|  |  |
| --- | --- |
| Protocol Number | *(Insert Number)* |
| Expected Trial Start Date | DD/MM/YYYY |
| Expected Completion Date | DD/MM/YYYY |
| Potential Use of Restricted Goods | *(Respond Yes or No)* |
| Full Title of Study |  |
| Trial Type | *(Insert Phase Number),* |
| Total Number of Patients to be Enrolled in Trial | *(Insert number)* |
| Therapeutic Area |  |
| This Trial | *(Insert study involves a medicine, or a device)* |

**Info for Medicinal Products and Placebo**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Trade / Product / Code Name** | **Combination**  **product? (Yes or No)** | **Type of Container (vial etc)** | **Dosage Form (injection, tablet etc)** | **Route of**  **Administration (oral, IV etc)** | **Indication** | **Dosage**  **Frequency (explain the dose, frequency and duration)** | **Intended Use (Insert Standard Care Therapy or Investigational Medicinal Product etc)** | **Medicine**  **Manufacture**  **in Australia**  **(Yes or No)** | **Manufacturer Details (Insert Manufacturer name)** | **Formulation**  **(Insert: Name, Quantity and Unit)** |

**Info for Devices**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Product Name** | **Is this a kit (insert if the device is a single device or a system)** | **Manufacturer** | **GMDN number** | **Description** | **Intended purpose (insert investigational product or other)** | **Other description** |

**Site and PI details**

Site Name:

Site Address Location:

Expected Site Start Date:

Principal Investigator Name:

Principal Investigator Contact Phone Number:

Principal Investigator Contact Email:

**Approving Authority Details**

Approving Authority Site Name:

Approving Authority Officers Name:

Approving Authority Position Title:

Approving Authority Contact Phone Number:

Approving Authority Contact Email:

**For multicentre studies please replicate the set of information for both “Site and PI details” and “Approving authority details” for each of the sites.**

**Please contact the Office for Research if you require assistance completing the form.**