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

Local ID: **Gilead MCN:** 2015-0180586

Patient Information:

Initials: BS Date of Birth: 27/Jan/1967 (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: 48 (yrs.) Height: 190 ☐ in ☒ cm Weight: 130 ☐ 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. Cardial problems	03-09-2015	Ongoing	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 discontinued traement on 14 th day from the start his Fibrosis level is F3, Genotype I he wasn't previously treated for chronic Hepatitis C. He had compinated treatment regimen Sof+Inf+Riba 12 weeks.

Reason for that was Cardiac problem, particularly Arrhythmia, effect of anti-arrhythmic drug wasn't usefull and doctors performed defibrillation by applying an electric shock, finally patient was hospitalized for 1 day for monitoring, he is still undergoing treatment for cardiac problems, though he diccnotinued treatment of Chronic Hepatitis C.

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

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. Sofosbuvir	400mg	PO	20/08/2015	03/09/15	Chronic Hep C	PWMKD		
2. Interferon	180mg	INJ	20/08/2015	03/09/15	Chronic Hep C	1906-5		
3. Ribavirin	200mg	PO	20/08/2015	03/09/15	Chronic Hep C	FGE2561		
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: Kate Mshvidobadze

Address: Infectious Diseases AIDS and Clinical Immunology Research Center - 16 Kazbegi av. Tbilisi. Georgia

☒ Doctor ☐ Nurse ☐ Pharmacist ☐ Consumer

☐ Other, please specify: _____

Preferred method of contact:

Telephone: +995 99 30 43 90

☐ Mail ☐ Fax ☒ Email ☐ Telephone

Fax:

Email: katemshvidobadze@yahoo.com

☐ Other, please specify: _____

Signature: _____ **Date:** 19/11/2015 (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.