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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **COMPASS TRIAL ADVERSE EVENT**  **REPORTING FORM** | | | | | | | | | **Office use only:** | | | |
| ID: 001XX | |  | |
|  | | | | | | | | | Date: XX/XX/XXXX | |  | |
| Please complete the below form when an Adverse event or Serious Adverse event occurs during the Compass Trial (Pilot and Main trial).  Please send to Attention: ***Prof Marion Saville PO Box 178, Carlton South, VIC, 3053*** or scan and send to ***Prof Marion Saville at*** [***directorate@vcs.org.au***](mailto:directorate@vcs.org.au) | | | | | | | | | | | | |
| **Site & Reporting Details** | | | | | | | | | | | | |
| **Site where event occurred:** | | |  | | | |  | | | | | |
| Name of Person Reporting: | | | Prof Marion Saville | | | |  | | | | | |
| Type of health practitioner: | General Practitioner  Nurse  VCS/VCCR staff  other Project Coordinator | | | | | | | | | | | |
| Date of report XX/XX/XXXX | |  | | | | | | | | | | |
| **Address of site where event occurred:** Unknown | | | | | | | | | | | | |
| Phone: N/A | | | | | **Fax** N/A |  | | | |  | |
| **Participant Details** | | | | | | | | | | | | |
| Compass ID (CEN): XXXXXXXXX Woman ID: XXXXXXX | | | | | | | | | | | | |
| **Date of Birth:** XX/XX/XXXX | |  | | | | | | | | | | |
| Adverse Event Details | | | | | | | | | | | | |
| **Time and Date event occurred:** XX/XX/XXXX, Time Unknown | | | | | | | | | | | | | |
| **Date Event Resolved:** XX/XX/XXXX | | | |  | | | | Ongoing | | | | |
| **Description of the event:** On the XX/XX/XXXX, the Principal Investigators and Compass study team were made aware of the death of a woman enrolled in Arm X of the Compass Main/Pilot trial. This information was received from the Victorian Registry of Births, Deaths and Marriages in the course of regular death data updates. I wrote to the Registry of Births, Deaths and Marriages to determine the cause of death for reporting and safety purposes.  On the XX/XX/XXXX correspondence from the Registry of Births, Deaths and Marriages was received stating that the primary cause of death was (primary cause of death) | | | | | | | | | | | | |
| **Severity of the event** *(please refer to the Adverse Event Reporting procedure to assist with classification of AE and SAE)* | | | |  | | | | | | | | |
| **Adverse** **event** | | | |
| **Severe** **adverse event** | | | |
| **Please further classify the severity of the event below** | | | |  | | | | | | | | |
| **Mild** | | | |
| **Moderate** | | | |
| **Severe** | | | |
| **Did the participant have any relevant preexisting conditions** | | | |  | | | | | | | | |
| **Yes** | | | |
| **No** | | | |
| **N/A** | | | |
| **Was treatment required** | | | | ***If yes, please describe treatment and ongoing management here*** | | | | | | | | |
| **Yes**  **No**  **N/A** | | | | Not known  GP assessment  none or symptomatic  Hospital emergency  Hospital admission: No# days:  Other please specify  ***Details*** | | | | | | | | |
| **Do you believe that this event may affect the ongoing ethical conduct of the study or the safety of the participants or their willingness to participate?** | | | | ***Please provide more details here:*** This serious adverse event is considered unrelated to the Compass study, and in my opinion does not pose risk to any other Compass participant. | | | | | | | | |
| **Yes** | | | |
| **No** | | | |
| **N/A** | | | |
| **Is there any other information that should be recorded?** | | | |  | | | | | | | | |
| **Yes** | | | |  | | | | | | | | |
| **No** | | | |
| **Does the adverse event require changes to the Protocol?** | | | |  | | | | | | | | |
| **Yes** | | | |  | | | | | | | | |
| **No** | | | |
| **Is the study continuing at all sites** | | | |  | | | | | | | | |
| **Yes** | | | |  | | | | | | | | |
| **No** | | | |
| **Statements of persons completing the form:** | | | | | | | | | | | | |
| Prof Marion Saville’s clinical recommendation is that the adverse event is not related to the trial, no further action is required in relation to safety and the trial conduct should continue as per the approved protocol.  The Chair of the IDSMC Committee confirms that no further action is required. | | | | | | | | | | | | |
|  | | | | | | | | | | | | |
| **Date**: XX/XX/XXXX | | | | | | | | | | | | |