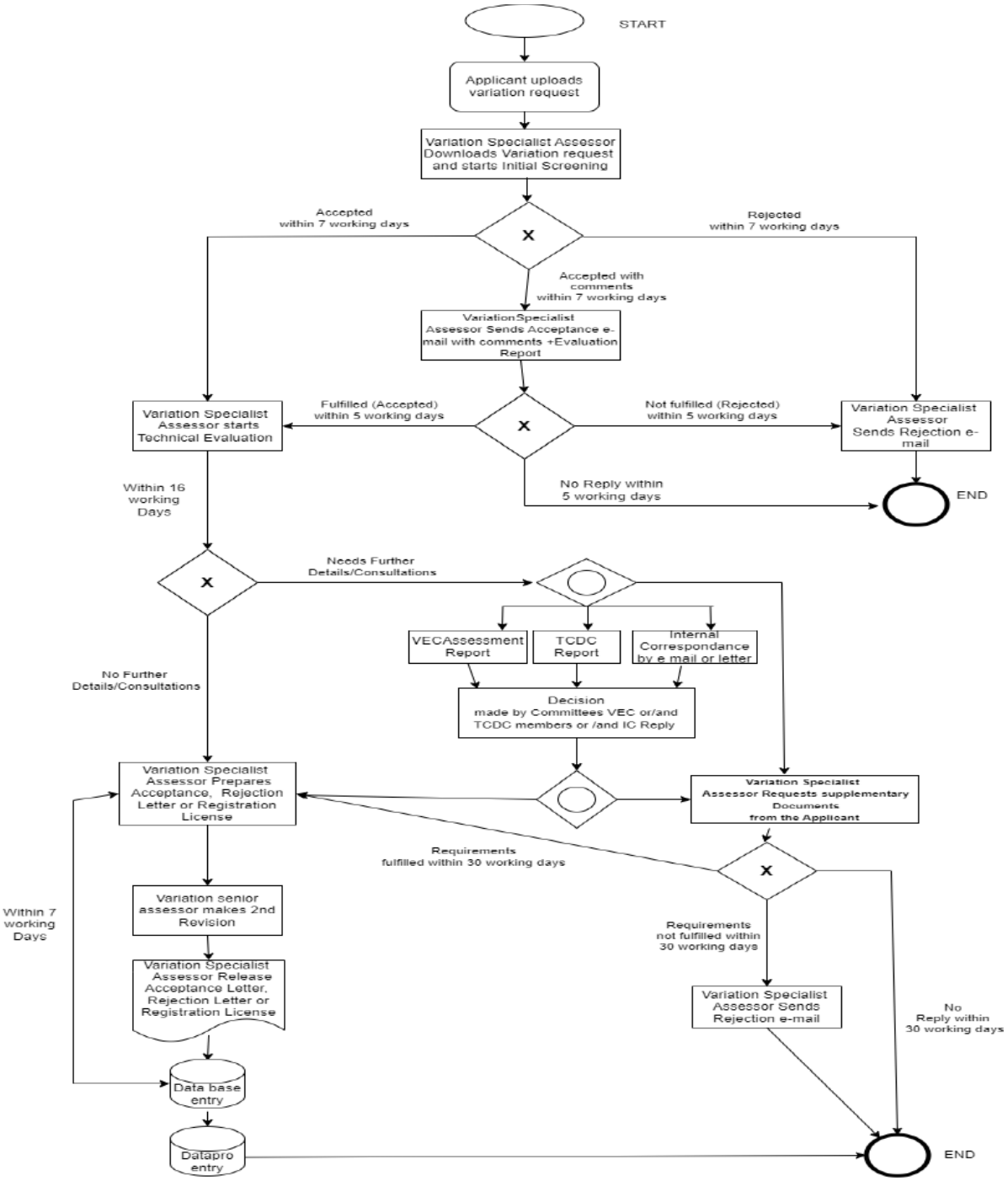
(Time Frame 21 Working Days)



2-For Local, Bulk & Under-license Pharmaceutical products Variation Requests

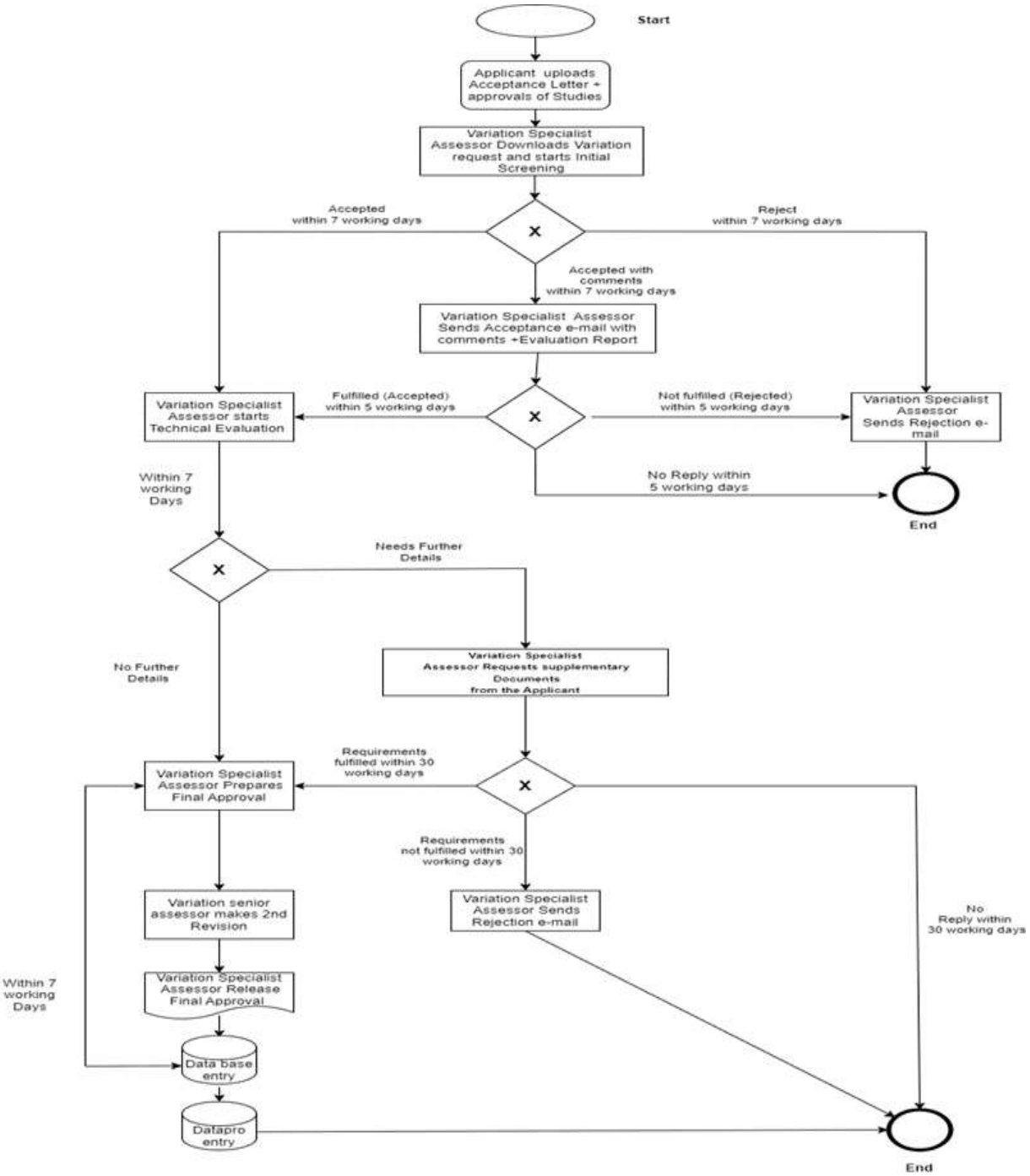
(Procedure Type PAC-B, PAC-II)

(Time Frame 30 Working Days)



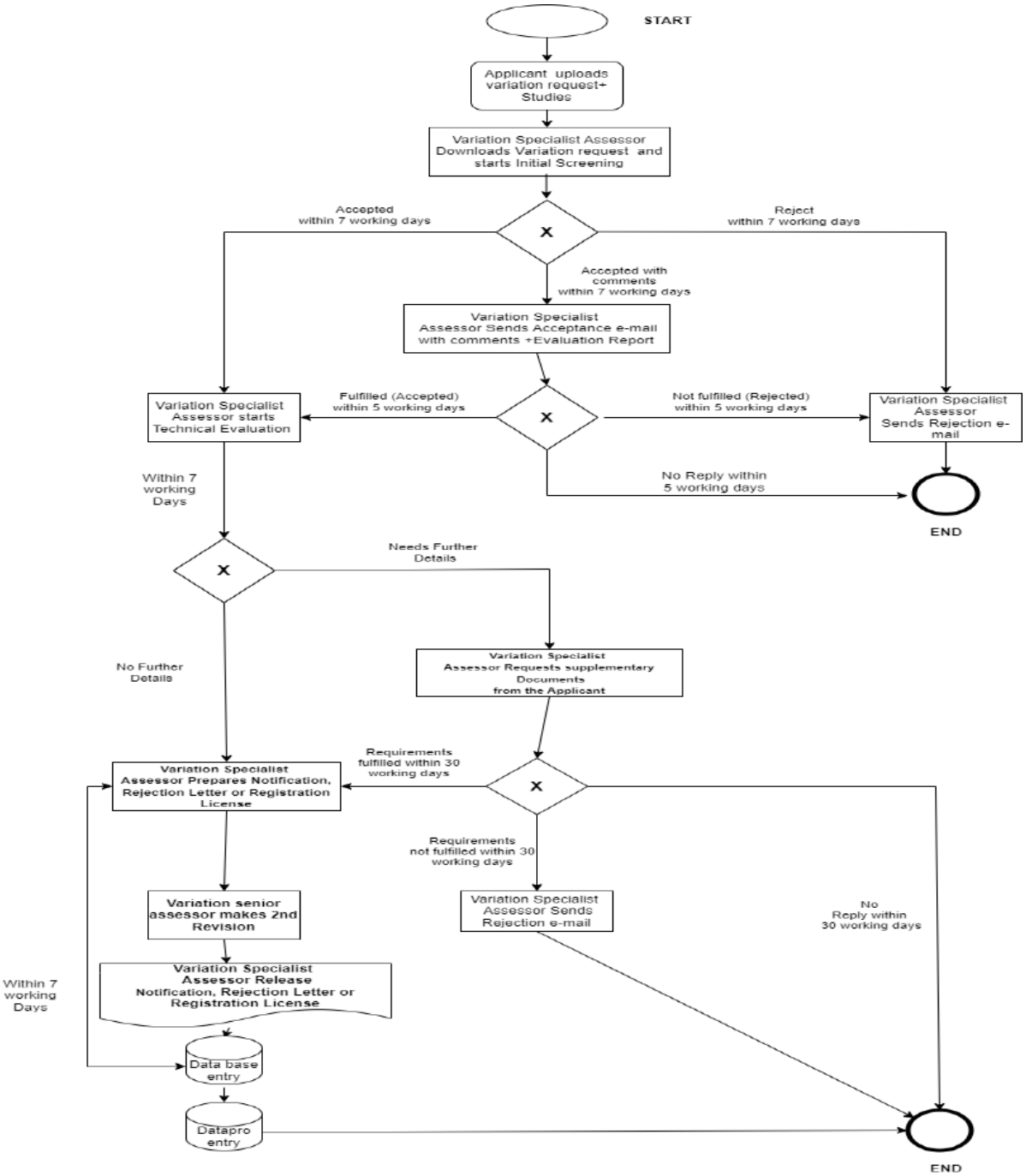
3-For Final Approvals

(Time Frame 21 Working Days)



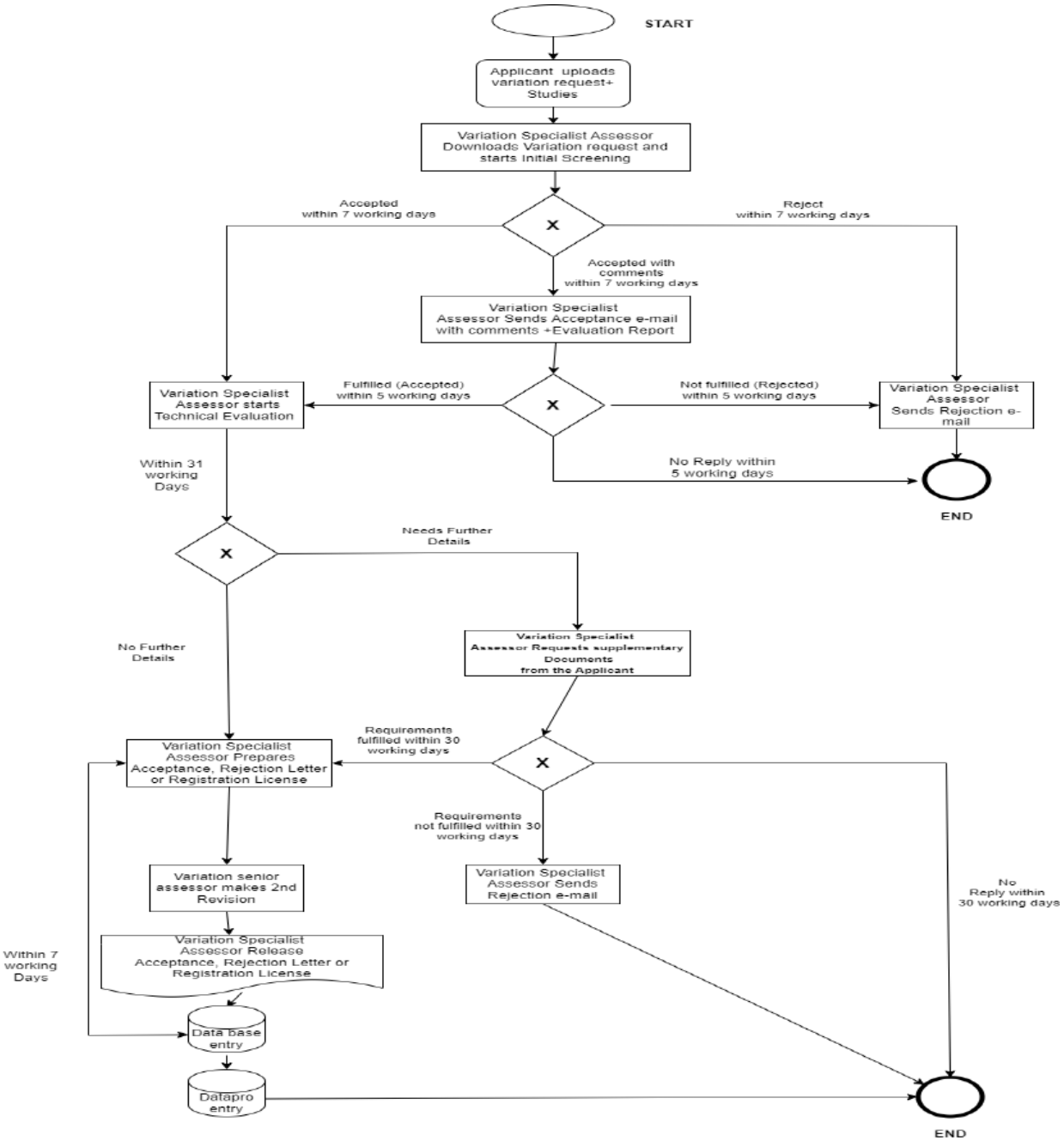
4- For Imported Pharmaceutical products from Reference Country and/or marketed in a reference country that has been approved Variation Requests by at least one reference requlatory authority (SRA) or WHO prequalification, (Procedure Type PAC- A, PAC-N)

(Time Frame 21 Working Days)



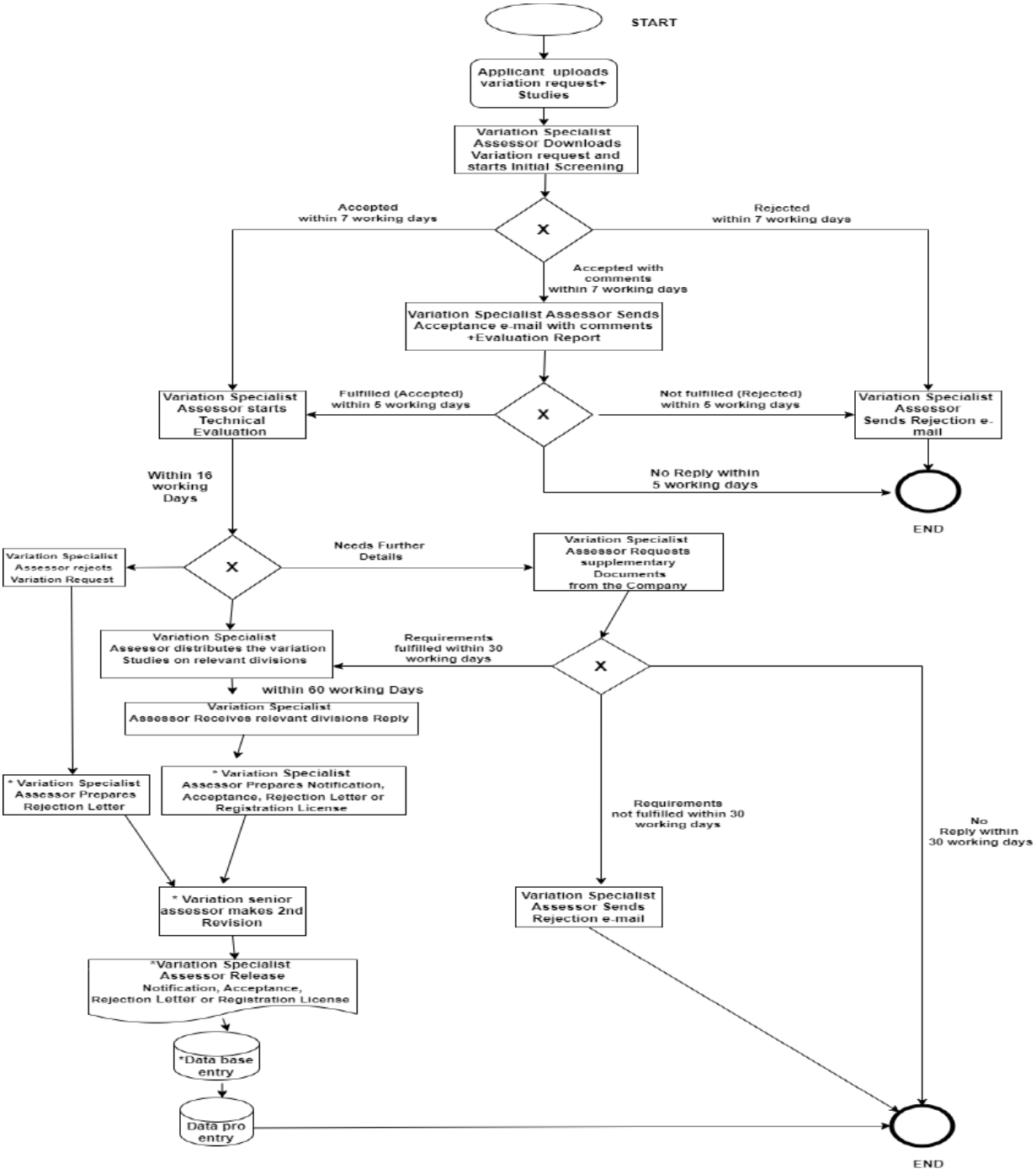
5- For Imported Pharmaceutical products from Reference Country and/or marketed in a reference country that has been approved Variation Requests by at least one reference requlatory authority (SRA) or WHO prequalification, Procedure Type PAC- B, PAC-II

(Time Frame 45 Working Days)



6- For Imported Pharmaceutical products from non-Reference Country and not marketed in a reference country Variation Requests

(Time Frame 90 Working Days)



*Within 7 Working Days

History of Change:

Versions (Effective Date)	Updated Sections	Summary of changes
21/1/2024	Update in Annex II (flow charts)	Current Change(s): * Update time frames according to category of variation in compliance with forth edition of Human Pharmaceuticals Variations Guidelines 2023