

Participant ID

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Nickname

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Date of visit

month	day	year			

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.

This form supplements the F01 Mid-Year Visit Inventory, F02 Annual Visit Inventory, F03 Interim Visit Inventory, and F06 Non-Clinic Visit Inventory forms.

A. Participant Identification

1. Clinic number

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2. Participant number

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3. Nickname

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4. Date of randomization

month	day	year			
5. Sex Male

1

 Female

2

6. Outcome visit VISIT

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7. Date of visit VSTDT
replaced with
DAYSRAND

month	day	year			

B. Metformin Status

1. Daily dose of METFORMIN per protocol F08DOSE 850 mg

1

 1700 mg

2

2. What is your best estimate of the participant's level of exposure to metformin per protocol? CHECK ONE ONLY
F08COMPM <80%

1

≥80%

2

did not return pill container

3

3. Since the last visit, has the participant had any problems taking his/her metformin pills as prescribed? F08PROB Yes

1

 No

2

If YES, complete section C.

F08FORMIN

Identification code of person reviewing completed form

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 Form entered in computer?

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C. Barriers and Strategies

Complete this section if the participant had any problems taking his/her metformin pills as prescribed.

1. What are the main problems in taking pills as prescribed?

	<i>CHECK ALL THAT APPLY</i>	
a. Forgets to take pills in general	F08FORG	<input type="checkbox"/>
b. Forgets to take evening dose	F08EVEN	<input type="checkbox"/>
c. Inconvenient to take pills as prescribed.....	F08INCON	<input type="checkbox"/>
d. GI reaction to pills	F08GIRCT	<input type="checkbox"/>
e. Disruption of regular routine	F08DISRP	<input type="checkbox"/>
f. Hospitalization/new illness/medical reason	F08MEDC	<input type="checkbox"/>
g. Lack of motivation	F08MOTV	<input type="checkbox"/>
h. Lost/misplaced pills	F08LOST	<input type="checkbox"/>
i. Other	F08OTHER	<input type="checkbox"/>
1. IF OTHER, specify:		

2. What plan or strategy will the participant use to deal with this problem?

		<i>F08STRAT</i>
<i>CHECK ONE MAIN STRATEGY</i>		
Continue current plan	<input type="checkbox"/>	1
New time routine	<input type="checkbox"/>	2
New strategy/routine	<input type="checkbox"/>	3
New reminder device	<input type="checkbox"/>	4
Change type and/or frequency of staff communication	<input type="checkbox"/>	5
Does NOT want to deal with the problem	<input type="checkbox"/>	6
Other main strategy	<input type="checkbox"/>	7

If option 1 (continue current plan) is selected,

		<i>CHECK ALL THAT APPLY</i>
a. Time routine (e.g. time of day, meal time).....	F08TIME	<input type="checkbox"/>
b. Strategy routine (e.g. takes with other pills; medication in a convenient place).....	F08STRRO	<input type="checkbox"/>
c. Reminder device (e.g. pill box, calendar).....	F08RMND	<input type="checkbox"/>
d. Other	F08OTHRS	<input type="checkbox"/>

If 'Other main strategy' (question 2, option 7) or 'Other [current plan]' (question 2.d),

e. Specify other strategy/plan:

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D. 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

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

a. Date of last menstrual period
month day year

b. Menstrual period more than one week late? Yes ¹ No ²

If YES, a pregnancy test must be performed. If NO, skip to question D.1.c.

1. Date of pregnancy test
month day year

2. Result of pregnancy test Positive ¹ Negative ²

If POSITIVE, study metformin must be discontinued and a Pregnancy Confirmation Report (Form E04) must be completed. Skip to Section E.

c. Does the participant plan on becoming pregnant within the next 6 months? Yes ¹ No ²

If YES, study metformin must be discontinued.

E. Complete 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. Hemoglobin F08HGLOB . g/dL

2. Hematocrit F08HCRIT . %

3. Platelet Count F08PLATE X10/ml