**Instructions:**

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

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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| --- | --- | --- |
| SECTION 1: APPLICATION TYPE | | |
| 1.1 | Please select application type: \* |  |

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| --- | --- | --- | --- | --- | --- | --- |
| SECTION 2: TRIAL INFORMATION | | | | | | |
| 2.1 | Title of Clinical Trial: \*^  *(as stated in Protocol document)* | | Click here to enter text. | | | |
| 2.2 | Brief Title of Clinical Trial for the Public: \*^  *(in easily understood, non-technical language)* | | Click here to enter text. | | | |
| 2.3 | Protocol Number: \*^ | | Click here to enter text. | | | |
| 2.4 | Protocol Acronym, if any: ^ | | Click here to enter text. | | | |
| 2.5 | Secondary ID(s), if any: \*^ | | *Please select checkbox if not applicable. Otherwise, please complete Section 2.5.1 and 2.5.2.* | | | |
|  | *(Repeat as necessary)*   |  |  | | --- | --- | | 2.5.1 ID Type: \*^  *(e.g. ClinicalTrials.gov Identifier, Eudra CT Number, name of organization that issued ID, etc)* | 2.5.2 ID: \*^ | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | | | | | | |
| 2.6 | Phase of Clinical Trial: \*^ | |  | | | |
| If Others, please specify: ^ Click here to enter text. | | | |
| 2.7 | Type of Sponsorship: \* | | Applicant is a | | | |
|  | IMPORTANT NOTE: For investigator-initiated trials (IIT) involving multiple sites where each site acts as a sponsor for their trial, one of the sponsors should be designated as the Lead Sponsor. The Lead Sponsor shall be the primary contact person for HSA. Please refer to our [Guidance on Multi-Sponsor IIT](https://www.hsa.gov.sg/clinical-trials/regulatory-guidances). | | | | | |
| 2.8 | Source of Monetary or Material Support for the clinical trial: \*^  *(e.g. name of funding company, agency, organisation, etc)* | | Click here to enter text. | | | |
| 2.9 | Therapeutic Area: \*^ | | Choose an item. | | | |
| If Others, please describe: ^ Click here to enter text. | | | |
| 2.10 | Health Condition(s) Studied: \*^ | | Click here to enter text. | | | |
| 2.11 | List the PRISM application number(s) of any previous application(s) for trials involving the same investigational product(s): \* | | *Please select checkbox if not applicable. Otherwise, please fill in below.*  Click here to enter text. | | | |
| **Trial Summary** | | | | | | |
| 2.12 | Involves: \* | |  | | | |
| 2.13 | Involves subjects who: \*  *(please select where applicable)* | | *Please select if not applicable. Otherwise please select options below.* | | | |
| 2.14 | Clinical Trial in Emergency Situation: \* | |  | | | |
| 2.15 | Study Type: \*^ | |  | | | |
| 2.16 | Purpose of Trial: \*^ | | Choose an item. | | | |
| If Others, please describe: ^ Click here to enter text. | | | |
| 2.17 | Primary Trial Objective(s): \* | | Click here to enter text. | | | |
| 2.18 | Primary Outcome Measure(s): \*^  *(please include outcome measure and timepoint of interest, e.g. all-cause mortality at 1 year, cognition as measured by ADAS-Cog at week 24, dose-limiting toxicities, maximum tolerated dose, recommended phase 2 dose, etc)* | | Click here to enter text. | | | |
| 2.19 | Key Secondary Outcome Measure(s): \*^  *(please include name of outcome, method of measurement and time point(s) of interest)* | | Click here to enter text. | | | |
| 2.20 | Allocation: \*^ | |  | | | |
| 2.21 | Blinding: \*^ | | Choose an item. | | | |
| If Others, please describe: ^ Click here to enter text. | | | |
| 2.22 | Intervention model: \*^ | | Choose an item. | | | |
| If Others, please describe: ^ Click here to enter text. | | | |
| 2.23 | Number of study arms/groups: \* | | Click here to enter a number. | | | |
|  | NOTE: The number of study arms/groups should correspond to the number of records for 2.23.1 to 2.23.4. | | | | | |
|  | *(Repeat as necessary)*   |  |  |  |  | | --- | --- | --- | --- | | 2.23.1 Study Arm / Group Type: \*^  *(i.e. Experimental, Control, Others (please describe))* | 2.23.2 Arm label: \*^  *(short name to identify arm, e.g. metformin, placebo, or lifestyle counselling)* | 2.23.3 Brief description of study arm: \*^  *(for drugs, use generic name and include route of administration, dose and dosing regimen/ administration schedule; for other interventions provide brief description of study arm)* | 2.23.4 Duration of drug dosing/ intervention: \*^ | | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | | | | | |
| 2.24 | Involves the use of: \*  *(please select where applicable)* | | *Please select if not applicable. Otherwise please select options below.* | | | |
| 2.25 | Number of Therapeutic Product / Medicinal Product / Cell, Tissue and Gene Therapy Product (excluding those containing cells and tissue) to be investigated: \* | | Click here to enter a number. | | | |
| 2.26 | Number of Cell, Tissue and Gene Therapy Product (containing cells and tissue) to be investigated: \* | | Click here to enter a number. | | | |
| 2.27 | Number of Comparator Therapeutic Product / Medicinal Product / Cell, Tissue and Gene Therapy Product used: \* | | Click here to enter a number. | | | |
| 2.28 | Number of Auxiliary Therapeutic Product used: \* | | Click here to enter a number. | | | |
| 2.29 | Key Inclusion and Exclusion Criteria: \*^ | | Click here to enter text. | | | |
| 2.30 | Describe the design of the trial If necessary to supplement the information provided above: | | Click here to enter text. | | | |
| 2.31 | Please provide the benefit-risk assessment for the clinical trial: \* | | Click here to enter text. | | | |
| 2.32 | Is there a Data Safety Monitoring Committee for this study? \* | |  | | | |
| 2.33 | Website URL link to the study record in ClinicalTrials.gov, if applicable: ^ | | Click here to enter the link. | | | |
|  | NOTE: If this clinical trial is already registered in ClinicalTrials.gov, please insert the URL link by copying and pasting the website address of the study specific record into this field. If the clinical trial is not yet registered in ClinicalTrials.gov, this information can be provided later via an administrative amendment to update this field. | | | | | |
| **Trial Sites** | | | | | | |
| 2.34 | Location of Trial Site(s): \* | |  | | | |
| 2.35 | List of Countries participating in the trial: ^ | | Click here to enter text. | | | |
| 2.36 | Number of Trial Site(s) in Singapore: \* | | Click here to enter a number. | | | |
| 2.37 | Planned Number of Trial Subjects in Singapore: \*^ | | Click here to enter a number. | | | |
| 2.38 | Total Planned Number of Trial Subjects per Protocol: \*^ | | Click here to enter a number. | | | |
| 2.39 | Overseas Sponsor: ^ | | Click here to enter text. | | | |
| **Regulatory Status of Study** | | | | | | |
| 2.40 | Is this a US IND/IDE study? \* | |  | | | |
| 2.41 | Is this a EUDRACT study? \* | |  | | | |
| 2.42 | Is there a negative opinion (including clinical hold) for this study elsewhere by a Regulatory Agency or Ethics Committee? \* | |  | | | |
| If yes, please provide reasons for negative opinion: \*  Click here to enter text. | | | |
| **Duration of Study** | | | | | | |
| 2.43 | Planned Study Start Date: \*^ | | Click here to enter a date. | | | |
| 2.44 | Planned Study Start Date in Singapore: \*^ | | Click here to enter a date. | | | |
| 2.45 | Planned Study End Date: \*^ | | Click here to enter a date. | | | |
| **Contacts for Public and Scientific Queries** | | | | | | |
| **Contact for Public Queries** | | | | | | |
| 2.46 | Salutation: ^ | | Choose an item. | | | |
| 2.47 | Name: \*^ | | Click here to enter text. | | | |
| 2.48 | Company / Organisation / Institution: \* | | Click here to enter text. | | | |
| 2.49 | Email: \*^ | | Click here to enter text. | | | |
| 2.50 | Telephone No.: \*^ | | Click here to enter text. | | | |
| 2.51 | Fax No.: | | Click here to enter text. | | | |
| 2.52 | Address: \*^ | | Click here to enter text. | | | |
| Postal Code: Click here to enter text. | | | |
| **Contact for Scientific Queries** | | | | | | |
| 2.53 | Salutation: ^ | | Choose an item. | | | |
| 2.54 | Name: \*^ | | Click here to enter text. | | | |
| 2.55 | Affiliation / Designation: \*^  *(e.g. principal investigator, medical director employed by the sponsor)* | | Click here to enter text. | | | |
| 2.56 | Company / Organisation / Institution: \* | | Click here to enter text. | | | |
| 2.57 | Email: \*^ | | Click here to enter text. | | | |
| 2.58 | Telephone No.: \*^ | | Click here to enter text. | | | |
| 2.59 | Fax No.: | | Click here to enter text. | | | |
| 2.60 | Address: \*^ | | Click here to enter text. | | | |
| Postal Code: Click here to enter text. | | | |
| **SECTION 3: INVESTIGATIONAL THERAPEUTIC (TP) / MEDICINAL PRODUCT (MP) / CELL, TISSUE AND GENE THERAPY PRODUCT (CTGTP) (EXCLUDING THOSE CONTAINING CELLS AND TISSUE)**  *(Repeat as necessary)* | | | | | |
| 3.1 | | Investigational TP / MP / CTGTP (excluding those containing cells and tissue): | | No. 1 | No. 2  *(This column is to be used only when > 1 Investigational TP/MP (excluding CTT Products) is indicated in Section 2.25)* |
| 3.2 | | Active Ingredient / Generic Name / Any code designation: \*^  *(please use the active ingredient/generic name stated in the Investigator Brochure)* | | Click here to enter text. | Click here to enter text. |
| 3.2.1 | | Standardised Investigational Product Name: ^ | | Click here to enter text. | Click here to enter text. |
|  | | NOTE: Please enter the appropriate Investigational Product Name to display in CT Register. This should correspond to the International Non-Proprietary Name, where applicable. If there is no suitable choice, please leave it blank. | | | |
| 3.3 | | Other Product Identifier(s), if any: ^ | | Click here to enter text. | Click here to enter text. |
| 3.4 | | Brand/Trade Name, if any: ^ | | Click here to enter text. | Click here to enter text. |
|  | | NOTE: Please enter the appropriate Brand/Trade Name to display in CT Register. | | | |
| 3.5 | | Pharmacological Class: \* | | Click here to enter text. | Click here to enter text. |
| 3.6 | | Is there any re-packaging and/or re-labelling done for the investigational product at local trial sites? \* | |  |  |
| 3.7 | | Does this product contain a psychotropic substance or a controlled drug? \* | |  |  |
|  | | Please note that a separate approval is required for the import of each consignment of therapeutic/medicinal product containing a psychotropic substance or a controlled drug. Please refer to [Controlled drugs and psychotropic substances](https://www.hsa.gov.sg/controlled-drugs-psychotropic-substances) for more information. | | | |

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| **Dosage Form, Route of Administration, Strength**  *(Repeat as necessary)* | | | | | | |
| IP No.: \*  *(Number stated in 3.1)* | 3.8  Dosage Form:\*^ | 3.9  Route of Administration: \*^ | 3.10 Strength: \*^ | 3.11  Category of Investigational Product: \*^ | 3.12  For Category IIB products, state countries in which marketing authorisation has been granted: \* | 3.13  For Category III or IV products, provided the Product Registration No.: \* |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| **3.11 Category of Investigational Product**  Category I Unregistered Product without any prior clinical trials (i.e. First-in-Human Clinical Trial)  Category IIA Unregistered Product with prior or ongoing clinical trials  Category IIB Product that is not registered in Singapore but is registered/authorised overseas  Category III Locally Registered Product being investigated in clinical trials for new intended purposes/indications, new target populations, new dosages and/or administration methods, etc  Category IV Locally Registered Product used in accordance with its approved label | | | | | **3.12 For Category IIB products, state countries in which marketing authorisation has been granted:**  NOTE: If the product is registered worldwide, it would be sufficient to state HSA’s reference countries, e.g. US, UK, Canada, Australia, in which the product is registered.  **3.13 For Category III or IV products, provided the Product Registration No.:**  Note: Use [Information Search](https://www.hsa.gov.sg/e-services/infosearch) to search for the relevant Product Registration No. | |

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| **Product Owner** | | | |
| 3.14 | Company Name: \* | Click here to enter text. | Click here to enter text. |
| 3.15 | Address: \* | Click here to enter text. | Click here to enter text. |
| 3.16 | Telephone No.: | Click here to enter text. | Click here to enter text. |
| 3.17 | Fax No.: | Click here to enter text. | Click here to enter text. |

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| **SECTION 4: INVESTIGATIONAL CELL, TISSUE AND GENE THERAPY PRODUCT (CTGTP) (CONTAINING CELLS AND TISSUE)**  *(Repeat as necessary)* | | | |
| 4.1 | Investigational CTGTP (containing cells and tissue): | No. 1 | No. 2  *(This column is to be used only when > 1 Investigational CTGTPs is indicated in Section 2.26)* |
| 4.2 | Active Ingredient / Generic Name / Any code designation: \*^ | Click here to enter text. | Click here to enter text. |
| 4.2.1 | Standardised Investigational Product Name: ^ | Click here to enter text. | Click here to enter text. |
|  | NOTE: Please enter the appropriate Investigational Product Name to display in CT Register. This should correspond to the International Non-Proprietary Name, where applicable. If there is no suitable choice, please leave it blank. | | |
| 4.3 | Brand/Trade Name, if any: ^ | Click here to enter text. | Click here to enter text. |
|  | NOTE: Please enter the appropriate Brand/Trade Name to display in CT Register. | | |
| 4.4 | Pharmacological Class: \* | Click here to enter text. | Click here to enter text. |
| 4.5 | Product Description: | Click here to enter text. | Click here to enter text. |
| 4.6 | Origin of Cells/Tissue: \* |  |  |
|  | Please describe, if necessary: | Click here to enter text. | Click here to enter text. |
| 4.7 | Cell/Tissue Type |  |  |
| 4.7.1 | If stem cells, please select: \* |  |  |
| If others, please describe: \* | Click here to enter text. | Click here to enter text. |
| 4.7.2 | If differentiated cells, please describe type of cells: \*  *(e.g. Keratinocytes, fibroblasts, chondrocytes etc)* | Click here to enter text. | Click here to enter text. |
| 4.8 | Please describe degree of cell/tissue processing/manipulation: \*  *(e.g. in vitro / ex vivo expansion / activation / differentiation / genetic manipulation / cyro conservation, etc)* | Click here to enter text. | Click here to enter text. |
| 4.9 | Proposed Use: \* |  |  |
| Please describe, if necessary: | Click here to enter text. | Click here to enter text. |
| 4.10 | Combined with Drug / Biologic / Device? \* |  |  |
|  | Please describe, if necessary: | Click here to enter text. | Click here to enter text. |
| 4.11 | Primary Intended Action: \* |  |  |
| 4.12 | Regulatory Classification in the US:  *(for product manufactured in US)* | *Please select checkbox if not applicable. Otherwise, please select options below.* | *Please select checkbox if not applicable. Otherwise, please select options below.* |
| 4.13 | Regulatory Classification in the EU:  *(for product manufactured in EU)* | *Please select checkbox if not applicable. Otherwise, please select options below.* | *Please select checkbox if not applicable. Otherwise, please select options below.* |
| 4.13.1 | If advanced therapy therapeutic product, please select: |  |  |
| 4.13.2 | If others, please specify: | Click here to enter text. | Click here to enter text. |
| 4.14 | Route of Administration: \* | Choose an item. | Choose an item. |
| 4.15 | Category of Investigational Product: \* | Choose an item. | Choose an item. |
| |  |  | | --- | --- | | Category I | Unregistered Product without any prior clinical trials (i.e. First-in-Human Clinical Trial) | | Category IIA | Unregistered Product with prior or ongoing clinical trials | | Category IIB | Product that is not registered in Singapore but is registered/authorised overseas | | Category III | Locally Registered Product being investigated in clinical trials for new intended purposes/indications, new target populations, new dosages and/or administration methods, etc | | Category IV | Locally Registered Product used in accordance with its approved label | | |
| 4.16 | For Category IIB products, state countries in which marketing authorisation has been granted: \* | Click here to enter text. | Click here to enter text. |
|  | NOTE: If the product has been registered worldwide, it would be sufficient to state HSA's reference countries, e.g. US, UK, Canada, Australia, in which the product is registered. | | |
| 4.17 | For Category III or IV products, provide the Product Registration No.: | Click here to enter text. | Click here to enter text. |
|  | Note: Use [Information Search](https://www.hsa.gov.sg/e-services/infosearch) to search for the relevant Product Registration No. | | |
| **Product Owner** | | | |
| 4.18 | Company Name: \* | Click here to enter text. | Click here to enter text. |
| 4.19 | Address: \* | Click here to enter text. | Click here to enter text. |
| 4.20 | Telephone No.: | Click here to enter text. | Click here to enter text. |
| 4.21 | Fax No.: | Click here to enter text. | Click here to enter text. |

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| **SECTION 5: MANUFACTURER PARTICULARS**  *(Repeat as necessary)* | | | | | |
| NOTE:  For Investigational Products that are registered in Singapore, manufacturer information is not required.  For Investigational Products that are not registered in Singapore, please include at least one manufacturer of Finished Product and one manufacturer of API/Drug Substance. | | | | | |
| 5.1 Investigational Product: \* | 5.2  Manufacturer Name: \* | 5.3  Manufacturer Type: \* | 5.4  Address: \* | 5.5  Telephone No.: | 5.6  Fax No.: |
| Click here to enter text. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
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| **SECTION 6: COMPARATOR THERAPEUTIC PRODUCT (TP) / MEDICINAL PRODUCT (MP) / CELL, TISSUE AND GENE THERAPY PRODUCT (CTGTP)**  *(Repeat as necessary)* | | | |
| 6.1 | Comparator TP / MP / CTGTP | No. 1 | No. 2  *(This column is to be used only when > 1 Comparator TP / MP / CTGTP is indicated in Section 2.27)* |
| 6.1.1 | Active Ingredient / Generic Name / Any code designation: \* | Click here to enter text. | Click here to enter text. |
| 6.1.2 | Brand/Trade Name, if any: | Click here to enter text. | Click here to enter text. |
| 6.1.3 | Pharmacological Class: \* | Click here to enter text. | Click here to enter text. |

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| **6.2 Dosage Form, Route of Administration, Strength**  *(Repeat as necessary)* | | | | | | |
| Comparator No.: \*  *(Number stated in 6.1)* | 6.2.1  Dosage Form:\*^ | 6.2.2  Route of Administration: \*^ | 6.2.3 Strength: \*^ | 6.2.4  Category of Comparator Product: \*^ | 6.2.5  For Category IIB products, state countries in which marketing authorisation has been granted: \* | 6.2.6  For Category III or IV products, provided the Product Registration No.: \* |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| **6.2.4 Category of Comparator Product**  Category I Unregistered Product without any prior clinical trials (i.e. First-in-Human Clinical Trial)  Category IIA Unregistered Product with prior or ongoing clinical trials  Category IIB Product that is not registered in Singapore but is registered/authorised overseas  Category III Locally Registered Product being investigated in clinical trials for new intended purposes/indications, new target populations, new dosages and/or administration methods, etc  Category IV Locally Registered Product used in accordance with its approved label | | | | | **6.2.5 For Category IIB products, state countries in which marketing authorisation has been granted:**  NOTE: If the product is registered worldwide, it would be sufficient to state HSA’s reference countries, e.g. US, UK, Canada, Australia, in which the product is registered.  **6.2.6 For Category III or IV products, provided the Product Registration No.:**  Note: Use [Information Search](https://www.hsa.gov.sg/e-services/infosearch) to search for the relevant Product Registration No. | |

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| **SECTION 7: AUXILIARY THERAPEUTIC PRODUCT**  *(Repeat as necessary)* | | | |
| 7.1 | Auxiliary Therapeutic Product: | No. 1 | No. 2  *(This column is to be used only when > 1 Auxiliary TP is indicated in Section 2.28)* |
| 7.1.1 | Active Ingredient / Generic Name / Any code designation: \* | Click here to enter text. | Click here to enter text. |
| 7.1.2 | Brand/Trade Name, if any: | Click here to enter text. | Click here to enter text. |
| 7.1.3 | Pharmacological Class: \* | Click here to enter text. | Click here to enter text. |

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| **6.2 Dosage Form, Route of Administration, Strength**  *(Repeat as necessary)* | | | | | | |
| TP No.: \*  *(Number stated in 7.1)* | 7.2.1  Dosage Form:\*^ | 7.2.2  Route of Administration: \*^ | 7.2.3 Strength: \*^ | 7.2.4  Category of Auxiliary Product: \*^ | 7.2.5  For Category IIB products, state countries in which marketing authorisation has been granted: \* | 7.2.6  For Category III or IV products, provided the Product Registration No.: \* |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| Click here to enter a number. | Choose an item. | Choose an item. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
| **7.2.4 Category of Auxiliary Product**  Category I Unregistered Product without any prior clinical trials (i.e. First-in-Human Clinical Trial)  Category IIA Unregistered Product with prior or ongoing clinical trials  Category IIB Product that is not registered in Singapore but is registered/authorised overseas  Category III Locally Registered Product being investigated in clinical trials for new intended purposes/indications, new target populations, new dosages and/or administration methods, etc  Category IV Locally Registered Product used in accordance with its approved label | | | | | **7.2.5 For Category IIB products, state countries in which marketing authorisation has been granted:**  NOTE: If the product is registered worldwide, it would be sufficient to state HSA’s reference countries, e.g. US, UK, Canada, Australia, in which the product is registered.  **7.2.6 For Category III or IV products, provided the Product Registration No.:**  Note: Use [Information Search](https://www.hsa.gov.sg/e-services/infosearch) to search for the relevant Product Registration No. | |

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| **SECTION 8: LOCAL TRIAL SITES, PI and IRB**  *(Repeat as necessary)* | | | |
| 8.1 | Trial Site No. | No. 1 | No. 2  *(This column is to be used only when > 1 Trial Site is indicated in Section 2.36)* |
| 8.2 | Name of Trial Site: \*^ | Choose an item. | Choose an item. |
| If others, please specify:  Click here to enter text. | If others, please specify:  Click here to enter text. |
| 8.3 | Planned No. of Trial Subjects: \* | Click here to enter a number. | Click here to enter a number. |
| **Principal Investigator Details** | | | |
| 8.4 | Salutation: | Choose an item. | Choose an item. |
| 8.5 | Name of Principal Investigator: \*^ | Click here to enter text. | Click here to enter text. |
| 8.6 | NRIC / FIN of PI: \* | NA | NA |
| 8.7 | Designation: \* | Click here to enter text. | Click here to enter text. |
| 8.8 | Qualified Area(s) of Specialty: \* | Choose an item. | Choose an item. |
| If others, please specify:  Click here to enter text. | If others, please specify:  Click here to enter text. |
| 8.9 | Name of Place of Practice: \* | Choose an item. | Choose an item. |
| If others, please specify:  Click here to enter text. | If others, please specify:  Click here to enter text. |
| 8.10 | Department: | Click here to enter text. | Click here to enter text. |
| 8.11 | Trial Site Address: \*^ | Click here to enter text. | Click here to enter text. |
| Postal Code: Click here to enter. | Postal Code: Click here to enter. |
| 8.12 | Telephone No.: | Click here to enter text. | Click here to enter text. |
| 8.13 | Fax No.: | Click here to enter text. | Click here to enter text. |
| 8.14 | Primary Email: \* | Click here to enter text. | Click here to enter text. |
| 8.15 | Alternative Email: | Click here to enter text. | Click here to enter text. |
| **Study Coordinator Details** | | | |
| 8.16 | Salutation: | Choose an item. | Choose an item. |
| 8.17 | Name of Study Coordinator: | Click here to enter text. | Click here to enter text. |
| 8.18 | Telephone No.: | Click here to enter text. | Click here to enter text. |
| 8.19 | Fax No.: | Click here to enter text. | Click here to enter text. |
| 8.20 | Email: | Click here to enter text. | Click here to enter text. |
| **Satellite Site(s) Details** | | | |
| 8.21 | Is there any satellite site(s) for this trial site? \* |  |  |
| *(Repeat as necessary)*   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | Trial Site No.:  *(Number stated in 8.1)* | 8.22  Name of Satellite Site: \* | 8.23  Trial activities to be carried out: \* | 8.24  Satellite Site Address: \* | 8.25  Telephone No.: \* | 8.26  Fax No.: \* | | Click here to enter a number. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | Click here to enter a number. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | Click here to enter a number. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | Click here to enter a number. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | Click here to enter a number. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | Click here to enter a number. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | | | | |
| **IRB Details** | | | |
| 8.27 | Name of responsible IRB: \* | Choose an item. | Choose an item. |
| 8.27.1 | If others, please specify: | Click here to enter text. | Click here to enter text. |
| 8.28 | IRB Address: \* | Click here to enter text. | Click here to enter text. |
| 8.29 | Telephone No.: \* | Click here to enter text. | Click here to enter text. |
| 8.30 | Fax No.: \* | Click here to enter text. | Click here to enter text. |
| **IRB Representative** | | | |
| 8.31 | Name of IRB Representative: \* | Click here to enter text. | Click here to enter text. |
| 8.32 | Email Address of IRB Representative: \* | Click here to enter text. | Click here to enter text. |
| 8.33 | NRIC / FIN of IRB Representative: \* | NA | NA |

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| **SECTION 9: LOCAL SPONSOR(S)** | | |
| 9.1.1 | UEN: \* | Click here to enter text. |
| 9.1.2 | Company name: \*^ | Click here to enter text. |
| 9.1.3 | Company Address: \* | Click here to enter text. |
| Postal Code: Click here to enter text. |
| **Sponsor Contact Person** | | |
| Note: Please indicate official contact details. | | |
| 9.2.1 | Salutation: | Choose an item. |
| 9.2.2 | Name of Contact Person: \* | Click here to enter text. |
| 9.2.3 | NRIC/FIN: \* | Click here to enter text. |
| 9.2.4 | Designation: \* | Click here to enter text. |
| 9.2.5 | Telephone No.: \* | Click here to enter text. |
| 9.2.6 | Fax No.: \* | Click here to enter text. |
| 9.2.7 | Mobile No.: | Click here to enter text. |
| 9.2.8 | Primary Email: \* | Click here to enter text. |
| 9.2.9 | Alternative Email: | Click here to enter text. |

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| **9.3 Other Sponsor(s)**  *(Repeat as necessary)* | | | |
| NOTE: This section is to be completed by other sites (i.e. other than Lead Sponsor) involved in investigator-initiated trials (IIT) involving multiple sites where each site acts as a sponsor for their trial. Please refer to our [Guidance on Multi-Sponsor IIT](https://www.hsa.gov.sg/clinical-trials/regulatory-guidances). | | | |
|  | Other Sponsor No. | No. 1 | No. 2 |
| 9.3.1 | Company Name: ^\* | Click here to enter text. | Click here to enter text. |
| 9.3.2 | UEN: \* | Click here to enter text. | Click here to enter text. |
| 9.3.3 | Address: \* | Click here to enter text. | Click here to enter text. |
| Postal Code: Click here to enter. | Postal Code: Click here to enter. |
| 9.3.10 | Telephone No.: \* | Click here to enter text. | Click here to enter text. |
| 9.3.11 | Fax No.: \* | Click here to enter text. | Click here to enter text. |
| **Other Sponsor Contact Person** | | | |
| Please note that only persons who are authorised by the company (e.g. given submitter role for new clinical trial applications for the company’s account) can endorse the application on behalf of the company. | | | |
| 9.4.1 | Name of Contact Person: \* | Click here to enter text. | Click here to enter text. |
| 9.4.2 | Primary Email: \* | Click here to enter text. | Click here to enter text. |
| **Other Sponsor Contact Details (To be filled by Endorser)** | | | |
| 9.5.1 | Salutation: | Click here to enter text. | Click here to enter text. |
| 9.5.2 | Name of Contact Person: \* | Click here to enter text. | Click here to enter text. |
| 9.5.3 | NRIC/FIN: \* | NA | NA |
| 9.5.4 | Designation: \* | Click here to enter text. | Click here to enter text. |
| 9.5.5 | Telephone No.: \* | Click here to enter text. | Click here to enter text. |
| 9.5.6 | Fax No.: \* | Click here to enter text. | Click here to enter text. |
| 9.5.7 | Mobile No.: | Click here to enter text. | Click here to enter text. |
| 9.5.8 | Primary Email: \* | Click here to enter text. | Click here to enter text. |
| 9.5.9 | Alternative Email: | Click here to enter text. | Click here to enter text. |

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| **SECTION 10: CLINICAL RESEARCH MATERIAL NOTIFICATION** | | |
| NOTE: Please complete this section only if the import of clinical research materials (i.e. therapeutic products / cell, tissue and gene therapy products / medical devices / medicinal products), or the supply of clinical research materials by a local manufacturer is required for this trial (i.e. if “Yes” is selected for 10.1). | | |
| 10.1 | Is at least one of the following required for this trial?  (a) Import of CRM (i.e. therapeutic products / cell, tissue and gene therapy products / medical devices / medicinal products)  (b) Supply of CRM by a local manufacturer \* |  |
| 10.2 | Please select all that applies: \* |  |
| 10.3 | Please select the type of CRM to be imported or supplied: \* |  |

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| *(Repeat as necessary)* | | |
| **Company Particulars** | | |
| 10.4 | Please select: \* |  |
| 10.5 | Is the importer/ manufacturer the local sponsor for this trial? \* |  |
|  | NOTE: You may search and retrieve the UEN from [www.uen.gov.sg](http://www.uen.gov.sg).  Please note that the name of company can only be retrieved based on the UEN No. if the importer/ manufacturer is CRIS registered, otherwise please enter the Company Name. | |
| 10.6 | UEN: \* | Click here to enter text. |
| 10.7 | Company Name: \* | Click here to enter text. |
| 10.8 | Company Address: \* | Click here to enter text. |
| Postal Code: Click here to enter text. |
| **10.9 Contact Particulars** | | |
| 10.9.1 | Salutation: | Choose an item. |
| 10.9.2 | Company Representative: \* | Click here to enter text. |
| 10.9.3 | NRIC: \* | NA |
| 10.9.4 | Designation: \* | Click here to enter text. |
| 10.9.5 | Telephone No.: \* | Click here to enter text. |
| 10.9.6 | Fax No.: \* | Click here to enter text. |
| 10.9.7 | Handphone: | Click here to enter text. |
| 10.9.8 | Email: \* | Click here to enter text. |

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| **10.10 Therapeutic Product / Medicinal Product / Cell, Tissue and Gene Therapy Product** | | | | | | | |
| 10.10.1  Active Ingredient / Generic Name / Any code designation: \* | 10.10.2  Brand/Trade Name, if any: | 10.10.3  Does this product contain a psychotropic substance or a controlled drug? \* | 10.10.4  Dosage Form: \* | 10.10.5  Route of Administration: \* | 10.10.6  Strength: \* | 10.10.8  Estimated Total Quantity: \* | 10.10.9 Remarks: |
| Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
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| Click here to enter text. | Click here to enter text. | Choose an item. | Choose an item. | Choose an item. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Notes  For 10.10.1, please use the active ingredient / generic name stated in the Product Label or Investigator Brochure.  For 10.10.3, please note that a separate approval is required for the import of each consignment of therapeutic/medicinal product containing a psychotropic substance or a controlled drug. Please refer to [Controlled drugs and psychotropic substances](https://www.hsa.gov.sg/controlled-drugs-psychotropic-substances) for more information. | | | | | | | |

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| **10.11 Medical Device for Investigational Purpose** | | | | | | | | | |
| 10.11.1  Device Name: \* | 10.11.2  Type of Medical Device: \* | 10.11.3  Identifier (e.g. Model No.): \* | 10.11.4  Description & Intended Purpose: \* | 10.11.5  Risk Class: \* | 10.11.6  Product Owner: \* | 10.11.7  Address of Product Owner: \* | 10.11.8  Registration / Marketing Status: \* | 10.11.9  Estimated Total Quantity: \* | 10.11.10  Remarks: |
| Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |
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| Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. | Choose an item. | Click here to enter text. | Click here to enter text. |

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| **10.12 Medical Device for Non-Investigational Purpose** | | | | | |
| 10.12.1  Device Name: \* | 10.12.2  Identifier (e.g. Model No.): \* | 10.12.3  Product Owner: \* | 10.12.4  Address of Product Owner: \* | 10.12.5  Estimated Total Quantity: \* | 10.12.6  Remarks: |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
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| **SECTION 11: SUPPORTING DOCUMENTS** | | |
| 11.1 | Clinical Trial Protocol | Refer to Section 6 of ICH E6 Good Clinical Practice (GCP) Guidelines |
| 11.2 | Patient Information Sheet & Informed Consent Form | Refer to Regulations 16 to 20 of the Health Products (Clinical Trials) Regulations and the Medicines (Clinical Trials) Regulations, and Section 4.8 of ICH E6 GCP Guidelines |
| 11.3 | Investigator’s Brochure / Product Insert | For Investigator’s Brochure, refer to Section 7 of ICH E6 GCP Guidelines |
| 11.4 | List of Overseas Trial Sites |  |
| 11.5 | Local Trial Centre’s Principal Investigator’s CV | To include academic and professional qualification and lists of clinical trials previously conducted and clinical trials currently undertaken |
| 11.6 | GMP Certificate for Manufacturer |  |
| 11.7 | Certificate of Analysis for study batches of Investigational Products |  |
| 11.8 | Chemistry, Manufacturing and Control (CMC) Information |  |
| 11.9 | IRB Approval Letter | Institutional Review Board (IRB) Approval Letter for each trial site is required for submission for Clinical Trial Notification (CTN). |
| 11.10 | Listing of Components in a Medical Device System | *A medical device system comprises of components that are compatible and intended to be used in combination to complete a common intended purpose.*  For a medical device system, the applicant may list the name of the “system” as one item in the relevant section.  A separate document that lists the breakdown of the medical device system (including quantity) should be submitted for the purpose of good documentation, accountability and custom clearance. |
| 11.11 | Packing list for Study-Visits Specific Kits | A complete packing list of the items in each Study-Visits Specific Kit can be provided to facilitate the submission in Section 10.12: Medical Device for Non-Investigational Purpose.  Information required in Section 10.12 should be provided in the packing list (i.e. Device Name, Identifier, Name and Address of Product Owner and Quantity). Study protocol number should also be indicated on the packing list for reference. |
| 11.12 | Other Supporting Documents |  |

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| **DECLARATION FOR CLINICAL TRIAL AUTHORISATION / NOTIFICATION** | | |
| **DECLARATION FOR LOCAL SPONSOR** | | |
| **All applicants under the Medicines Act (MA) / Health Products Act (HPA) / Poisons Act (PA) must comply where applicable, with the MA/HPA/PA and their corresponding regulations. Applicants must also comply with all other applicable laws and their regulations.**   1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate. 2. I, on behalf of my company, shall abide by the Health Products Act, the Health Products (Clinical Trials) Regulations, any requirement imposed by the relevant Institutional Review Board, and any other conditions imposed by the Health Sciences Authority in the conduct of the clinical trial. 3. I, on behalf of my company, agree to the publication of information provided in the fields marked ^, and subsequent changes to such information, in a publicly accessible Clinical Trials Register. 4. I, on behalf of my company, shall inform the Health Sciences Authority of any substantial changes to the information submitted in the application. 5. I, on behalf of my company, shall submit status reports of the clinical trial every 6 months and when there is a change to the status of the clinical trial to the Health Sciences Authority. 6. I, on behalf of my company, undertake to indemnify and hold the Health Sciences Authority harmless against all actions, claims or proceedings in respect to any loss, injury or death of any person whomsoever arising out of or in connection with the clinical trial.   *The following is applicable only if applicant is also the Lead Sponsor:*   1. *As a lead sponsor, I, on behalf of my company, shall evaluate on an on-going basis the safety of the investigational therapeutic product(s) being tested or used in the trial.* 2. *As a lead sponsor, I, on behalf of my company, shall promptly notify all participating site sponsors and principal investigators of any information which suggests that the safety of subjects of the trial could be adversely affected (including any unexpected serious adverse drug reactions), and any findings which could impact the conduct of the trial.* 3. *As a lead sponsor, I, on behalf of my company, shall ensure that all unexpected serious adverse drug reactions and serious breaches of the trial protocol, the principles of Good Clinical Practice, or the Health Products (Clinical Trials) Regulations are reported to the Health Sciences Authority in accordance with applicable regulatory requirements.* 4. *As a lead sponsor, I, on behalf of my company, shall be responsible for all trial-related regulatory submissions and notifications to the Health Sciences Authority.* | |
| Signed on behalf of:    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Company  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation in Company    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |
| **DECLARATION FOR CLINICAL TRIAL AUTHORISATION / NOTIFICATION** | | |
| **DECLARATION FOR OTHER SPONSOR** | | |
| **All applicants under the Medicines Act (MA) / Health Products Act (HPA) / Poisons Act (PA) must comply where applicable, with the MA/HPA/PA and their corresponding regulations. Applicants must also comply with all other applicable laws and their regulations.**   1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate. 2. I, on behalf of my company, shall abide by the Health Products Act, the Health Products (Clinical Trials) Regulations, any requirement imposed by the relevant Institutional Review Board, and any other conditions imposed by the Health Sciences Authority in the conduct of the clinical trial. 3. I, on behalf of my company, agree to the publication of information provided in the fields marked ^, and subsequent changes to such information, in a publicly accessible Clinical Trials Register. 4. I, on behalf of my company, undertake to indemnify and hold the Health Sciences Authority harmless against all actions, claims or proceedings in respect to any loss, injury or death of any person whomsoever arising out of or in connection with the clinical trial. 5. As a participating site sponsor, I, on behalf of my company, shall immediately report to the lead sponsor any serious adverse event which occurs in a subject during the clinical trial conducted at the participating site, except those specified in the protocol as not requiring immediate reporting, and furnish to the lead sponsor a detailed written report on the event as soon as possible thereafter. 6. As a participating site sponsor, I, on behalf of my company, shall promptly report to the lead sponsor any information which suggests that the safety of any subject of the trial could be adversely affected, and any findings which could impact the conduct of the trial. 7. As a participating site sponsor, I, on behalf of my company, shall provide all relevant information to the lead sponsor that is necessary for the lead sponsor to perform trial-related regulatory submissions and notifications to the Health Sciences Authority. | |
| Signed on behalf of:    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Company  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation in Company    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date | |

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| **DECLARATION FOR CLINICAL TRIAL AUTHORISATION / NOTIFICATION** | | |
| **DECLARATION FOR PRINCIPAL INVESTIGATOR** | | |
| 1. I, on behalf of my company, shall abide by the Health Products Act, the Health Products (Clinical Trials) Regulations, any requirement imposed by the relevant Institutional Review Board, and any other conditions imposed by the Health Sciences Authority in the conduct of the clinical trial. 2. I shall not initiate this trial until the Health Sciences Authority has granted a clinical trial authorisation / accepted the clinical trial notification for the clinical trial. 3. I shall not initiate this trial until the relevant Institutional Review Board has granted approval for the clinical trial. | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Trial Site  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Principal Investigator    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Trial Site  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Principal Investigator    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |

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| **DECLARATION FOR CLINICAL TRIAL AUTHORISATION / NOTIFICATION** | |
| **DECLARATION FOR IMPORTER / LOCAL MANUFACTURER** | |
| 1. I, on behalf of my company, confirm that the information in Section 10 (relating to CRM imported or supplied by local manufacturer for this trial) of this application is true and accurate. 2. I, on behalf of my company, shall abide by the Medicines Act and the Medicines (Medicinal Products as Clinical Research Materials) Regulations, or the Health Products Act and the Health Products (Clinical Research Materials) Regulations and/or the Health Products (Medical Devices) Regulations, where applicable. 3. I, on behalf of my company, shall not supply the CRM stated in Section 10 of the application except for the purpose of this clinical trial.   Signed on behalf of:    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Company  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation in Company    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |

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| --- | --- | --- |
| **DECLARATION FOR CLINICAL TRIAL CERTIFICATE** | | |
| **DECLARATION FOR LOCAL SPONSOR** | | |
| **All applicants under the Medicines Act (MA) / Health Products Act (HPA) / Poisons Act (PA) must comply where applicable, with the MA/HPA/PA and their corresponding regulations. Applicants must also comply with all other applicable laws and their regulations.**   1. I confirm that the information submitted in this application is true and accurate. 2. I shall abide by the Medicines Act, the Medicines (Clinical Trials) Regulations, any requirement imposed by the relevant Institutional Review Board, and any other conditions imposed by the Health Sciences Authority in the conduct of the clinical trial. 3. I agree to the publication of information provided in the fields marked ^, and subsequent changes to such information, in a publicly accessible Clinical Trials Register. 4. I shall inform the Health Sciences Authority of any substantial changes to the information submitted in the application. 5. I shall submit status reports of the clinical trial every 6 months and when there is a change to the status of the clinical trial to the Health Sciences Authority. 6. I undertake to indemnify and hold the Health Sciences Authority harmless against all actions, claims or proceedings in respect to any loss, injury or death of any person whomsoever arising out of or in connection with the clinical trial.   *The following is applicable only if applicant is also the Lead Sponsor:*   1. *As a lead sponsor, I shall evaluate on an on-going basis the safety of the investigational medicinal product(s) being tested or used in the trial.* 2. *As a lead sponsor, I shall promptly notify all participating site sponsors and principal investigators of any information which suggests that the safety of subjects of the trial could be adversely affected (including any unexpected serious adverse drug reactions), and any findings which could impact the conduct of the trial.* 3. *As a lead sponsor, I shall ensure that all unexpected serious adverse drug reactions and serious breaches of the trial protocol, the principles of Good Clinical Practice, or the Medicines (Clinical Trials) Regulations are reported to the Health Sciences Authority in accordance with applicable regulatory requirements.* 4. *As a lead sponsor, I shall be responsible for all trial-related regulatory submissions and notifications to the Health Sciences Authority.* | |
| Signed on behalf of:    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Company  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No. | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation in Company    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |

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| **DECLARATION FOR CLINICAL TRIAL CERTIFICATE** | |
| **DECLARATION FOR OTHER SPONSOR** | |
| **All applicants under the Medicines Act (MA) / Health Products Act (HPA) / Poisons Act (PA) must comply where applicable, with the MA/HPA/PA and their corresponding regulations. Applicants must also comply with all other applicable laws and their regulations.**   1. I, on behalf of my company, confirm that the information submitted in this application is true and accurate. 2. I, on behalf of my company, shall abide by the Medicines Act, the Medicines (Clinical Trials) Regulations, any requirement imposed by the relevant Institutional Review Board, and any other conditions imposed by the Health Sciences Authority in the conduct of the clinical trial. 3. I, on behalf of my company, agree to the publication of information provided in the fields marked ^, and subsequent changes to such information, in a publicly accessible Clinical Trials Register. 4. I, on behalf of my company, undertake to indemnify and hold the Health Sciences Authority harmless against all actions, claims or proceedings in respect to any loss, injury or death of any person whomsoever arising out of or in connection with the clinical trial. 5. As a participating site sponsor, I, on behalf of my company, shall immediately report to the lead sponsor any serious adverse event which occurs in a subject during the clinical trial conducted at the participating site, except those specified in the protocol as not requiring immediate reporting, and furnish to the lead sponsor a detailed written report on the event as soon as possible thereafter. 6. As a participating site sponsor, I, on behalf of my company, shall promptly report to the lead sponsor any information which suggests that the safety of any subject of the trial could be adversely affected, and any findings which could impact the conduct of the trial. 7. As a participating site sponsor, I, on behalf of my company, shall provide all relevant information to the lead sponsor that is necessary for the lead sponsor to perform trial-related regulatory submissions and notifications to the Health Sciences Authority. |
| Signed on behalf of:    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Company  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation in Company    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |

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| **DECLARATION FOR CLINICAL TRIAL CERTIFICATE** | | |
| **DECLARATION FOR PRINCIPAL INVESTIGATOR** | | |
| 1. I, on behalf of my company, shall abide by the Medicines Act, the Medicines (Clinical Trials) Regulations, any requirement imposed by the relevant Institutional Review Board, and any other conditions imposed by the Health Sciences Authority in the conduct of the clinical trial. 2. I shall not initiate this trial until the Health Sciences Authority has granted a clinical trial certificate for the clinical trial. 3. I shall not initiate this trial until the relevant Institutional Review Board has granted approval for the clinical trial. | |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Trial Site  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Principal Investigator    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Trial Site  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Principal Investigator    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |

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| **DECLARATION FOR CLINICAL TRIAL CERTIFICATE** | |
| **DECLARATION FOR IMPORTER / LOCAL MANUFACTURER** | |
| 1. I, on behalf of my company, confirm that the information in Section 10 (relating to CRM imported or supplied by local manufacturer for this trial) of this application is true and accurate. 2. I, on behalf of my company, shall abide by the Medicines Act and the Medicines (Medicinal Products as Clinical Research Materials) Regulations, or the Health Products Act and the Health Products (Clinical Research Materials) Regulations and/or the Health Products (Medical Devices) Regulations, where applicable. 3. I, on behalf of my company, shall not supply the CRM stated in Section 10 of the application except for the purpose of this clinical trial.   Signed on behalf of:    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name of Company  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Name    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  NRIC No. / Foreign Identification No.    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Designation in Company    \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Date |