DEATH			
Protocol Identifier	**Subject Identifier**		**Visit Description** **Treatment Period** **Visit XYZ**

DEATH CERTIFICATE

A. Date of death: **Day** **Month** **Year**

B. Cause of death on Death Certificate"

List the **immediate cause**: Final disease or condition resulting in death

____

List the **conditions:** If any, leading to the cause listed on line a.

____

List the **underlying cause**: Disease or injury that initiated the events resulting in death

____

C. Certifier from Death Certificate: (✓all that apply)

- ☐ Investigator
- ☐ Primary Care Physician
- ☐ Treating Physician
- ☐ Medical Examiner
- ☐ Other, Specify

____

D. Was autopsy performed? [Y] ☐Yes [N] ☐No [NK] Not Known

If Yes submit report.

COURSE OF DEATH	
Was the death witnessed?	[Y] ☐Yes [N] ☐No [NK] Not Known
If Yes, describe signs and symptoms that preceded death:	_________________________
Was resuscitation attempted?	[Y] ☐Yes [N] ☐No [NK] Not Known
If No, was this because there was a DNR order?	[Y] ☐Yes [N] ☐No [NK] Not Known
If the death was un-witnessed, when was subject last seen or heard alive?	**Day** **Month** **Year** **Hrs:Mins (00:00-23:59)**

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Where did death occur (e.g. hospital, home, and street)?	____
Did the subject have a condition that made him/her terminal or pre-terminal? * terminal: death expected within less than one month; pre-terminal: death expected in 1 to 6 months	[Y] ☐Yes [N] ☐No [NK] Not Known
Was death sudden (without warning or within 24 hours of onset of symptoms)?	[Y] ☐Yes [N] ☐No [NK] Not Known
If Yes, what were the circumstances?	☐During Sleep ☐Normal Daily Activity ☐During Exertion
Did the subject have any clinical signs or symptoms that may have indicated a potential cause of death?	[Y] ☐Yes [N] ☐No [NK] Not Known
If Yes, specify:	____
Was death attributed to a cardiovascular procedure or cardiovascular surgery?	[Y] ☐Yes [N] ☐No [NK] Not Known

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PRIMARY CAUSE OF DEATH (✓**only one**)

Cardiovascular Causes

Was primary cause of death Cardiovascular ? [Y] ☐Yes [N] ☐No ☐ [NK] Not Known

If Yes, specify if able:

☐Myocardial Infarction

☐ Sudden Cardiac Death

☐Heart Failure

☐Stroke

☐Cardiovascular Procedures (including cardiovascular surgery)
If Yes, complete Revascularization CRF

☐ Cardiovascular Hemorrhage

☐Other Cardiovascular Causes – Specify:____

Non-cardiovascular Causes

Was primary cause of death Non-cardiovascular ? [Y] ☐Yes [N] ☐No ☐ [NK] Not Known

If Yes, specify if able:

☐ Pulmonary

☐ Renal

☐ Gastrointestinal

☐ Hepatobiliary

☐ Pancreatic

☐ Infection (include sepsis) -note source of infection(e.g. pneumoniaetc.)_______________________________________

☐ Non-infectious (e.g., systemic inflammatory response syndrome [SIRS])

☐ Hemorrhage that is neither cardiovascular bleeding or a stroke

☐ Non-CV procedure or surgery

☐Trauma -specify:____

☐Suicide – specify mode of death:____

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Did the subject have risk factors for suicide? [Y] ☐Yes [N] ☐No

If Yes, specify:____

If Yes, complete suicide eCRF (if applicable)

☐Non-prescription drug reaction or overdose

☐Prescription drug reaction or overdose

☐Neurological (non-cardiovascular)

☐Cancer (Malignancy)

(✓**only one if known**)

☐Disease under study * Only applicable/permitted for oncology studies

☐Other cancer

☐Previously known, specify: ____________________________________

☐Recurrent [Y] ☐Yes [N] ☐No ☐ [NK] Not Known

☐Disease progression [Y] ☐Yes [N] ☐No ☐ [NK] Not Known

☐Newly diagnosed, specify: ____________________________________

☐Other non-CV, specify:

____

SECONDARY CAUSE(s) OF DEATH

Cardiovascular Causes

Were there any secondary cause(s) of death?[Y] ☐Yes [N] ☐No

If Yes, (✓all that apply)

☐Myocardial Infarction

Complete MI/Unstable Angina eCRF.

☐Cardiac Arrhythmia

Complete Cardiac Arrhythmia eCRF.

☐Heart Failure

Complete Heart Failure eCRF.

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☐Stroke

Complete Cerebrovascular Events Stroke/TIA eCRF.

☐Cardiovascular Procedures (including cardiovascular surgery)
If Yes, complete Revascularization CRF

☐Cardiovascular Hemorrhage

☐Haemorrhage – specify organ: ____

☐Other Cardiovascular Causes – Specify:____

Non-cardiovascular Causes

Was secondary cause(s) of death Non-cardiovascular? [Y] ☐Yes [N] ☐No ☐ [NK] Not Known

If Yes, specify if able:

☐ Pulmonary

☐ Renal

☐ Gastrointestinal

☐ Hepatobiliary

☐ Pancreatic

☐ Infection (include sepsis) -note source of infection (e.g. pneumonia etc.)____

☐ Non-infectious (e.g., systemic inflammatory response syndrome [SIRS])
*may include anaphylaxis (e.g., peanut allergy)

☐ Hemorrhage that is neither cardiovascular bleeding or a stroke

☐ Non-CV procedure or surgery

☐Trauma -specify:____

☐Suicide – specify mode of death:____

Did the subject have risk factors for suicide? [Y] ☐Yes [N] ☐No

If Yes, specify:____
If Yes, complete suicide eCRF (if applicable)

☐Non-prescription drug reaction or overdose
*may include anaphylaxis

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☐Prescription drug reaction or overdose
*may include anaphylaxis

☐Neurological (non-cardiovascular)

☐Cancer (Malignancy)

(**✓only one if known**)

☐Disease under study * Only applicable/permitted for oncology studies

☐Other cancer

☐Previously known, specify: ____

☐Recurrent [Y] ☐Yes [N] ☐No ☐ [NK] Not Known

☐Disease progression [Y] ☐Yes [N] ☐No ☐ [NK] Not Known

☐Newly diagnosed, specify: ____

☐Sepsis -note source of sepsis (e.g. pneumonia, etc.)_____________________________________

☐Trauma – specify:____

☐Suicide – specify mode of death:____

Did the subject have risk factors for suicide? [Y] ☐Yes [N] ☐No ☐ [NK] Not Known

If Yes, specify:____

☐Other –specify: ____

MEDICAL/CLINICAL HISTORY

Was there a particular risk of death from clinical history (e.g., chronic disease such as underlying diabetes, renal failure, liver disease, etc.)? [Y] ☐Yes [N] ☐No ☐ [NK] Not Known

Ensure relevant clinical history is recorded on the **Medical Conditions form**.

If Yes and death is associated with SAE, complete ________________of SAE form.

If Yes and death is not associated with SAE, record details:

____
____
____

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Is there is any other information (test results, medical history, etc.) you think would help understand why this subject died?

[Y] ☐Yes [N] ☐No ☐ [NK] Not Known

If Yes and death is associated with SAE, complete ____________________of SAE form.
If Yes and death is not associated with SAE, record details:

____
____
____

Were there any new medications or changes in doses of chronic medications within the four weeks prior to death that may have contributed to death?

[Y] ☐Yes [N] ☐No ☐ [NK] Not Known

Ensure all medications up till the time of death are recorded on the **Concomitant Medication form**, including the new medications or changes in chronic medications. For studies where applicable, ensure the column, "Was medication stopped due to toxicity?" has been completed.

If Yes and death is associated with SAE, complete ___________________of SAE form.
If Yes and death is not associated with SAE, name drug and give reason:
____
____
____

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