F	Participant ID							

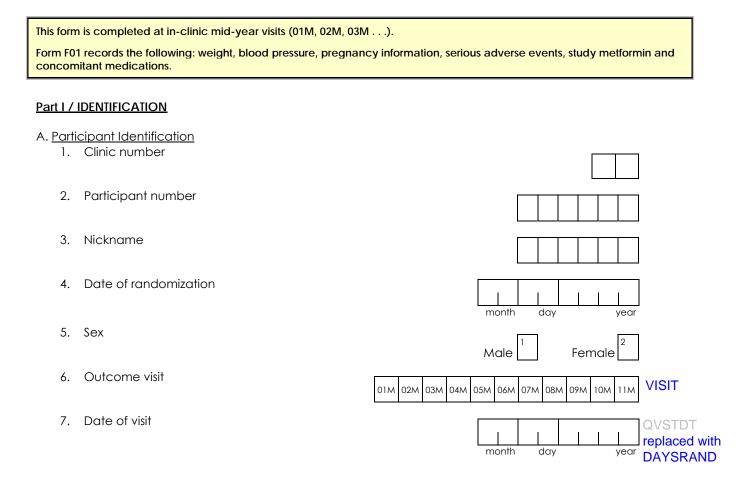


Outcome visit										
01M	02M	03M	04M	05M	06M	07M	08M	09M	10M	11M

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Diabetes Prevention Program - Outcomes Study

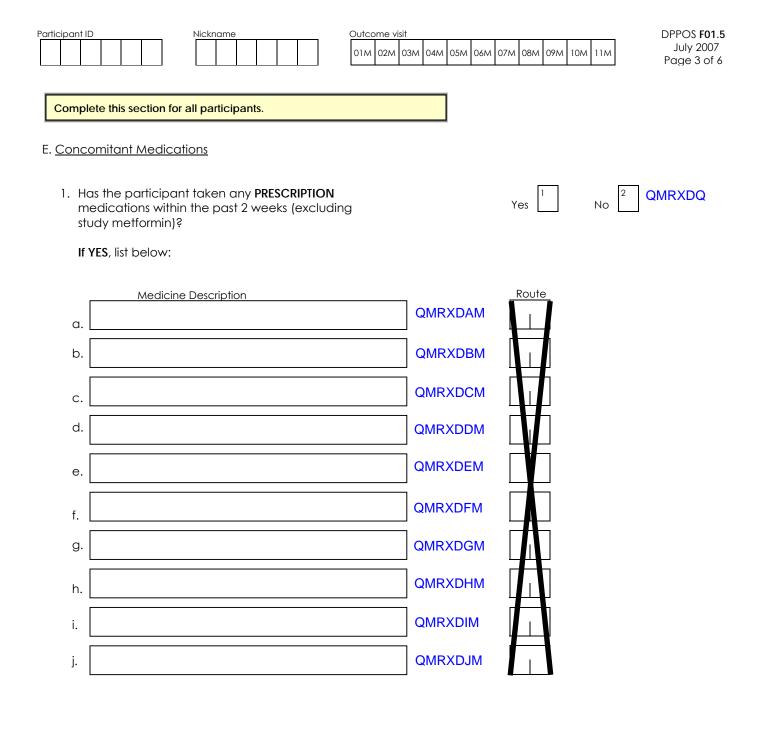
F01 MID-YEAR VISIT INVENTORY

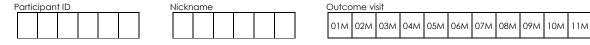


Identification code of person reviewing completed form			Form entered in computer?
	FORMIN	J	

irticipant ID	Nickname	Outcome visit	и обм отм овм орм 10м 11м	DPPOS F01.5 July 2007 Page 2 of 6
Part II / PHYSICAL				1 0 0 0 1 0 1 0
B. <u>Blood Pressure</u>				
	Arm Blood Pressure		Systolic Diastolic	
	d Pressure Reading 1 r sitting 5 minutes)	QPSBP1		QPDBP1
	d Pressure Reading 2 r waiting 30 seconds)	QPSBP2		QPDBP2
The participa	nt and PCP via letter if nt is NON-DIABETIC and if systolic BP nt is DIABETIC and if systolic BP <u>></u> 130	OR		
C. Anthropometri	ics			
1. Weight				
a. First r	neasurement			kg QPWGHT1
b. Secc	and measurement			kg QPWGHT2
Record 1c. only it	f first 2 measurements are not within 0	.2 kg (200gm).		
c. Third	measurement			
D. <u>Events</u>				
1. Since the	e last contact or visit, has the par	ticipant experiencec	any of the following? CHECK ALL THAT APPLY	
a.	Any acute life threatening eve	nt?	······ 1 7 0	QPACTT
b.	Permanent or severe disability?			QPDISA
C.	Required or prolonged hospita	lization?	<u> </u>	QPHOSP
d.	Overdose of any medication?.		QPOVDO 1	If checked, complete ►E08 for each event.
e.	Pregnancy resulting in congeni	tal abnormality or bir	th defect?	QPCONG
f.	Required intervention or treatm	nent to prevent seriou	us adverse event? 1	QPTSAE
g.	Possible CVD event?			QPPCVD
If any of question	s a. – g. are checked, complete a se	parate E08 for each eve	ent. For multiple CVD events t	hat

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.





QMTAKM

QMDOSE

QMCOMPM

QMPROB

No 2

1700 mg

<80%

≥80%

No

did not return pill container

Yes

850 mg

Yes

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. <u>Metformin Status</u>

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

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

- a. Daily dose of METFORMIN per protocol
- b. What is your best estimate of the participant's level of exposure to metformin per protocol?

2.	Since the last visit, has the participant had any problems taking his/her

metformin pills as prescribed?

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

	CHECK ALL THAT A	PPLY	
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

Participant ID	If YES to Question 2, what plan or strat		обм 07м 08м 09м 10м 11м t use to deal with this problem?	DPPOS F01.5 July 2007 Page 5 of 6
		CHECK ONE	E MAIN STRATEGY	
	Will continue current plan		1 QMSTRAT	
	New time routine		2	
	New strategy/routine		3	
	New reminder device			
	Change type and/or frequency of	DPP-OS staff commun	ication ⁵	
	Does NOT want to deal with the pr	oblem	6	
	Other (specify):	MSTRSPEC	7	
	If option 1 (will continue curren	t plan) is selected,		
		CHECK ALL THA	T APPLY	
	i. time routine (e.g. time of	day, meal time)		
	ii. strategy routine (e.g. tak medication in a conveni			
	iii. reminder device (e.g. pil	box, calendar)		
	iv. other		¹ QMOTHR	

G. Pregnancy Questions

iv. other

Complete this question for all MLS women who are actively taking study metform	min.]
1. Does the participant have reproductive potential?	Yes No 2	QPPREM
If YES, review menstrual history, confirm use and form of contraception and	CONTINUE.]
a. Date of last menstrual period	month day year	QPDOLM
i. Menstrual period more than one week late?	Yes No	QP1WK

Participant ID Nickname Outcome visit 01M 02M 03M 04M 05M 06M 07M 08M 09M 11M	DPPOS F01.5 July 2007 Page 6 of 6
IF 1.a.i is YES, a pregnancy test must be performed.	
IF NO, skip to question 1. b.	
a.) Date of pregnancy test	QPDOPT
b.) Result of pregnancy test Positive Negative	ve 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	² QPLAN
IF YES, study metformin must be discontinued.	
H. <u>Dispensing of Metformin</u>	
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.