Diabetes Prevention Program

SERIOUS ADVERSE EVENT REPORT

The initial Serious Adverse Event Report (E02) and the corresponding Adverse Event Report (E01) should be FAXED to the Coordinating Center IMMEDIATELY at (301) 881-8752.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number [ ][ ]

2. Participant Identification Number (Complete a **OR** b)

   a. If before randomization, Screening number [S][ ][ ][ ][ ][ ]

   b. If after randomization, Participant number [ ][ ][ ][ ][ ][ ]

3. Participant's initials [ ][ ][ ][ ] (first last)

4. Participant's date of birth [ ][ ] / [ ][ ] / [ ][ ] (month / day / year)

B. Report Identification

1. Date of report [ ][ ] / [ ][ ] / [ ][ ] (month / day / year)

2. Date of onset of serious adverse event [ ][ ] / [ ][ ] / [ ][ ] (month / day / year)

3. Type of report
   - [1] Initial
   - [2] Follow-up

4. Type of visit
   - [1] In Clinic / Home Visit
   - [2] Unattended

C. Instructions for Form E02 Completion

This form is to be completed if the participant has had a Serious Adverse Event (SAE) recorded on the Adverse Event Report (E01).

Initials of person reviewing completed form [ ][ ][ ][ ] (first last) Form entered in computer? [ ]

Signature of P.I. _____ Date: _____

Part II / ADVERSE EVENT DESCRIPTION

D. General Classification

1. Event Number (from Form E01; column 1) [ ][ ]

   a. Classification term from Form E01: [ ]

2. Did the adverse experience result in: *(check all that apply)*

   a. Required or prolonged hospitalization . . . . . [1]

   b. Permanent or severe disability . . . . . [1]

   c. Death . . . . . [1]

If Death checked, CONTINUE. If Death not checked, SKIP to Question 3.

   i. Date of death [ ][ ]/[ ][ ]/[ ][ ] (month day year)

   ii. Probable cause of death

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3. Was the adverse experience: *(check all that apply)*

   a. Congenital anomaly . . . . . [1]

   b. Cancer . . . . . [1]

   c. Life-threatening . . . . . [1]

   d. Due to an overdose . . . . . [1]

   e. Treatment to prevent a serious event . . . . . [1]

E. Event Information

Complete question E1 if assigned the pharmacological treatment.
Skip to question E2 for troglitazone and lifestyle participants.

	YES	NO
1. Was the participant on coded metformin at the time of the adverse experience?	1	2

If YES, CONTINUE.
If NO, SKIP to Question E.2.

	YES	NO
a. Was the coded metformin interrupted or stopped as a result of the event?	1	2

If YES, CONTINUE.
If NO, SKIP to Question E.2.

	YES	NO
i. Was the adverse experience reversible when the coded metformin was withdrawn?	1	2
ii. Was the coded metformin re-started?	1	2

If YES, CONTINUE.
If NO, SKIP to Question E.2.

a) How long was the participant off coded metformin? ____

1 days
2 weeks
3 months

	YES	NO
b) Did the symptoms recur?	1	2

2. Describe the adverse event in detail: (i.e. issues leading up to event, procedures or test completed, date stopped intervention if applicable, etc.)

3. Duration of adverse experience

<1day 1
1day - 1week 2
>1week 3

4. Treatment administered for the adverse event:

check all that apply

a. Out-patient - changes in medications . . . . . [1]

b. Out-patient - procedure . . . . . [1]

c. Hospitalization . . . . . [1]

i. Total length of stay [ ][ ] days

d. Skilled nursing facility . . . . . [1]

i. Total length of stay [ ][ ] days

e. Out-patient rehabilitation . . . . . [1]

i. Total days [ ][ ] days

f. In-patient rehabilitation . . . . . [1]

i. Total days [ ][ ] days

5. During the adverse event was insulin therapy used? YES [1] NO [2]

If YES,
a. Is insulin therapy continuing? YES [1] NO [2]

6. Outcome

recovered, no residual effect [1]
residual effect, no treatment [2]
residual effect, being treated [3]
persistent, no treatment [4]
persistent, being treated [5]
death [6]

F. Conclusion

1. Additional comments: (i.e. note if former troglitazone participant, whether or not they have experienced this problem before, any follow-up plans, etc.)

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