

Participant ID

Nickname

Outcome visit

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, serious adverse events, study metformin status and concomitant medications.

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

Identification code of person reviewing completed form

QPF0RMIN

Form entered in computer?

Participant ID

--	--	--	--	--	--	--	--

Nickname

--	--	--	--	--	--	--	--

Outcome visit

--	--	--

Part II / PHYSICAL AND HISTORY

B. Blood Pressure

1. Seated Arm Blood Pressure

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

Systolic **Diastolic** **QPDBP1**

QPSBP1

--	--	--

 /

--	--	--

 mmHg

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

QPDBP2

QPSBP2

--	--	--

 /

--	--	--

 mmHg

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

For C.1 – record Measure 3 only if first 2 measurements are not within 0.2 Kilograms (200g).

1. Weight

<p>Measure 1</p> <table border="1"> <tr> <td></td><td></td><td></td> </tr> </table> <p>QPWGHT1</p>				<p>Measure 2</p> <table border="1"> <tr> <td></td><td></td><td></td> </tr> </table> <p>QPWGHT2</p>				<p>Measure 3</p> <table border="1"> <tr> <td></td><td></td><td></td> </tr> </table> <p>QPWGHT3</p>			

D. 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?
CHECK ALL THAT APPLY

a. Any acute life threatening event?.....	<input type="checkbox"/>	{ If checked, complete E08 for each event.
b. Permanent or severe disability?.....	<input type="checkbox"/>	
c. Required or prolonged hospitalization?.....	<input type="checkbox"/>	
d. Overdose of any medication?.....	<input type="checkbox"/>	
e. Pregnancy resulting in congenital abnormality or birth defect?.....	<input type="checkbox"/>	
f. Required intervention or treatment to prevent serious adverse event?....	<input type="checkbox"/>	
g. Possible CVD event?	<input type="checkbox"/>	
h. Renal failure?.....	<input type="checkbox"/>	
i. Kidney transplant?.....	<input type="checkbox"/>	

Participant ID

Nickname

Outcome visit

- j. Eye procedure?..... → Complete E09
- k. Gastric reduction surgery?..... → Complete E11

If any of options a. – i. 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.

If option j is checked, complete an E09 form. If option k is checked, complete an E11 form.

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 No QMTAKM

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

F. 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.

Participant ID
[][][][][][][][]

Nickname
[][][][][][][][]

Outcome visit
[][][][]

Part IV / CONCOMITANT MEDICATIONS

Complete this section for all participants.

G. Concomitant Medications

- Has the participant taken any **PRESCRIPTION** medications within the past 2 weeks (excluding study metformin)?

QMRXDQ Yes [1] No [2]

If YES,

- Total number of medications taken (including any medications listed on supplemental sheets)

[][] QMTOTMEDS

- List medications below: QMDRUG1-30

	Medicine Description	Route
1.	[]	[]
2.	[]	[]
3.	[]	[]
4.	[]	[]
5.	[]	[]
6.	[]	[]
7.	[]	[]
8.	[]	[]
9.	[]	[]
10.	[]	[]
11.	[]	[]
12.	[]	[]
13.	[]	[]
14.	[]	[]
15.	[]	[]

Specify additional medications by appending the CONMED supplemental sheet to this form as needed.