

Diabetes Prevention Program BRIDGE PERIOD- STANDARD FOLLOW-UP VISIT INVENTORY

This form is completed for all participants at Mid-year and Quarterly follow-up visits, including phone visits during the bridge period (End-month 42, 54, 66,...). Form F01 records the following: weight, blood pressure, pregnancy information, coded and concomitant medication. Please follow the MRW Guidelines for medication dispensing.

Part I / IDENTIFICATION

A. Participant Identification

1. Clinic number

		CLINIC
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2. Participant number

						PATID
--	--	--	--	--	--	-------

3. Participant's initials

				INITS
first	last			

4. Participant's date of birth

					DOB
month	day	year			

5. Participant's sex

Male		SEX
Female		

B. Visit Information

1. Date of visit

					QVSTDT
month	day	year			replaced with DAYSRAND

2. Week of visit

			QVSTWK
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3. Type of visit

In Clinic		QVSTVIS
Home Visit		
Phone Visit		

*SEE SECTION C

4. Outcome visit

			VISIT
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5. End of Study

Yes		QVEOS
No		

C. Instructions for Form F01 Completion

This form is used for all participants completing a Mid-year or Quarterly visit. These visits can be conducted in clinic, off site, or over the phone. Please read the instructions above each section for further clarification as to when each section should be completed. Refer to the detailed procedures document for additional information.

Initials of person reviewing completed form

first	last		

Form entered in computer?

Participant's initials

first		last	

Date of birth

month	day	year

Date of visit

month	day	year

Part II / PHYSICAL AND HISTORY

Complete Section D for all participants during an in clinic Mid-year visit (End-month 42, 54, 66,...).

D. Anthropometrics - complete only during an in clinic Mid-year visit

1. Weight

a. First measurement

			.	
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kg QPWGHT1

b. Second measurement

			.	
--	--	--	---	--

kg QPWGHT2

Record c. only if first 2 measurements are not within 0.2 kilogram (200

c. Third measurement

			.	
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kg QPWGHT3

Complete Section E for all participants during an in clinic or home Mid-year visit (End-month 42, 54, 66,...).

E. Blood Pressure - complete only during any in person Mid-year visit

1. Seated Arm Blood Pressure

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

Systolic QPSBP1			Diastolic QPDBP1		
			/		

mmHg

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

QPSBP2			QPDBP2		
			/		

mmHg

Hypertension management aims at maintaining blood pressure < 140/90 mmHg.

Initials of data collector completing page 2 of this form

first		last	

Participant's initials

first		last	

Date of birth

month	day	year

Date of visit

month	day	year

Complete Section F for all participants at each Mid-year and Quarterly visit (in clinic, home or phone)

F. Adverse Events

1. During the interval since the last visit, has the participant had any new symptoms, injuries, illness or side effects, or worsening of pre-existing conditions?

YES

NO

QPAEQ

If YES, an Adverse Event Report (E01) form MUST be completed.

Complete Section G at each Mid-year or Quarterly visit for women who are **assigned to and actively taking Metformin**.

- G. Pregnancy Questions - complete only for women participants assigned to and actively taking Metformin.

1. Does the participant have reproductive potential?

YES

NO

QPPREM

If YES, Review menstrual diary and confirm use and form of contraception and CONTINUE.
If NO, SKIP to Part III - Medications.

2. Date of last menstrual period

month	day	year

QPDOLM

- a. Menstrual period more than one week late?

YES

NO

QP1WK

If 2a is YES, a pregnancy test must be performed.
If NO, skip to question G.5.

3. Date of pregnancy test

month	day	year

QPDOPT

4. Result of pregnancy test

Positive

Negative

QPREG

If POSITIVE, Metformin must be discontinued and complete a Pregnancy Confirmation Report (Form E04). Skip to Section H.

5. Does the participant plan on becoming pregnant within the next 3 months?

YES

NO

QPLAN

If YES, Metformin must be discontinued.

Participant's initials

first		last	

Date of birth

month	day	year

Date of visit

month	day	year

Part III / MEDICATIONS

Complete question H1 at each Mid-year or Quarterly visit for all Metformin participants. Complete Questions H1a - H1c and H2 **in addition** to H1 at any in clinic or home visit at which you would dispense Metformin, **following MRW guidelines**.

H. Metformin

YES NO

1. Has the participant taken any METFORMIN since the last visit?

QMTAKM

If YES,

a. Daily dose of METFORMIN per protocol

850 mg 1700 mg

QMDOSE

b. What is your best estimate of the participant's level of exposure to metformin per protocol?

< 80%

≥ 80%

QMCOMP

did not return pill container

c. For the most recent typical week, what is the participant's estimate of the number of days when the metformin pills were taken as

days QMDAYSM

2. Dispensing of Medication

2a. METFORMIN LABEL

Remove label from medication before dispensing and affix here.

2b. If not dispensed, check here

QMNOMET

2c. METFORMIN LABEL

Remove label from medication before dispensing and affix here.

2d. If not dispensed, check here

QMNOME2

Participant's initials

first		last	

Date of birth

month	day	year

Date of visit

month	day	year

Complete Section I for all participants during an in clinic Mid-year or Quarterly visit. This section may also be completed during a home Mid-year visit.

I. Concomitant Medications

1. Is the participant currently taking any PRESCRIPTION medications other than the metformin?

YES

NO

QMRXDQ

If YES, list below:

	Medicine Description	Route
a.	QMRXDAM	
b.	QMRXDBM	
c.	QMRXDCM	
d.	QMRXDDM	
e.	QMRXDEM	
f.	QMRXDFM	
g.	QMRXDGM	
h.	QMRXDHM	
i.	QMRXDIM	
j.	QMRXDJM	

Diuretic agents, beta blockers, and fluoxetine > 20 mg/day (or equivalent dose of SSRI) are discouraged.