**Instructions:**

Please note that this application form is intended as a reference to assist the Sponsors to prepare for the online submission of Amendment Application for Clinical Trial Authorisation, Clinical Trial Notification or Clinical Trial Certificate via PRISM. **This form should be used with the application form for Application for Clinical Trial Authorisation, Clinical Trial Notification or Clinical Trial Certificate.**

Unless otherwise stated, this application form is not intended for offline submission. All submissions must be made via PRISM.

In order to proceed with PRISM submission, please ensure that your company has a CRIS account set up with the Health Sciences Authority. Please refer to our webpage on [Client Registration and Identification Service (CRIS)](https://www.hsa.gov.sg/e-services/cris) for more details.

**Legend:**

Fields marked with an asterisk (\*) are mandatory.

Fields marked with ^ will be displayed in the Clinical Trials Register.

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| AMENDMENT TRIAL INFORMATION | |
| Title of Clinical Trial: \* | Click here to enter text. |
| Protocol No.: \* | Click here to enter text. |

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| AMENDMENT TYPES |
| Please select type of amendment (more than one can be selected): \* |

NOTE: Please complete the applicable Amendment Summary for the Amendment Types selected above.

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| --- | --- | --- |
| AMENDMENT SUMMARY FOR - 1. PROTOCOL & ICF AMENDMENT | | |
| 0.1.1 | Please select: \* |  |
| 0.1.2 | Rationale for Protocol Amendment: \* | Click here to enter text. |
| 0.1.3 | Rationale for ICF Amendment: \* | Click here to enter text. |
| 0.1.4 | IRB Approval: \* |  |

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| AMENDMENT SUMMARY FOR - 2. CHANGE OF PI OR ADD SATELLITE SITE / ADD TRIAL SITE | | |
| 0.2.1 | Please select: \* |  |
| 0.2.2 | Reason for Change of Principal Investigator: \* | Click here to enter text. |
| 0.2.3 | IRB Approval: \* |  |

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| AMENDMENT SUMMARY FOR - 4. CHANGE OF MANUFACTURER / CMC INFO | | |
| 0.4.1 | Please select: \* |  |
| 0.4.2 | Reason for Change of Manufacturer: \* | Click here to enter text. |
| 0.4.3 | Description for CMC Amendment: \* | Click here to enter text. |

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| AMENDMENT SUMMARY FOR - 5. IB UPDATE / NEW SAFETY INFORMATION | | |
| 0.5.1 | Is an updated Investigator Brochure being submitted: \* |  |

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| --- | --- | --- |
| AMENDMENT SUMMARY FOR - 6. CHANGE OF CLINICAL RESEARCH MATERIAL (CRM) NOTIFICATION | | |
| 0.6.1 | Reason for Change of Clinical Research Material (CRM) Notification Information: \* | Click here to enter text. |

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| AMENDMENT SUMMARY FOR - 7. OTHER ADMIN / CT REGISTER CHANGES | | |
| 0.7.1 | Summary of Changes: \* | Click here to enter text. |

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| SUPPLEMENTARY INFO | | |
| 0.8.1 | Please provide supplementary information, if necessary: |  |