



# Round 3 ADJUDICATION MANUAL

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# 1. Responsibilities of PURE Adjudicators

The PURE Adjudicators are charged with the responsibility of validating all reported fatal and non-fatal top 5 events. Their decisions will be based on completed case report forms (CRFs), Verbal Autopsy (VA) reports and applicable source documentation, as provided. If no supporting documentation and/or VA reports are available, they must give their best estimate of the *underlying cause of death or event outcome*, based on individual's medical history. Their decisions will be used for the final analysis.

## 1.1 Adjudicator Selection Training

Adjudicators will be selected based on their expertise, experience and language(s). Qualifications include:

- Allopathic Doctor (mandatory)
- Familiarity with adult medicine (mandatory)
- Prior experience with clinical event adjudication/death certification (asset)

All new Adjudicators are required to accurately review and adjudicate test cases which have been selected to represent examples of each of the study endpoints. Sites must therefore keep PHRI informed of all Adjudicator activity (i.e. when existing ones leave/resign and when new ones are hired). A master list of eligible Adjudicators will be retained by PHRI.

# 2. Event Adjudication Process

All reported top 5 events will be independently adjudicated by Adjudicator. Supporting documents of all captured events (medical records, narrative summaries and such) will be uploaded to the ROME database via attached photo. Each Adjudicator will review the related forms and acknowledge their agreement/disagreement with the reported event on the corresponding adjudication CRF. If a different diagnosis is determined, an explanation and alternative diagnosis must be given with proper PURE and ICD-10 codes.

*Refer to Appendices I & II for the PURE Adjudicator Thought Process flow diagrams of Fatal and Non-Fatal events.*

## 2.1 Event Overview

Each electronic dossier can include the following items:

- Completed Event CRF
- Corresponding Event Adjudication Report Form
- Verbal Autopsy Report, if available
- Narrative summary, when available
- Medical records, if available
- Baseline & Follow up reports (medical history, events, tobacco and alcohol usage etc)
- Any other important information (from all individual data gathered to date that will help the Adjudicator(s) make a final decision on event outcome.)

**\*\*All Adjudicators must have the most current PURE definitions and code sheet\*\***

## 2.2 Event Case Report Forms (CRFs)

*Refer to Appendix III for adjudicated top 5 events captured and their corresponding CRF.*

Each time event details are provided, the Site Research Coordinator (RC) or delegate, records details of the event on the appropriate event CRF. Respondent's answers should be recorded verbatim. Do not change wording. Any applicable supporting documentation for the reported event should be obtained, if available. Narrative summaries, along with supporting documentation is to be uploaded as a photo or pdf.

Site Coordinators are responsible for reviewing all top 5 events prior to adjudication. Once confirmed via the checkbox indicated below, the top 5 events will then be added to the Adjudicator's queue. Please note that it will take 1 hour to appear in the adjudication queue.

☒ I confirm that the above event information is complete to my knowledge. The event may proceed to adjudication.

## 2.3 Event Adjudication Form

There is a separate Event Adjudication Form for each type of event that requires adjudication (i.e. Death, MI, Stroke, Heart Failure and Cancer). This corresponding Event Adjudication Form will be included with each top 5 event and is to be completed by the Adjudicator to record their decision.

*Refer to Appendix IV for PURE Adjudication CRFs*

## 2.4 Event Definitions and Adjudication Codes

Event definitions and associated PURE codes can be found in *the Appendices mentioned below*. Adjudicators must refer to these event definitions and their associated codes during the adjudication process, to ensure the event being adjudicated either meets or does not meet the event criteria. These documents will also ensure proper usage of PURE and ICD-10 adjudication codes.

*Refer to Appendix V for the Fatal PURE Adjudication code sheet and Appendix VI for the Non-Fatal PURE Adjudication code sheet.*

*Refer to Appendix VII for PURE ICD-10 Adjudication codes.*

*Refer to Appendix VIII for Fatal Event Definitions and IX for Non-Fatal Event Definitions*

### 3. Completing an Event Adjudication Form

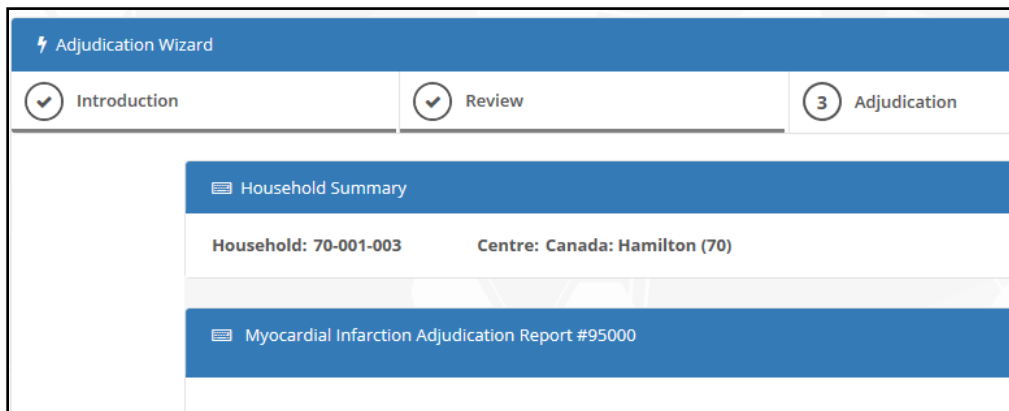
The Event Adjudication form(s) will contain the Adjudicator's final decision regarding the event that is being reviewed. These decisions will be used for analysis. Before completing the event Adjudication Report form, all information contained within the online event dossier must be carefully reviewed, to ensure the final decision is accurate.

#### 3.1 Participant & Report Identifiers

This section refers to ALL event adjudication forms

**Anonymized Patient Identifiers** such as Subject ID, Household Number, Community and Centre Number are prepopulated in the online system.

**Adjudication Report #** is also prepopulated and recorded internally. There is no need to assign report #s.

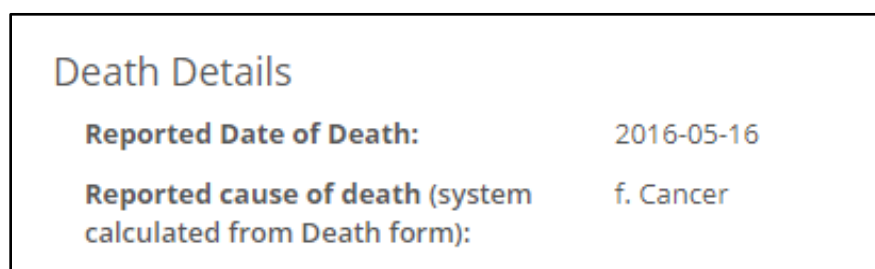


The screenshot shows the 'Adjudication Wizard' interface. At the top, there is a blue header bar with a lightning bolt icon and the text 'Adjudication Wizard'. Below this, there is a progress bar with three steps: 'Introduction' (marked with a checkmark), 'Review' (marked with a checkmark), and 'Adjudication' (marked with a circled '3'). The main content area is divided into two sections. The top section is titled 'Household Summary' and contains the text 'Household: 70-001-003' and 'Centre: Canada: Hamilton (70)'. The bottom section is titled 'Myocardial Infarction Adjudication Report #95000'.

#### 3.2 Event Details

**Event Details** This section is prepopulated, based on the corresponding event CRF. Reported event (MI, Stroke, HF or Cancer), as well as reported date of event will be shown.

**Death Details** This section is prepopulated, based on the corresponding death event CRF. Reported cause of death, as well as reported date of death will be shown.



The screenshot shows the 'Death Details' section. It contains two rows of information. The first row is 'Reported Date of Death:' followed by '2016-05-16'. The second row is 'Reported cause of death (system calculated from Death form):' followed by 'f. Cancer'.

To begin, you must hit the 'Begin Adjudication' button.

Begin Adjudication

### 3.3 Adjudicator Decision

For each event there is an 'Adjudication Decision' area to be completed by the Adjudicator. Please note that ALL questions must be completed with diagnosis given, whether in agreement or disagreement.

**Source Document Section:** 'Diagnosis was' is to record details of aids used by the Adjudicator to arrive at their decision. The Adjudicator is allowed to check one or more boxes provided. For example, if both medical records/documents and Verbal Autopsy reports were used, check both boxes.

1. Diagnosis was:

*(Check ALL that apply)*

☐ Medical record derived

☐ Verbal autopsy derived

☐ Other

For MI, Stroke, HF and Cancer events, Adjudicator must mark whether the event is Fatal or Non-Fatal before moving on to the PURE/ICD codes.

2. Was Event: ☐ Fatal ☐ Non - Fatal

**Final Date of Event:** Should Adjudicator find a different event date based on source documents, this date is to be entered in this section. You will see a notice that confirms this. This date is **NOT** the date of completion.

a. Final Date of Event:

**(Important: This field is *not* to be confused for the date of completion. Please enter the final event date based on your review of source documentation.)**

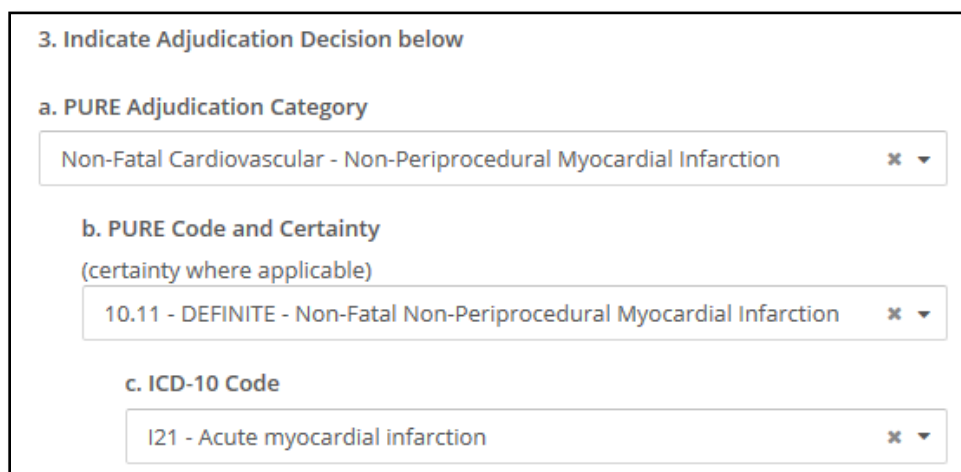
Year

Month

## Adjudicator Decision/Outcome

Adjudicators will simply start to type the event outcome in the field for PURE Adjudication Category then select from the drop down menu. *For example, the Adjudicator's decided outcome is Mouth Cancer. You can type Cancer or you can type Mouth.*

Once the category is selected, a new drop down will appear. This will give you the corresponding options for Mouth Cancer. After selecting the category and PURE code, the system will generate one of two messages. Either you are agreeing with the reported cause of death or disagreeing and providing an alternative cause of death.



The screenshot shows a form titled "3. Indicate Adjudication Decision below". It contains three sections, each with a dropdown menu:

- a. PURE Adjudication Category**: The dropdown menu is open, showing "Non-Fatal Cardiovascular - Non-Periprocedural Myocardial Infarction".
- b. PURE Code and Certainty**: The dropdown menu is open, showing "10.11 - DEFINITE - Non-Fatal Non-Periprocedural Myocardial Infarction". Below the dropdown is the text "(certainty where applicable)".
- c. ICD-10 Code**: The dropdown menu is open, showing "I21 - Acute myocardial infarction".

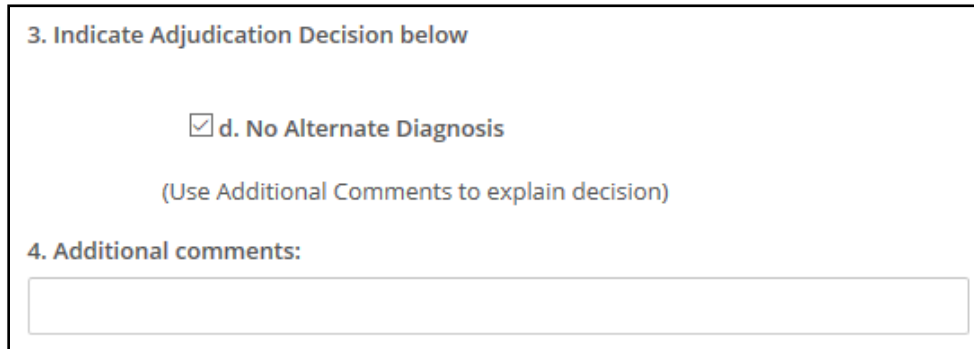
If you AGREE, it means that you agree with the reported event or cause of death and believe the event **fulfills the criteria** as outlined by the study definitions. You will indicate your diagnosis by providing the corresponding PURE Adjudication code and ICD-10 code that matches your adjudication decision.

If you DISAGREE, it means that you do not agree with the reported event or cause of death and do not believe the event fulfills the criteria outlined in the study definitions. Explanation of decision to disagree is to be provided in the additional comments section.

When disagreeing with an event or reported cause of death, alternative diagnosis is required and Adjudicator will indicate new diagnosis as well as appropriate PURE and ICD-10 codes.

The third drop-down is for ICD-10 code selection. Adjudicators are required to provide the corresponding ICD-10 code to the PURE code selected in the previous drop down. *Please note for PURE codes that do not have a corresponding ICD-10 code (i.e. sudden CV, presumed CA and presumed CV), the system will not prompt a response.*

For non-fatal MI, Stroke, HF and Cancer events, if Adjudicator cannot provide a possible plausible outcome then 'No Alternative Diagnosis' can be checked. Adjudicator will be required to provide an explanation of this decision in the additional comments section.



3. Indicate Adjudication Decision below

☒ d. No Alternate Diagnosis

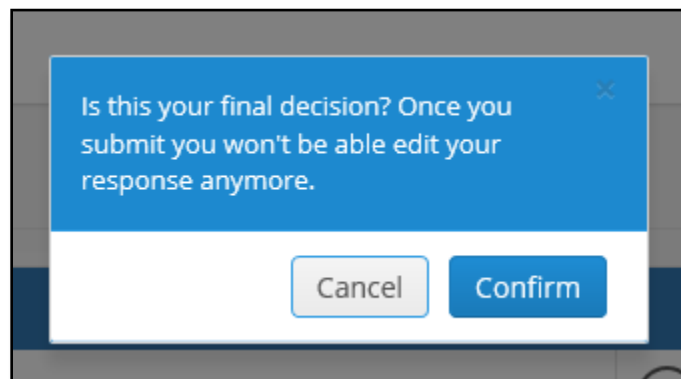
(Use Additional Comments to explain decision)

4. Additional comments:

**Additional Comments:** Comments can be provided on an optional basis for outcomes in agreement or disagreement of the reported cause of death.

### 3.4 Completion

Each Adjudicator is required to acknowledge and confirm the information recorded on the adjudication form by hitting the 'Submit' button. A pop up message will appear, asking the Adjudicator to confirm their final decision.





## 4. Quality Control Review

Occasionally, events (both confirmed and refuted) will be reviewed for quality control purposes. This helps to determine the consistency of the event adjudication process and final decisions made. Results of Quality Control Review could indicate any or all of the following:

- More adjudication training is required (for all adjudicators, or for just one or two individuals; country variances may also appear, which may lead to further discussions and decisions)
- Current event definitions need clarification and/or revision
- Current adjudication review processes require clarification and/or change
- Change of the current final decision of the event

A random sample of all types (for example 20% of all reported/adjudicated events) will be randomly selected by PHRI for subsequent Quality Control Review.

## Questions and Comments

Questions or comments may be directed to Dawn Agapay ([Dawn.Agpay@phri.ca](mailto:Dawn.Agpay@phri.ca)) or Sumathy Rangarajan ([Sumathy.Rangarajan@phri.ca](mailto:Sumathy.Rangarajan@phri.ca)) as required.