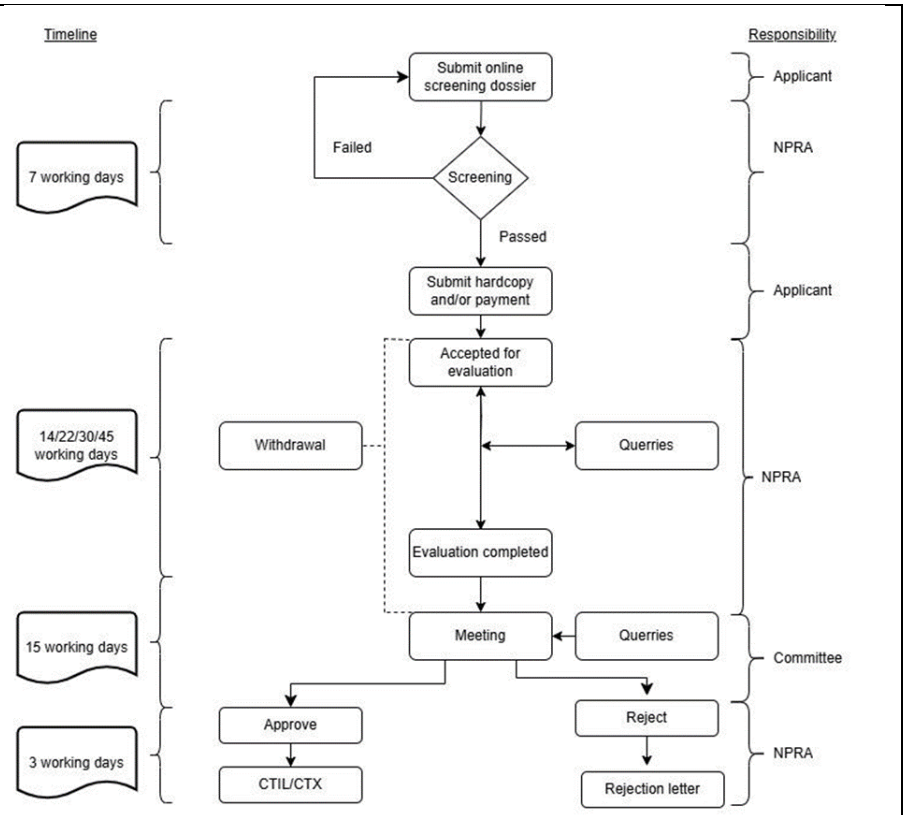
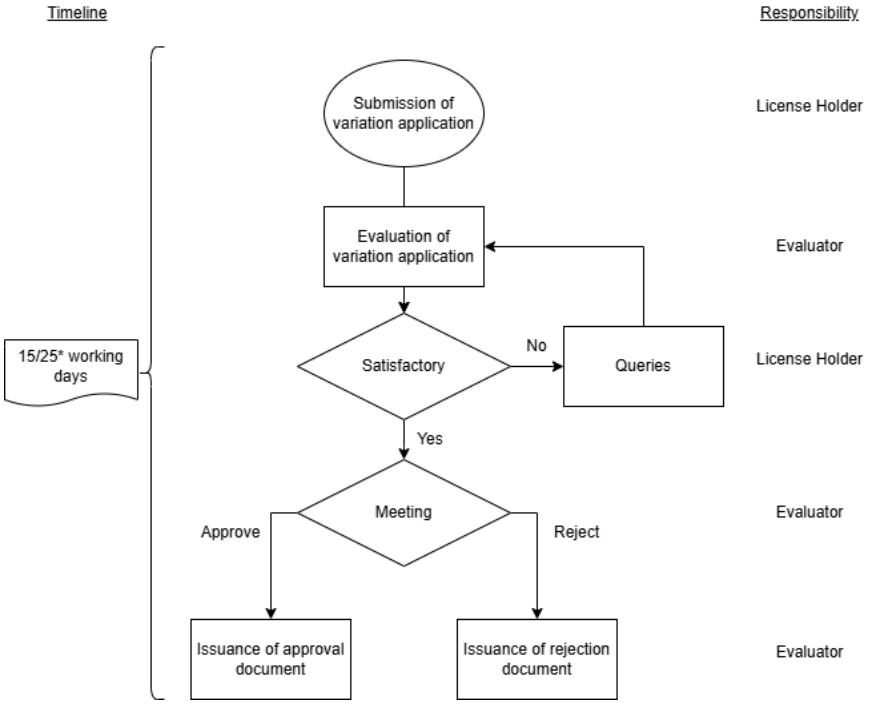
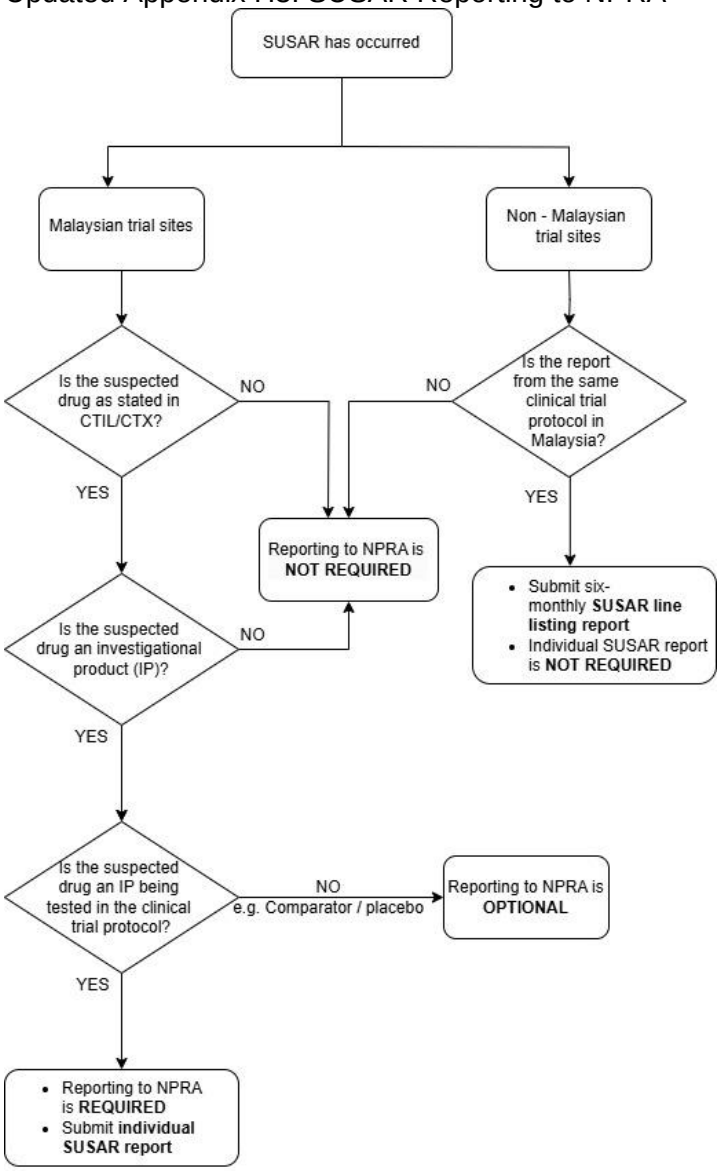
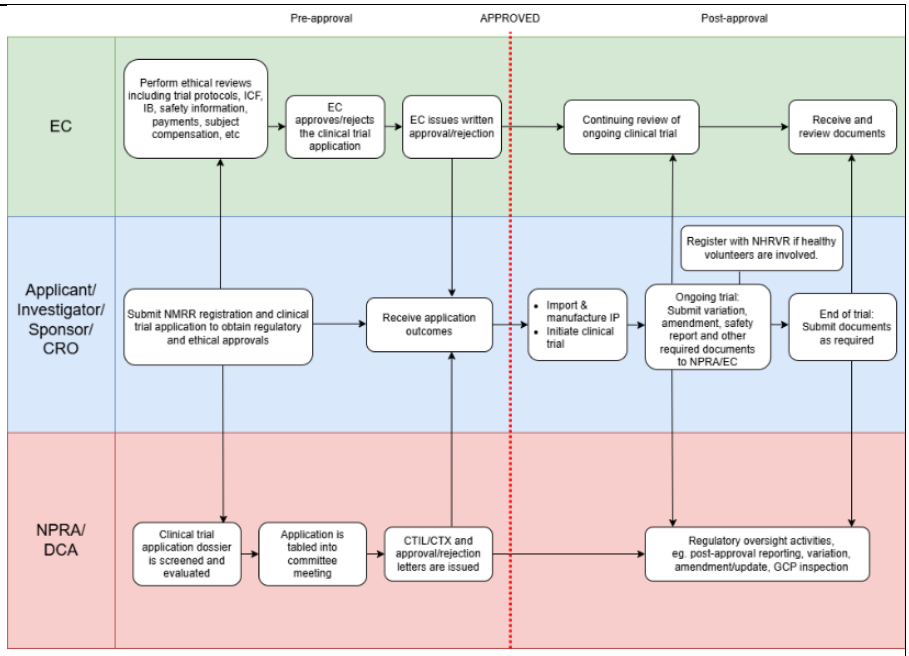
HISTORY of REVISION

No	Section*	Description
1.	Abbreviation	Added the abbreviations for AEFI and AESI
2.	Glossary	Added definition for AEFI and AESI
3.	Glossary	Added definition for Herbal Products with Unapproved Claim, Modern Claim for Herbal Products and Therapeutic Claim for Herbal Products. Changed the term Herbal Medicinal Products to Herbal Products.
4.	1	The inclusion of stakeholders, including research centres, researchers, sponsors, clinical research organisations (CROs), and all relevant institutions, to comply with the Malaysian Guideline for Good Clinical Practice has been added
5.	1.1	Addition of the scope the guideline
6.	2.3, 4.5.7, 5.2, Appendix D5	Therapeutic claim updated to unapproved claim to cover for modern claim as well
7.	3	*3. Products that require CTIL CTX* was deleted. The information was included under 1.1 Scope
8.	4.1.2	Removal of the CRO abbreviation, as it is already mentioned in Section 1.
9.	4.4.3	Update on CTIL and CTX application form numbers.
10.	4.4.13	Added the clause “Extrapolation of stability data if justifiable.”
11.	4.4.13	Reduced minimum duration of stability studies to 1 month for all IPs. Note: removed clause on stability for FIH IPs
12.	4.5.7	Updates on the acceptance of the FIH for CGTP
13.	5.1	Flow Chart for CTIL/CTX application process is updated

		
14.	6	Added decisions of NPRA/DCA: approval / conditional approval
15.	10	All variation applications will be processed within 15 working days except applications involving issuance of CTIL or CTX which will be processed within 25 working days.
16.	10	Flowchart for processing of variation application added  * Applications involving issuance of CTIL or CTX will be processed within 25 working days.

17.	12	Reporting of Suspected Unexpected Serious Adverse Reaction changed to Safety Reporting of Investigational Products. Recommendation for causality assessment added.
18.	12.1	Updated requirement for SUSAR reporting
19.	12.2	Reporting of serious AEFI and AESI in Vaccine Clinical Trials added.
20.	12.3	Updated requirement for DSUR reporting.
21.	12.5	Updated requirement for submission of safety reports.
22.	References and Directives	Updated latest “ICH (2025). ICH E6(R3): Guideline for Good Clinical Practice, Step 4 version, dated 6 January 2025” in reference list
23.	Appendix H2	Updated Appendix H2: Safety Reporting Requirements
24.	Appendix H3	Updated Appendix H3: SUSAR Reporting to NPRA 
25.	Appendix H4	Updated Appendix H4: Template of Cover Letter for Safety Reporting of Investigational Products.
26.	Appendix I	Updated latest Appendix I: 75th WMA General Assembly, Helsinki, Finland, October 2024
27.	Appendix J	Diagram for Clinical Trial Oversight

		
28.	Appendix K	Timeline of Communication Between Applicant & NPRA added