

Participant ID

Nickname

Outcome visit

Diabetes Prevention Program Outcomes Study

F01 MIDYEAR VISIT INVENTORY

This form is interviewer-administered for all participants at the midyear visit. Form F01 records adverse events and procedures, and study metformin status at phone visits year 13 and on.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number

2. Participant number

3. Nickname

4. Date of randomization

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
month	day	year			

5. Sex

Male ¹ Female ²

6. Outcome visit

VISIT

7. Date of visit

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
month	day	year			

QVSTDT
replaced with
DAYSRAND

8. Visit Location

MARK WITH AN 'X' ONLY ONE QPVISLOC

Clinic ¹

Phone ²

Home ³

Non-clinic medical facility ⁴

Identification code of person reviewing completed form

Form entered in computer?

Participant ID

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Nickname

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Outcome visit

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Part II / EVENTS

B. Events and Procedures

- Query the participant for any events or procedures experienced since the last contact or visit.
- At the visit during which a participant is queried for eye, gastric reduction, renal failure and kidney transplant procedures for the first time, ask the participant if s/he underwent any of these procedures since randomization in DPP.
- At subsequent visits, query for procedures done since the last contact or visit.
- Eye procedures to be queried are: laser/Intravitreal treatment for diabetic retinopathy or diabetic macular edema, or other retinal procedures/surgeries.
- Gastric reduction surgeries include reversals of prior surgeries.

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?..... | <input type="checkbox"/> | } If marked, complete E08 for each event. | |
| b. Permanent or severe disability?..... | <input type="checkbox"/> | | |
| c. Required or prolonged hospitalization?..... | <input type="checkbox"/> | | |
| <p>If 'Required or prolonged hospitalization' is selected, mark any events that caused or occurred during the hospitalization.</p> | | | |
| 1. Infection (including nosocomial)?..... | <input type="checkbox"/> | } If marked, complete E08 for each event. | |
| 2. Fracture?..... | <input type="checkbox"/> | | |
| d. Pregnancy resulting in congenital abnormality or birth defect?..... | <input type="checkbox"/> | | |
| e. Required intervention or treatment to prevent serious adverse event?..... | <input type="checkbox"/> | | |
| f. Possible CVD event?..... | <input type="checkbox"/> | | |
| g. Renal failure?..... | <input type="checkbox"/> | | |
| h. Kidney transplant?..... | <input type="checkbox"/> | } Complete E16 | |
| i. Joint replacement?..... | <input type="checkbox"/> | | |
| j. Eye procedure?..... | <input type="checkbox"/> | | } Complete E09 |
| k. Gastric reduction surgery?..... | <input type="checkbox"/> | | |
| l. Cancer event?..... | <input type="checkbox"/> | | Complete E11 |
| | | Complete E12 | |

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 i is marked, complete an E16 form. If option j is marked, complete an E09 form. If option k is marked, complete an E11 form. If option l is marked, complete an E12 form.

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Part III / MLS PARTICIPANT SECTION

Complete sections C and D for all MLS participants.

C. Metformin Status

1. Has the participant taken any STUDY METFORMIN since the last visit?

Yes

No

QMTAKM

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

D. 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)?

QMDISP

METFORMIN LABELS:

Remove label from metformin before dispensing and affix here.

Remove label from metformin before dispensing and affix here.

IF metformin is NOT dispensed for reasons other than a previously reported permanent condition, a Metformin Discontinuation Form (Form F07) must be completed.