Cause of Death Form (CRF)

CoDe

*Study:_____

*Patient ID code: _____

*Date of death : ____ – _____ – ____
(dd/mmm/yy eg 01-FEB-05)

If the patient experienced any D:A:D event(s), please report such event(s) on a designated D:A:D event form in addition to the completion of the CoDe form

Section 1 ♦ Background demographics

- *** A.** Year of birth (yyyy) _ _ _ _   **B**. Gender : ☐male ☐female
- **C.** Height (cm):_ _ _ **D.** Weight (kg) : _ _ _   **E.** Date :_ _ – _ _ _ – _ _
(most recent before death)   (dd-mmm-yy; weight measured)

Section 2 ♦ What data sources were available for the completion of this form? (please mark all that apply)

- **A.** Hospital files   ☐Yes, complete ☐Yes, incomplete ☐No
- **B.** Outpatient clinic chart   ☐Yes, complete ☐Yes, incomplete ☐No
- **C.** Autopsy report   ☐Yes, complete ☐Yes, incomplete ☐No
- **If other, specify:**
- **D.** Registry   ☐   • **G.** Patient's medical provider ☐
- **E.** Obituary   ☐   • **H.** Nursing home   ☐
- **F.** Patient's relatives or partner ☐   • **I.** Other:_____

Section 3 ♦ Risk factors:

A. Ongoing risk factors in the year prior to death:

1. Cigarette smoking	☐ Yes	☐ No	☐ Unknown
2. Excessive alcohol consumption	☐ Yes	☐ No	☐ Unknown
3. Active illicit injecting drug use	☐ Yes	☐ No	☐ Unknown
4. Active illicit non-injecting drug use	☐ Yes	☐ No	☐ Unknown
5. Opiate substitution (methadone)	☐ Yes	☐ No	☐ Unknown

Section 4 ♦ Co-morbidities:

A. Ongoing chronic conditions:

1. Hypertension	☐ Yes	☐ No	☐ Unknown
2. Diabetes mellitus	☐ Yes	☐ No	☐ Unknown
3. Dyslipidemia	☐ Yes	☐ No	☐ Unknown

B. Prior cardiovascular disease   ☐ Yes ☐ No ☐ Unknown
(*myocardial infarction, stroke or invasive cardiovascular procedure*)

C. History of depression   ☐ Yes ☐ No ☐ Unknown

D. History of psychosis   ☐ Yes ☐ No ☐ Unknown

E. Liver disease:

1. Chronic elevation of liver transaminases	☐ Yes	☐ No	☐ Unknown
2. Chronic HBV infection	☐ Yes	☐ No	☐ Unknown
3. Chronic HCV infection	☐ Yes	☐ No	☐ Unknown
4. HDV infection	☐ Yes	☐ No	☐ Unknown
5. History of previous liver decompensation	☐ Yes	☐ No	☐ Unknown
6. Clinical signs of liver failure in the 4 weeks before death	☐ Yes	☐ No	☐ Unknown
7. Liver histology available (ever)	☐ Yes	☐ No	☐ Unknown

*Please note that if any mandatory fields remain empty the CRF will not be registered

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If Yes, please indicate:

the date of most recent biopsy _ _ - _ _ _ -_ _ the stage of fibrosis (0-4): |__|

(dd-mmm-yy eg 01-FEB-05)

Section 5♦ Cause of death

A. Was the death sudden?   ☐ Yes ☐ No ☐ Unknown

B. Was the death unexpected?   ☐ Yes ☐ No ☐ Unknown

C. Please complete the table below by recording all illnesses and conditions (acute and chronic) or injuries that the patient had at the time of death.

	Illness / Condition / Injury (text)	Date of onset dd/mmm/yy (eg 01-FEB-05)	Certainty of diagnosis[a]		
			Definite	Likely	Possible
1.		____ – _____ – ____	☐	☐	☐
2.		____ – _____ – ___	☐	☐	☐
3.		____ – _____ – ____	☐	☐	☐
4.		____ – _____ – ____	☐	☐	☐
5.		____ – _____ – ____	☐	☐	☐
6.		____ – _____ – ____	☐	☐	☐
7.		____ – _____ – ____	☐	☐	☐
8.		____ – _____ – ____	☐	☐	☐
9.		____ – _____ – ____	☐	☐	☐

[a]**Certainty of Diagnosis: Definite=**95-100% certainty, **Likely=**80-95% certainty**, Possible=**50-80% certainty

*D. Brief narrative of the sequence of events leading to death (please include means of diagnosis of illnesses):

_____

_____

_____

_____

_____

_____

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E. In summary, the causal relation between the conditions leading to death was (complete this section with the corresponding number from table C above):

1. Condition that directly caused death (immediate cause):_____

2. Due to or as a consequence of :_____

3. Due to or as a consequence of:_____

4. Condition that initiated the train of morbid events (the underlying condition):_____

Section 6♦ Post-mortem / Autopsy:

A. Has autopsy been performed: ☐ Yes   ☐ No   ☐ Unknown

B. Did the autopsy reveal any evidence of intoxication?

☐ Yes, with the agent:_____   ☐ No   ☐ Unknown

Please provide a brief summary of the findings from the autopsy report (please also include a copy of the full report):

_____

_____

_____

_____

_____

Section 7 ♦ ART and laboratory values prior to death

A. Has the patient EVER received ART: ☐ Yes   ☐ No   ☐ Unknown

If YES, when was ART started (in months before death):

☐ ≤ 1 month before   ☐ ≤ 3 months before   ☐ ≤ 6 months before   ☐ More than 6 months before

B. Did the patient receive ART at the time of death? ☐ Yes   ☐ No   ☐ Unknown

o *If No*, Date of stopping __ __ – __ __ __ – __ __ **(dd/mmm/yy eg 01-FEB-05)**

C. Laboratory values (please complete all fields where data is available)

Laboratory values	Time	Value	Unit	Date dd/mmm/yy (eg 01-FEB-05)
CD4+ cell count	1. Most recent prior to last stopping ART		Cells/mm^3	__ __ – __ __ __ __ – __ __
	2. Most recent prior to death		Cells/mm^3	__ __ – __ __ __ __ – __ __
HIV RNA	1. Most recent at time of stopping ART		Copies/mL	__ __ – __ __ __ __ – __ __
	2. Most recent prior to death		Copies/mL	__ __ – __ __ __ __ – __ __
Haemoglobin	Most recent prior to death		/	__ __ – __ __ __ __ – __ __

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Section 8 ♦ Adverse effects to any type of medical treatment

A. Was the death considered to be related to a medical treatment? ☐ Yes ☐ No ☐ Possibly

B. The suspected relation was to: ☐ Antiretroviral treatment ☐ Other medical treatment

Please provide a brief narrative of the suspected association including the name of the medication and the date of starting:

_____

_____

_____

_____

> Please refer to the 'CoDe instructions' for definitions and guidelines for the completion of this form

Completed by: Name (in print) _____

Position : ☐ Physician ☐ Nurse ☐ Other, describe _____

Directly involved in the medical care of the patient around the time of death? ☐Yes ☐ No

Date (dd/mmm/yy)**:__ __ – __ __ __ – __ __ Signature:** _____

*Please note that if any mandatory fields remain empty the CRF will not be registered