Form Approved
OMB No. 0920-0773
Expiration Date: xx/xx/xxxx

National Surveillance for Severe Adverse Events (NSSAE) Data Collection Form

Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; Attn: PRA (0920-0773)

Information contained on this form which would permit identification of any individual has been collected with a guarantee that it will be held in strict confidence, will be used for surveillance purposes, and will not be disclosed or released without the consent of the individual in accordance with Section 308(d) of the Public Health Service Act (42 U.S.C. 242m).

Part 3. To be completed by the physician. If this information is unavailable, it will be provided by the nurse who will access the information from the clinics and other facilities where the patient has visited previously.

MONITORING DURING THERAPY

Monitoring strategy:
Clinical observation only _____ Laboratory testing only _____ Combination _____
Clinical monitoring:
Evaluated by a licensed medical professional Yes ____No _____
Frequency of scheduled clinic appointment:
Weekly _____
Every two weeks _____
Monthly _____
Frequency of actual evaluation:
Weekly _____
Every two weeks _____
Monthly _____
Frequency of laboratory testing:
None _____
Baseline only _____
Weekly _____
Every two weeks _____
Monthly _____
Supervision of treatment:
Self supervised _____
Directly observed therapy (DOT)/supervised _____
By a trained medical professional? _____
Combination _____

HEPATITIS LIVER INJURY DIAGNOSIS

Liver biopsy: Yes_____ No______
Date: ___________ Result:____

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Date of blood test	AST U/L	ALT U/L	Total bilirubin mg/dL	Prothrombin (PT) (seconds)	International Normalized Ratio (INR) test results
	Normal range (-)	Normal range (-)	Normal range (-)	Normal range (-)	