

Participant ID

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Nickname

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Date of visit

month		day		year			

Diabetes Prevention Program Outcomes Study
F03 INTERIM VISIT INVENTORY

This form is interviewer-administered at follow-up visits year 13 and on for all participants when the Midyear Visit Inventory (Form F01), and Annual Visit Inventory (Form F02) or Annual Non-Clinic Visit Inventory (Form F06) are not completed. Form F03 is used to document the following: SAEs and all CVD events, pregnancy, metformin management, arm blood pressure for hypertension management, or collection of CBL specimens for visits that are not midyear or annual.

PART I / IDENTIFICATION

A. Participant Identification

1. Clinic number
2. Participant number
3. Nickname
4. Date of randomization
month day year
5. Sex Male ¹ Female ²
6. Date of visit
month day year
JIVSTDT replaced with DAYSRAND
7. Outcome visit
VISIT
8. Visit location *JIVISLOC* Clinic ¹ Home ² Phone ³
Non-clinic medical facility ⁴

B. Reason for Interim Visit

Complete the corresponding sections of this form for the reason(s) marked below. Part II, section D must be completed regardless of reason(s) for interim visit.

MARK WITH AN 'X' ALL THAT APPLY

1. Study metformin management..... ¹ *JIMEDMG*
2. Hypertension management..... ¹ *JIHYPMG*
3. Pregnancy management..... ¹ *JIPRGMG*
4. Serious adverse event and CVD management..... ¹ *JISAEMG*
5. Collection of specimen for CBL (e.g. OGTT)..... *JISPEC* ¹ → Complete CBL specimen transmittal form.
6. Repeat collection of outcome found to be deficient..... ¹ *JIOUT*
7. Diabetes diagnosed by PCP..... ¹ *JIDBMG*
8. Other..... ¹ *JIOTH*

a. IF OTHER, specify: *JIOTHERSP*

Identification code of person reviewing completed form Form entered in computer?

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C. Blood Pressure

1. Seated Arm Blood Pressure

a. Blood Pressure Reading 1
(after sitting 5 minutes)

JISBP1 **Systolic** **Diastolic** JIDBP1

mmHg

b. Blood Pressure Reading 2
(after waiting 30 seconds)

JISBP2 **Systolic** **Diastolic** JIDBP2

mmHg

For participants **without** diabetes follow the JNCP guidelines and for participants **with** diabetes follow the ADA guidelines (referred to in Chapter 6 of the Manual of Operations) to determine if a blood pressure letter needs to be sent to the participant and their PCP.

PART II / HISTORY

This section must be completed for all participants.

D. Events and Procedures

1. Since the last contact or visit, has the participant experienced any of the following?

MARK WITH AN 'X' ALL THAT APPLY

a. Any acute life threatening event?.....

b. Permanent or severe disability?.....

c. Required or prolonged hospitalization?.....

If marked, complete E08 for each event.

If 'Required or prolonged hospitalization' is selected, mark any events that caused or occurred during the hospitalization.

1. Infection (including nosocomial)?.....

2. Fracture?.....

3. Joint replacement?.....

d. Pregnancy resulting in congenital abnormality or birth defect?.....

e. Required intervention or treatment to prevent serious adverse event?.....

f. Possible CVD event?.....

g. Renal failure?.....

h. Kidney transplant?.....

If marked, complete E08 for each event.

i. Eye procedure?..... → Complete E09

j. Gastric reduction surgery?..... → Complete E11

k. Cancer event?..... → Complete E12

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If any of options a. – h. are marked, complete a separate E08 for each event. For multiple CVD events that may occur during the same hospitalization, complete an E08 for the first CVD diagnosis and report subsequent events (from the same hospitalization) on the same E08 form. If option c.1 is marked complete the E14 form. If option c.2 is marked complete the E15 form. If option c.3 is marked complete the E16 form.

If option i is marked, complete an E09 form. If option j is marked, complete an E11 form. If option k is marked, complete an E12.

PART III/ MLS PARTICIPANT SECTION

Complete sections E and F for all MLS participants.

E. Metformin Status

1. Has the participant taken any STUDY METFORMIN since the last visit? Yes 1 No 2 JITAKMT

IF YES, complete the F08 Metformin Safety & Adherence Form for this participant.

F. Dispensing of Metformin

Complete the Metformin Safety and Adherence Checklist for all participants receiving study metformin before metformin is dispensed.

1. How many months of metformin was dispensed (0, 3, 6)?..... JIDISP

METFORMIN LABELS:

Remove label from metformin before dispensing and affix here.

Remove label from metformin before dispensing and affix here.