**Initial notification** (complete all sections of the form)

**Change to existing notification** (only complete the sections which have changed)

1. **TRIAL DETAILS**
   1. **Protocol number (must be a minimum of 4 and maximum of 20 characters)**

**1.2 Expected trial start date** The date you estimate the trial will be initiated at the first Australian site. The date cannot be retrospective.

Click to enter a date or type dd/mm/yyyy

**1.3 Expected completion date** The date you estimate the trial will be completed at all Australian sites.

Click to enter a date or type dd/mm/yyyy

**1.4 Will this trial include the potential use of restricted goods?**

**Yes** **No**

**1.5 Title of study and Description (**Must be a minimum of 250 characters up to a maximum of 2500 characters.**)**

**1.6 This trial:**

Involves the use of a Medicine Is comparator controlled

Involves the use of a Medical Device Involves animal excipients

Involves the use of a Biological Has relevant preceding trials^

Involves a Genetically Modified Organism Is a multicentre trial in Australia

Involves gene therapy Is being conducted in other countries

Is placebo controlled

**^** Only relevant preceding trials with CTNs. Please provide CTN identifier(s):

**1.7 Trial type:**

Phase 0

Phase 1

Phase 2

Phase 3

Phase 4

Bioequivalence

**1.8 Is this a First in Human Trial?**

**Yes** **No**

**1.9 Has this trial, in part or as a whole, been halted/stopped/withdrawn or rejected in another country due to safety concerns?**

**Yes** **No**

**1.10 Total number of participants to be enrolled in the trial**

Choose a number from the drop down list.

**1.11 Therapeutic area**

Select a therapeutic area from the drop down list

For all ticked boxes at 1.6, complete the corresponding table/s below. Copy each table as required for each excipient, medicine or device involved in the trial. Delete the tables which are not applicable.

\* Always required fields

**Medicine details**

|  |  |
| --- | --- |
| Trade/Product/Code Name\* |  |
| Is this a combination product?\* | **Yes**  **No** |
| Is this a cannabis product?\* | **Yes**  **No** |
| Type of Container\* |  |
| Dosage Form\* |  |
| Route of Administration\* |  |
| Medicines Ingredient Details  Formulation- **ingredient name\*** |  |
| Medicines Ingredient Details  Formulation – **quantity\*** |  |
| Medicines Ingredient Details  Formulation – **unit\*** |  |
| Indication\* |  |
| Dosage and Frequency\* |  |
| Intended Use\* | Comparator  Investigational Medicinal Product  Standard Care Therapy  Other |
| Is the medicine manufactured in Australia?\* | **Yes** **No** |
| GMP licence/clearance number or relevant exemption |  |
| Manufacturer details – **Name\*** |  |
| Manufacturer details – **Address\*** |  |

**Medical Device details**

|  |  |
| --- | --- |
| Product Name\* |  |
| Is this a\* | Medical Device  In Vitro Diagnostic Medical Device (IVD) |
| Is this a cannabis product?\* | **Yes**  **No** |
| Classification\* | Class I  Class I Measurement  Class I Sterile  Class IIa  Class IIb  Class III |
| Is this device software or does it incorporate software (this may include firmware)? \* | **Yes**  **No** |
| Is it an invasive device\* | **Yes**  **No** |
| Is it an implantable device\* | **Yes**  **No** |
| GMDN search context | Name  Code |
| GMDN |  |
| Description/Intended Purpose for Medical Device (details of design, composition, specification, mode of action and application, method of use) |  |
| Intended Purpose for Trial\* | Ancillary Product  Comparator  Investigational Medicinal Product  Standard Care Therapy  Other |
| Manufacturer details – **Name\*** |  |
| Manufacturer details – **Address\*** |  |

**Biological details**

View the biologicals framework information provided in this link. Confirm if your therapeutic good meets the definition of a biological: <https://www.ebs.tga.gov.au/ebs/help2.nsf/All%20-%20by%20key/CT_WhatIsBiological>

|  |  |
| --- | --- |
| Trade/Product/Code Name\* |  |
| Is this a combination product?\* | **Yes**  **No** |
| Product Description\* |  |
| Class of Biological\* | Class 1  Class 2  Class 3  Class 4 |
| Type of Container\* |  |
| Dosage Form\* |  |
| Route of Administration\* |  |
| Biologic Ingredient Details  Formulation- **ingredient name\*** |  |
| Biologic Ingredient Details  Formulation – **quantity\*** |  |
| Biologic Ingredient Details  Formulation – **unit\*** |  |
| Biologic Ingredient Details  Formulation – **Country of origin** |  |
| Indication\* |  |
| Dosage and Frequency\* |  |
| Intended Use\* | Comparator  Investigational Medicinal Product  Standard Care Therapy  Other |
| Is the biological manufactured in Australia?\* | **Yes** **No** |
| Manufacturer details – **Name\*** |  |
| Manufacturer details – **Address\*** |  |
| GMP licence/clearance number or relevant exemption |  |

**Genetically Modified Organism**

|  |  |
| --- | --- |
| Details of Genetically Modified Organism\* |  |

**Gene Therapy**

|  |  |
| --- | --- |
| Details of Gene Therapy\* |  |

**Placebo details**

|  |  |
| --- | --- |
| Product Name\* |  |
| Route of Administration\* |  |
| Description (including dosage form)\* |  |

**Animal excipients**

|  |  |
| --- | --- |
| Product Name\* |  |
| Species of Origin\* |  |
| Tissue\* |  |
| Preparation\* |  |
| Country of Origin\* |  |

**Trial in other countries**

|  |  |
| --- | --- |
| List other countries |  |

1. **TRIAL SITE DETAILS**

**2.1 Site**

|  |  |
| --- | --- |
| Site Name\* |  |
| Site Physical Location\* |  |
| State or Territory\* |  |
| Expected site start date\* | Click to enter a date or type dd/mm/yyyy |

**2.2 Principal Investigator Details**

|  |  |
| --- | --- |
| Name\* |  |
| Contact Phone\* (10 digit number, no spaces) |  |
| Contact Email\* |  |

* 1. **Human Research Ethics Committee (HREC) details**

|  |  |
| --- | --- |
| HREC Name | Alfred Hospital Ethics Committee |
| HREC Code (NHMRC code) | EC00315 |
| HREC Contact Officer | Professor John J McNeil |
| Position | Chair, Ethics Committee |
| Contact Phone Number | 0390762281 |
| Contact email | a.henjak@alfred.org.au |

* 1. **Approving authority details**

|  |  |
| --- | --- |
| Name of Authority | Alfred Health |
| Authority Contact Officer | Professor Stephen Jane |
| Position | Director of Research |
| Contact Phone | 0390762281 |
| Contact Email | a.henjak@alfred.org.au |

1. **ADDITIONAL TRIAL SITE DETAILS** Add as many sites as required. Only complete section 3.3 when the HREC is different to 2.3.

**3.1 Site**

|  |  |
| --- | --- |
| Site Name\* |  |
| Site Physical Location\* |  |
| State or Territory\* |  |
| Expected site start date\* | Click to enter a date or type dd/mm/yyyy |

**3.2 Principal Investigator Details**

|  |  |
| --- | --- |
| Name\* |  |
| Contact Phone\* (10 digit number, no spaces) |  |
| Contact Email\* |  |

* 1. **Human Research Ethics Committee (HREC) details\***

|  |  |
| --- | --- |
| HREC Name |  |
| HREC Code(NHMRC code) |  |
| HREC Contact Officer |  |
| Position |  |
| Contact Phone Number |  |
| Contact email |  |

* 1. **Approving authority details#**

|  |  |
| --- | --- |
| Name of Approving Authority\* |  |
| Approving Authority Contact Officer\* |  |
| Position\* |  |
| Contact Phone\* (10 digit number, no spaces) |  |
| Contact Email\* |  |

\* A copy of the ethics approval will be required to finalise the notification

# A copy of the site authorisation will be required to finalise the notification