Diabetes Prevention Program - Outcomes Study

F01 MID-YEAR VISIT INVENTORY

This form is completed at in-clinic mid-year visits (01M, 02M, 03M . . .).

Form F01 records the following: weight, blood pressure, pregnancy information, serious adverse events, study metformin and concomitant medications.

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. Outcome visit — 01M 02M 03M 04M 05M 06M 07M 08M 09M 10M 11M — VISIT
7. Date of visit — month day year — QVSTDT replaced with DAYSRAND

Identification code of person reviewing completed form — FORMIN

Form entered in computer?

Part II / PHYSICAL AND HISTORY

B. Blood Pressure

1. Seated Arm Blood Pressure

		Systolic	Diastolic	
a.	Blood Pressure Reading 1 (after sitting 5 minutes)	QPSBP1 ___	/ ___ mmHg	QPDBP1
b.	Blood Pressure Reading 2 (after waiting 30 seconds)	QPSBP2 ___	/ ___ mmHg	QPDBP2

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.**

C. Anthropometrics

1. Weight

a.	First measurement ___ . ___ kg	QPWGHT1
b.	Second measurement ___ . ___ kg	QPWGHT2

Record 1c. only if first 2 measurements are not within 0.2 kg (200gm).

c.	Third measurement ___ . ___ kg	QPWGHT3

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	QPACTT
b.	Permanent or severe disability?	1	QPDISA
c.	Required or prolonged hospitalization?	1	QPHOSP
d.	Overdose of any medication? QPOVDO	1	If checked, complete E08 for each event.
e.	Pregnancy resulting in congenital abnormality or birth defect?	1	QPCONG
f.	Required intervention or treatment to prevent serious adverse event?	1	QPTSAE
g.	Possible CVD event?	1	QPPCVD

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 for the first CVD diagnosis and report subsequent events (from the same hospitalization) on the same E08 form.

Complete this section for all participants.

E. Concomitant Medications

1. Has the participant taken any **PRESCRIPTION** medications within the past 2 weeks (excluding study metformin)? Yes [1] No [2] QMRXDQ

   If YES, list below:

	Medicine Description		Route
a.		QMRXDAM	
b.		QMRXDBM	
c.		QMRXDCM	
d.		QMRXDDM	
e.		QMRXDEM	
f.		QMRXDFM	
g.		QMRXDGM	
h.		QMRXDHM	
i.		QMRXDIM	
j.		QMRXDJM	

Part III / MLS PARTICIPANT SECTION

Complete question F1 for all MLS participants. Complete the rest of section F if participant has taken study metformin since last visit. IF NOT MLS, STOP. FORM IS COMPLETE.

F. Metformin Status

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

IF NO, PROCEED to Section H.
IF YES, CONTINUE with Section F.

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

b. What is your best estimate of the participant's level of exposure to metformin per protocol? QMCOMPM
<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] QMPROB

IF YES, what are the main problems in taking pills as prescribed?
CHECK ALL THAT APPLY

a. Forgets to take pills in general ..... [1] QMFORG
b. Forgets to take evening dose ..... [1] QMEVEN
c. Inconvenient to take pills as prescribed ..... [1] QMINCON
d. GI reaction to pills ..... [1] QMGIRCT
e. Disruption of regular routine ..... [1] QMDISRP
f. Hospitalization/new illness/ medical reason..... [1] QMMEDC
g. Lack of motivation ..... [1] QMMOTV
h. Lost/misplaced pills ..... [1] QMLOST
i. Other (specify): _____ [1] QMSPEC

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	QMSTRAT
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): QMSTRSPEC	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	QMTIME
ii. strategy routine (e.g. takes with other pills; medication in a convenient place)	1	QMSTRRO
iii. reminder device (e.g. pill box, calendar)	1	QMRMND
iv. other	1	QMOTHR

G. 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] QPPREM

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

a. Date of last menstrual period [ ][ ][ ] QPDOLM (month day year)

i. Menstrual period more than one week late? Yes [1] No [2] QP1WK

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) QPDOPT

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

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] QPLAN

IF YES, study metformin must be discontinued.

H. 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)? ..... [ ] QMDISP

METFORMIN LABEL

Remove label from metformin before dispensing and affix here.

METFORMIN LABEL

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.