

Recommended elements to include in an Acute Myocardial Infarction Event Case Report Form in trials including people receiving haemodialysis

A case report form is the tool used by clinical trialists to collect data from each participating patient. The case report form should be completed by the trial site. It enables efficient and complete data collection and together with appropriate source documents, allows for improved adjudication by a clinical events committee.

Recommended elements	Details to include																																										
General event information	<ul style="list-style-type: none"> • Suspected/confirmed myocardial infarction • Date of event • Time of event • Was the event the primary reason for hospitalisation? • Was the event the primary cause of death? (separate CRF recommended for fatal events) 																																										
Clinical presentation	Symptoms suspicious of acute myocardial ischemia including: <ul style="list-style-type: none"> • Chest pain/discomfort • Sweating • Arm/throat/neck/jaw pain or discomfort • Shortness of breath • Non-specific pain, discomfort or nausea, over and above or different to, usual background pain, discomfort or nausea. 																																										
ECG	When available, ECGs should be provided, clearly labelled with date and time. Ideal timepoints might include as many of the following as possible: <ul style="list-style-type: none"> • ECG obtained at entry to study • ECG prior to event but at a time when patient was stable and asymptomatic • ECG at time of symptom presentation • Serial ECGs subsequent to initial presentation ECG • ECG post event when patient is stable 																																										
Cardiac enzyme/markers	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;"></th> <th style="width: 10%;">Date</th> <th style="width: 10%;">Time</th> <th style="width: 15%;">Cardiac enzyme</th> <th style="width: 10%;">Local lab URL</th> <th style="width: 10%;">Result</th> <th style="width: 5%;">Unit</th> </tr> </thead> <tbody> <tr> <td>Initial (at presentation with symptoms)</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Peak</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>*Subsequent 1</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>**Subsequent 2</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>**Subsequent 3</td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table> <p>*If the initial cardiac enzyme result is above the sex specific 99th percentile URL and the delta from the initial result to the peak result is >20% then subsequent results are not required ** Any dynamic change in cTn or strong clinical suspicion should prompt further cTn samples so as not to miss a significant delta, eg at 2 hrs, 4hrs and 6hrs.</p>		Date	Time	Cardiac enzyme	Local lab URL	Result	Unit	Initial (at presentation with symptoms)							Peak							*Subsequent 1							**Subsequent 2							**Subsequent 3						
	Date	Time	Cardiac enzyme	Local lab URL	Result	Unit																																					
Initial (at presentation with symptoms)																																											
Peak																																											
*Subsequent 1																																											
**Subsequent 2																																											
**Subsequent 3																																											
Imaging evidence	<ul style="list-style-type: none"> • Is there Imaging evidence of new loss of viable myocardium or new regional wall motion abnormality in a pattern consistent with an ischemic etiology? 																																										

	<ul style="list-style-type: none"> • Modality of imaging • Date of imaging • Time of imaging
Identification/exclusion of coronary thrombus	<ul style="list-style-type: none"> • Yes/No • Procedure performed to identify a coronary occlusion thrombus • Date of procedure • Time of procedure
Recommended source documents	<ol style="list-style-type: none"> 1. Admission summary 2. Discharge summary 3. ECGs as described above 4. Imaging reports 5. Angiography/PCI/CABG reports