

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

Public reporting burden of this collection of information is estimated to average 4 hours 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 2. To be completed by the nurse

***The information requires input from the medical clerk by searching the records of the admitting hospital and other hospitals where the patient might have been evaluated in the past.**

Able to speak English? Yes _____ No _____

If No, what is the primary language? _____

Preferred language (please answer even if patient speaks English): _____

Language in which follow-up and monitoring visits were conducted _____

Adverse event leading to hospitalization or death associated with LTBI treatment:

Anaphylaxis _____ Metabolic acidosis _____ Other, specify _____

Liver injury _____ Severe dermatitis _____

***Admission to hospital:** Yes _____ No _____ Unknown _____

If Yes: Date: _____ Date discharged: _____

Reason: _____

Severity of adverse event outcome: (Check all that apply)

Still Sick _____ Full recovery _____ Pending _____

Recovery with residual effects _____

Evaluated for possible liver transplant but did not have transplant _____

Liver transplant _____ Unknown _____

Death: Yes _____ No _____ Date died: _____

LTBI DIAGNOSIS AND TREATMENT

Reason(s) for tuberculin skin test (TST)/Interferon Gamma Release Assay (IGRA) for LTBI

Check all that apply:

Contact to person with TB disease _____ Recently (past 2 years)? _____

Risk factors for TB

HIV infection: _____ HIV test date: _____

Diabetes _____ Renal failure _____ Organ transplant _____

Cancer or leukemia _____ Abnormal chest radiograph _____ Chronic steroid administration _____

Immunosuppressive therapy other than chronic steroid administration _____, Specify _____

Excessive alcohol use within the past year _____

Illicit drug use within the past year _____

Unknown _____

Congregational setting: Jail ___ Prison ___ Homeless shelter ___
 Long-term care facility ___ Other, specify _____

Occupational risk of exposure _____
 health care worker _____, correctional facility worker _____, migrant/seasonal worker _____

Routine/administrative work requirement _____

Foreign born _____

School admission requirement _____

Unknown _____

TST: Date TST placed: _____ Date TST read: _____
 TST result: _____mm Positive ___ Negative ___
 Converter (documented negative baseline TST)? Yes _____ No _____

If IGRA performed, which test?
 QuantiFERON TB Gold test (QFT-G) _____
 QuantiFERON-TB Gold-in-tube test (QFT-GIT) _____
 T-Spot TB test _____

Date of IGRA performed: _____

Test result*:
 Result: Positive _____ Negative _____ Indeterminate _____
 Quantitative results (list all available values): _____
 Converter (documented negative baseline IGRA)? (Yes/No _____

*Refer to the following guideline to interpret results: CDC. Updated Guidelines for Using Interferon Gamma Release Assays to Detect Mycobacterium tuberculosis Infection --- United States, 2010, MMWR, Recommendations and Reports, June 25, 2010 / 59(RR05);1-25
http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5905a1.htm?s_cid=rr5905a1_e

LTBI TREATMENT REGIMEN(S): Please specify the medication(s) taken by the patient.

Medication	Daily or twice weekly	Initial regimen dosage (mg)	Second regimen dosage (mg)
INH			
RIF			
PZA			

Initial TLTBI start date: _____ **End date:** _____
Second TLTBI start date: _____ **End date:** _____
Medication lot number: _____
Medication manufacturer: _____
Patient's weight: _____ lbs