

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 (P920-0773)

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: _____

