

Diabetes Prevention Program Outcomes Study

# F01 MID-YEAR VISIT INVENTORY

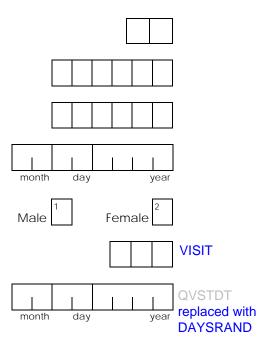
This form is completed at in-clinic mid-year visits (01M, 02M, 03M . . .).

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
- 5. Sex
- 6. Outcome visit
- 7. Date of visit



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

ticipant ID		Nickname C	Dutcome visit			DPPOS <b>F01.6</b> July 2013 Page 2 of 4
Par	t II / PHY	ICAL AND HISTORY				
В. <u>I</u>	Blood Pre	ssure				
	1. Sea	ed Arm Blood Pressure		Systolic Dia	astol	ic
	а.	Blood Pressure Reading 1 (after sitting 5 minutes)	QPSBP1			QPDBP1 mmHg
	b.	Blood Pressure Reading 2 (after waiting 30 seconds)	QPSBP2			QPDBP2 mmHg
	The	articipant and PCP via letter if articipant is NON-DIABETIC and if systo articipant is DIABETIC and if systolic BP	OR			
C.	Anthrop	ometrics				
	For C.1	- record Measure 3 only if first 2 measur	ements are not within 0.2 k	(ilograms (200g).		
	1. Weig	Measure 1	kg QPWGHT2	kg	Veas PWG	sure 3 
	<ul> <li>At the transmost of tr</li></ul>	y the participant for any events or proce e visit during which a participant is quere plant procedures for the first time, ask to omization in DPP. bsequent visits, query for procedures du procedures to be queried are: laser/Intr ha, or other retinal procedures/surgeries ic reduction surgeries include reversals	ried for eye, gastric reduct he participant if s/he unde one since the last contact avitreal treatment for diabo s.	ion, renal failure and rwent any of these p or visit.	l kidno proceo	
	1. Since	the last contact or visit, has the pa		any of the following CHECK ALL THAT APPL		
	a.	Any acute life threatening event?			$\Box$	QPACTT
	b.	Permanent or severe disability?				QPDISA
	C.	Required or prolonged hospitaliza	tion?	1		QPHOSP
	d.	Overdose of any medication?				QPOVDO
	e.	Pregnancy resulting in congenital	abnormality or birth def	ect?QPCONG		If checked, complete E08 for each event.
	f.	Required intervention or treatmen		1		QPTSAE QPPCVD
	g. h.	Possible CVD event?		1		QPRENFL
	i.	Kidney transplant?		1	/	QPKIDTRNS

Participant ID	Nickname	Outcome visit		DPPOS <b>F01.6</b> July 2013 Page 3 of 4
	j. Eye procedure?		QPRETINA	<sup>1</sup> — Complete E09
	k. Gastric reduction surgery	?	QPGAS	<sup>1</sup> — Complete E11
	If any of options a. – i. are check may occur during the same hos subsequent events (from the same If option j is checked, complete	pitalization, complete ar ne hospitalization) on the	n E08 for the first CVD diagnos e same E08 form.	is and report

# Part III / MLS PARTICIPANT SECTION

	Comp	ete sections E and F for all MLS participants.		
E	E. <u>Metfo</u>	ormin Status		QMTAKM
	1.	Has the participant taken any STUDY METFORMIN since the last visit?	Yes 1	No 2

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)? .....

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.



### Part IV / CONCOMITANT MEDICATIONS

Complete this section for all participants.

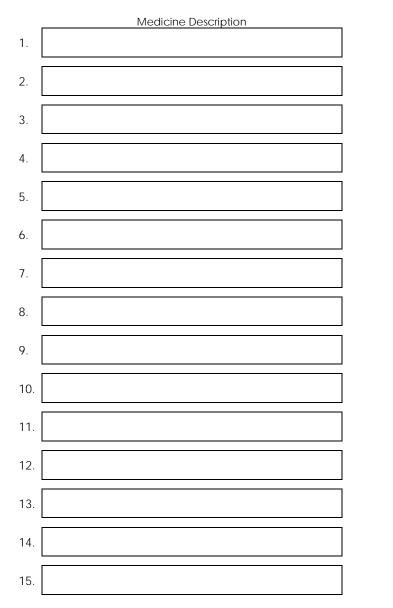
### G. Concomitant Medications

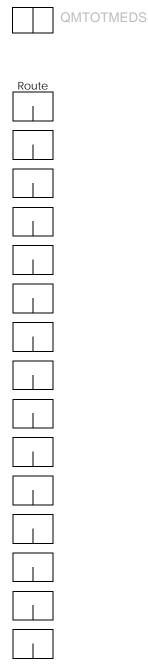
1. Has the participant taken any **PRESCRIPTION** medications within the past 2 weeks (excluding study metformin)?

# If YES,

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

#### b. List medications below: QMDRUG1-30





No

QMRXDQ Yes

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