GILEAD	POST MARKETING ADVERSE EVENT REPORT FORM (FOSTER CITY)	GF-21043B (2.0)

Local ID: **Gilead MCN:** 2015-0184943

Patient Information:

Initials: CT Date of Birth: 28- / 12 / 1955 (DD / MMM / YYYY)

Age Group: ☐ Child (< 18 yrs.) ☒ Adult (≥ 18 yrs. < 65 yrs.) ☐ Elderly (≥ 65 yrs.)

Race: ☒ Caucasian ☐ Hispanic ☐ Of African Descent ☐ Asian ☐ Other (specify) _____

Sex: ☒ Male ☐ Female

Age at onset of event: 59 (yrs.) Height: 175 ☐ in ☒ cm Weight: 75 ☐ lb. ☒ kg

Adverse Event (s) or other Safety Information: Adverse Event Description (provide diagnosis, if known)	**Start Date** (DD/MON/YYYY)	**Stop Date** (DD/MON/YYYY)	**Outcome** (A)Resolved (B)Resolved with sequelae (C)Resolving (D)Not resolved (E)Died due to event (F)Unknown
1. Lung Cancer		2015/10/31	A ☐ B ☐ C ☐ D ☐ E ☒ F ☐
2.			A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
3.			A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
4.			A ☐ B ☐ C ☐ D ☐ E ☐ F ☐
5.			A ☐ B ☐ C ☐ D ☐ E ☐ F ☐

Did the event(s) result in: ☒ Hospitalization ☐ Prolongation of hospitalization ☐ Significant disability

Was the event: ☐ Life threatening (immediate risk of death at time of event) ☐ Fatal (please provide autopsy report)

Date of death: ____/____/____

Summary of Event(s) / Other Relevant Information:

Please provide a short summary of the event(s) and include any treatment given, relevant medical history, risk factors, outcome, and the results of any supportive laboratory data or other investigations (append results separately, if necessary).

Patient started treatment 27-08-2015 and discontiniued treatment after taking 1 pill of Sovaldi,
His death reason was not related to drug he had Lung cancer though there are no additional details in regards of treatment of cancer he was smoker, though we dont have his
He had HCV3, his treatment regimen was 24 Weeks Sof+ Rib

If medical intervention was required to prevent the reported event becoming serious as defined above, please check here ☐ and provide reasons.

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Medication Details:

List all medications (including non-prescription and herbal preparations) the patient was receiving at the time of the event(s). Append separate sheet, if necessary.

Name	Dose	Route	Start Date (DD/MON/YYYY)	Stop Date (DD/MON/YYYY)	Indication	Lot/Batch No	Suspect[1]	Non-Suspect[2]
1. Sovaldi	400mg		27-08-2015	31-10-2015		SFMTD		
2. Ribavirin	200mg		27-08-2015	31-10-2015				
3.								
4.								
5.								
6.								
7.								
8.								

[1]Considered to be causally associated with the reported event(s) [2]Considered not to be causally associated with the reported event(s)

Action taken with Gilead Drug(s):

Due to the event, was the dosage of the Gilead drug(s):

☐ Continued unchanged ☒ Discontinued ☐ Reduced (new dosage ____) ☐ Unknown

If the dose was reduced or drug discontinued, did the symptoms:

☐ Resolve ☐ Improve ☐ Remain the same

If the Gilead drug was restarted, did the event reappear?

☐ No ☐ Yes (provide details): _____

Reporter Details:

Name: _____

Address: _____

_____

_____

_____

Telephone: _____

Fax: _____

Email: _____

☐ Doctor ☐ Nurse ☐ Pharmacist ☐ Consumer

☒ Other, please specify: _____

Preferred method of contact:

☐ Mail ☐ Fax ☐ Email ☐ Telephone

☐ Other, please specify: _____

Signature: _____ **Date:** _____ (DD/MON/YYYY)

Gilead Representative Details (if applicable):

Name: _____ Responsible Region/Territory: _____

Email: _____@gilead.com _____

Telephone:

Email or FAX Completed Form as soon possible to:

Email: Safety_FC@gilead.com

Fax: +1-650-522-5477

Or Report by:

Mail: Gilead Sciences,
Drug Safety and Public Health
333 Lakeside Drive.,
Foster City, CA 94404 USA

Telephone: +1-800-445-3235 (USA)

Please be aware that information provided to Gilead relating to you, may be used to comply with applicable laws and regulations. By providing us with information you are consenting to the control and processing of this personal or sensitive data by Gilead in accordance with applicable data protection laws and the Gilead privacy policy, available to you either on www.gilead.com/privacy or upon request.