Participant ID	Nickname					Date of visit					
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	 		•			month	dav			V	ear

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Diabetes Prevention Program Outcomes Study

F08 Metformin Safety & Adherence Form

This form is completed for MLS participants if the participant has taken any study metformin since the last scheduled visit. DO NOT COMPLETE THIS FORM FOR PARTICIPANTS WHO HAVE PERMANENTLY DISCONTINUED METFORMIN.

\	Dort	icinant Identification			
٨.	<u>Part</u>	icipant Identification			
	1.	Clinic number			
	2.	Participant number			
	3.	Nickname			
	4.	Date of randomization		month day	 year
	5.	Sex		Male 1 Fem	nale ²
	6.	Outcome visit		VISIT	
	7.	Date of visit	VSTDT replaced with DAYSRAND	month day	year
	<u>Met</u>	formin Status			
	1.	Daily dose of METFORMIN per protocol	F08DOSE	850 mg 1 1700	mg ²
	1.	Daily dose of METFORMIN per protocol What is your best estimate of the participant's level of exposure to metformin per protocol?	F08DOSE	CHECK C	mg ² DNE ONL 80% ¹ 80% ²
		What is your best estimate of the participant's level of		CHECK C	2 80%
		What is your best estimate of the participant's level of	dic	CHECK C F08COMPM < ≥ d not return pill conta	2 80%
	2.	What is your best estimate of the participant's level of exposure to metformin per protocol? Since the last visit, has the participant had any problem	dic ns taking his/her	CHECK C F08COMPM < ≥ d not return pill conta	80% 2 siner 2
	2.	What is your best estimate of the participant's level of exposure to metformin per protocol? Since the last visit, has the participant had any problem metformin pills as prescribed?	dic ns taking his/her	CHECK C F08COMPM < ≥ d not return pill conta	80% 2 siner 2

COII	nplete	this section	on if the	e particip	oant had	any probler	ms taking	his/he	er metfo	ormin pills	s as presc	ribed.		
1.	What	t are the	main	probler	ns in tal	king pills as	prescrib	ed?						
												CHECK	ALL THAT	APPLY
	a.	Forget	s to ta	ke pills i	in gene	ral						F08F	ORG	1
	b.	Forget	s to ta	ke ever	ning do	se						F0	BEVEN	. 1
	C.	Inconv	enien/	t to tak	e pills a	s prescribed	d					F08	INCON	1
	d.	GI rea	ction t	o pills								F08	GIRCT	1
	e.	Disrup	tion of	regular	routine	ý						F08	DISRP	1
	f.	·				medical rea						Engl	MEDC	1
		•				nealearree						F08	MOTV	1
	g.											F08I	OST	1
	h.		·	·								F080	OTHER	1
	i.	Other												
2.	Wha			R , spec		icipant use				F08OTI		ECK ONE	MAIN STRA	F08S
2.	Wha											ECK ONE	MAIN STRA	
2.	What										СН	ECK ONE		ATEGY
2.	Wha										СН		rent plar	1 1 2
2.	Wha										сн Con	tinue cur	rent plar	ATEGY 1 2 3
2.	Wha										сн Con Nev	tinue cur New tim	rent plar e routine y/routine	ATEGY 1 2 3 4
2.	Wha					icipant use	to deal	with t	his pro	blem?	СН Con Nev New	tinue cur New tim v strateg	rent plar e routine y/routine er device	ATEGY 1 2 3 4
2.	What					icipant use	to deal	with the	his pro	blem?	CH Con New New	tinue cur New tim v strateg	rent plar e routine y/routine er device unicatior	3 3 4 5 5 6
2.	What					icipant use	to deal	with the	his pro	blem?	CH Con New New Cy of star	tinue cur New tim v strateg reminde	rent plar e routine y/routine er device unication problem	ATEGY 1 2 3 4 5 1 7
2.		t plan or	strate	gy will t	he parti	icipant use	to deal	with the	his pro	blem?	CH Con New New Cy of star	tinue cur New tim v strateg reminde ff commu with the her main	rent plar e routine y/routine er device unicatior problem strategy	ATEGY 1 2 3 4 5 1 7
2.	If opt	t plan or	strate	gy will the	he parti	icipant use Ch	to deal	with the with the with the with the windows and with the	his pro	requenc	CH Con New Cy of stat t to deal Ot	New time our New time vistrategor reminder frommulation with the CHECK	rent plar e routine y/routine er device unicatior problem strategy	ATEGY 1 2 3 4 5 1 7
2.		t plan or	strate: ontinue	gy will the current (e.g. tir	he parti	icipant use Ch is selected, ay, meal tir	to deal	with the with the with the with the windows and with the	his pro	requenc	CH Con New Cy of stat t to deal Ot	New time our New time victorial vict	rent plar e routine y/routine er device unicatior problem strategy ALL THAT	ATEGY 1 2 3 4 5 1 7
2.	If opt	t plan or tion 1 (co Time ro Strateo	ontinue outine	gy will the current (e.g. tirtine (e.g. tirt	he parti	icipant use Ch	to deal	with the property of the prope	his pro	requenc	CH Con New New Cy of stat t to deal	New time v strateg reminder frommu with the her main CHECK F083	rent plar e routine y/routine er device unicatior problem strategy ALL THAT TIME	ATEGY 1 2 3 4 5 1 7
2.	If opt	tion 1 (co Time ro Strateo medic	ontinue outine gy rout ation i	gy will the correction of the	nt plan) me of day, takes	icipant use Ch is selected, ay, meal tir with other	nange ty	with the property of the prope	his pro	requence OT wan	CH Con New New Cy of stat t to deal	New time v strategy reminder ff community with the her main CHECK F081	rent plar e routine y/routine er device unicatior problem strategy ALL THAT TIME ETTRO	ATEGY 1 2 3 4 5 1 7

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Partic	ipant II)		Nickname Date of visit DPPOS F08	2 1									
				July 2013	3									
	•			month day year Page 3 of	3									
D.	Pred	ınanc	y Ques	ations										
		mplete this question for all MLS women who are actively taking study Metformin.												
	1.	Does	Does the participant have reproductive potential? F08PREM Yes 1											
		If YES, review menstrual history, confirm use and form of contraception and CONTINUE.												
		a.	Date	e of last menstrual period F08DOLM replaced with DAYSPERIOD month day year	ear									
		b.	Mer	nstrual period more than one week late? F081WK Yes No	2									
			If Y	ES, a pregnancy test must be performed. If NO, skip to question D.1.c.										
				F08DOPT	_									
			1.	Date of pregnancy test replaced with replaced with	ear									
			2.	Result of pregnancy test F08PREG Positive Negative	2									
				If POSITIVE, study metformin must be discontinued and a Pregnancy Confirmation Report (Form E0must be completed. Skip to Section E.	4)									
		C.		s the participant plan on becoming pregnant within the next 6 Yes No	2									
			If Y	ES, study metformin must be discontinued.										
E.	Con	nplete	Blood	Count										
Complete this section at annual visits only. IF THIS IS NOT AN ANNUAL VISIT, STOP: FORM IS COMPLETE. If the MLS participant is actively taking study metformin, record the CBC results below.														
	1.	Hem	oglobi	n F08HGLOB . g/o	dL									
	2.	Hem	atocri	F08HCRIT	, 5									
	3.	Plate	elet Co	unt F08PLATE X10/m	าไ									