**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:**

Evaluatedby 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** **( - )** |  |
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