Diabetes Prevention Program Outcomes Study

F03 INTERIM VISIT INVENTORY

This form is completed at follow-up visits for all participants when the Mid-year Visit Inventory (Form F01) and Annual Visit Inventory (Form F02) 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 mid-year or annual.

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 — INT — VISIT
8. Visit Location — Clinic [1] Home [2] Phone [3] — JIVISLOC
   Non-clinic medical facility [4]

B. Reason for Interim Visit

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

CHECK 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)..... [1] JISPEC
   → 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

Identification code of person reviewing completed form [ ] [ ] [ ] FORMIN

Form entered in computer? [ ]

C. Blood Pressure

1. Seated Arm Blood Pressure

		Systolic	Diastolic	
a. Blood Pressure Reading 1 (after sitting 5 minutes)	JISBP1	___ /	___	mmHg JIDBP1
b. Blood Pressure Reading 2 (after waiting 30 seconds)	JISBP2	___ /	___	mmHg JIDBP2

Inform participant and PCP via letter if
- **The participant is NON-DIABETIC and if systolic BP ≥ 140 or diastolic BP ≥ 90 on the mean of 1a and 1b.**

OR
- **The participant is DIABETIC and if systolic BP ≥ 130 or diastolic BP ≥ 80 on the mean of 1a and 1b.**

PART II / HISTORY

This section must be completed for all participants.

D. Events

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

CHECK ALL THAT APPLY

a. Any acute life threatening event?	1	JIACTT
b. Permanent or severe disability?	1	JIDISA
c. Required or prolonged hospitalization?	1	JIHOSP
d. Overdose of any medication? JIOVDO	1	If checked, complete E08 for each event.
e. Pregnancy resulting in congenital abnormality or birth defect?	1	JICONG
f. Required intervention or treatment to prevent serious adverse event?	1	JITSAE
g. Possible CVD event?	1	JIPCVD

If any of questions a. – g. are checked, complete a separate E08 for each event. For multiple CVD events that may occur during the same hospitalization: complete an E08 form for the first CVD diagnosis and report subsequent events (from the same hospitalization) on the same E08 form.

Part III/ MLS PARTICIPANT SECTION

Complete question E1 for all MLS participants. Complete the rest of section E if participant has taken study metformin since last visit. IF NOT MLS, STOP. FORM IS COMPLETE.

E. Metformin Status

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

If NO, PROCEED to Section G.
If YES, CONTINUE with Section E.

a. Daily dose of METFORMIN per protocol — 850 mg [1] 1700mg [2] JIDOSE

b. What is your best estimate of the participant's level of exposure to metformin per protocol? JICOMPM
- <80% [1]
- ≥80% [2]
- did not return pill container [3]

2. Since the last visit, has the participant had any problems taking his/her metformin pills as prescribed? Yes [1] No [2] JIPROB

IF YES, what are the main problems in taking pills as prescribed?

CHECK ALL THAT APPLY

a. Forgets to take pills in general..... [1] JIFORG

b. Forgets to take evening dose..... [1] JIEVEN

c. Inconvenient to take pills as prescribed..... [1] JIINCON

d. GI reaction to pills..... [1] JIGIRCT

e. Disruption of regular routine..... [1] JIDISRP

f. Hospitalization/new illness/ medical reason..... [1] JIMEDC

g. Lack of motivation..... [1] JIMOTV

h. Lost/misplaced pills..... [1] JILOST

i. Other (specify):_____ JIOTHSP _____ [1] JIOTHE

3. **If YES** to question 2, what plan or strategy will the participant use to deal with this problem?

CHECK ONE MAIN STRATEGY

Will continue current plan……..	1	JISTRAT
New time routine……..……	2	
New strategy/routine..……	3	
New reminder device……	4	
Change type and/or frequency of DPP-OS staff communication…	5	
Does NOT want to deal with the problem…..……	6	
Other (specify): JISPEC2	7	

If option 1 (will continue current plan) is selected,

CHECK ALL THAT APPLY

i. time routine (e.g. time of day, meal time)	1	JITIME
ii. strategy routine (e.g. takes with other pills; medication in a convenient place)	1	JISTRRO
iii. reminder device (e.g. pill box, calendar)	1	JIRMND
iv. other	1	JIOTHR

F. Pregnancy Questions

Complete this question for all MLS women who are actively taking study metformin.

1. Does the participant have reproductive potential? Yes [1] No [2] JIPREM

If YES, review menstrual history, confirm use and form of contraception and CONTINUE.

a. Date of last menstrual period (month day year) JIDOLM

i. Menstrual period more than one week late? Yes [1] No [2] JI1WK

If 1.a.i. is YES, a pregnancy test must be performed.

If NO, skip to question 1.b.

a.) Date of pregnancy test (month day year) JIDOPT

b.) Result of pregnancy test Positive [1] Negative [2] JIPREG

IF POSITIVE, study metformin must be discontinued and a Pregnancy Confirmation Report (Form E04) must be completed. THIS FORM IS COMPLETE.

b. Does the participant plan on becoming pregnant within the next 6 months? Yes [1] No [2] JIPLAN

IF YES, Metformin must be discontinued.

G. Dispensing of Metformin

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

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

METFORMIN LABEL | Remove label from metformin before dispensing and affix here.

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