

Diabetes Prevention Program

INTERIM FOLLOW-UP VISIT INVENTORY

This form is completed at titration visits for coded metformin and follow-up visits when the Standard Follow-up Visit Inventory (Form F01) and Major Follow-up Visit Inventory (Form F02) are not completed. Form F03 records the following: adverse events, pregnancy questions, coded medication and arm blood pressure for hypertension management.

Part I / IDENTIFICATION

A. Participant Identification

- 1. Clinic number CLINIC
- 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 JIVSTDT

month day year

replaced with
DAYSRAND
- 2. Week of visit JIVSTWK
- 3. Type of visit In Clinic JVSTTYP
Unattended

C. Reason for Interim Visit

Complete Part II of this form for all reasons listed below.

check all that apply

- 1. Coded metformin management JIMEDMG
 - 2. Hypertension management JIHYPMG Complete Part II and Part III
 - 3. Lipid management JILIPMG
 - 4. Pregnancy management JIPRGMG
 - 5. Adverse event management JIAEMG
 - 6. Collection of specimen for CBL (e.g. OGTT) JISPEC Complete CBL Specimen
Transmittal Form
 - 7. Repeat collection of outcome found to be deficient JIOUT
 - 8. Other JIOTH
- a. specify: _____

Initials of person reviewing completed form Form entered in computer?

first last

Participant's initials

first		last	

Date of birth

month	day	year

Date of visit

month	day	year

Part II / HISTORY

D. 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 1 NO 2 JIAEQ

If YES, an Adverse Event Report (Form EO1) MUST be completed.

E. Pregnancy Questions- Women Only

If the participant was randomized to troglitazone, skip section E pregnancy questions.

1. Does the participant have reproductive potential? YES 1 NO 2 JIPREM

If YES, Review menstrual diary and confirm use and form of contraception and CONTINUE.
If NO, SKIP to Section F - Coded Medication.

2. Date of last menstrual period

month	day	year

 JIDOLM

If participant is assigned to pharmacologic treatment, answer 2.a.
If participant is assigned to intensive lifestyle treatment, answer 2.b.

- a. Menstrual period more than one week late? YES 1 NO 2 JI1WK
- b. Menstrual period more than two weeks late? 1 2 JI2WK

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

3. Date of pregnancy test

month	day	year

 JIDOPT

4. Result of pregnancy test Positive 1 Negative 2 JIPREG

If POSITIVE, coded metformin must be discontinued and complete a Pregnancy Confirmation Report (Form E04). Skip to Section F - Coded Medication.

5. Does the participant plan on becoming pregnant within the next 3 months? YES 1 NO 2 JIPLAN

If YES, coded metformin must be discontinued.

Participant's initials

first		last	

Date of birth

month	day	year

Date of visit

month	day	year

F. Coded Medication

Complete Section F if the participant was assigned metformin/placebo. Do not complete for troglitazone or lifestyle participants.

- | | | | |
|--|--|---------------------------------------|---------|
| | YES | NO | |
| 1. Has the participant taken any coded METFORMIN since the last visit? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 | JITAKMT |
| If YES, | | | |
| a. Daily dose of METFORMIN per protocol | 850 mg
<input type="checkbox"/> 1 | 1700 mg
<input type="checkbox"/> 2 | JIDOSE |
| b. What is your best estimate of the participant's level of exposure to metformin per protocol? | < 80% <input type="checkbox"/> 1 | ≥ 80% <input type="checkbox"/> 2 | JICOMPM |
| | did not return pill container <input type="checkbox"/> 3 | | |
| c. For the most recent typical week, what is the participant's estimate of the <u>number of days</u> when the metformin pills were taken as prescribed by DPP staff? | <input type="checkbox"/> | days | JIDAYSM |

2. Dispensing of Medication

METFORMIN LABEL

Remove label from medication before dispensing and affix here. If not dispensed, check here 1 JINOMET

Part III / HYPERTENSION MANAGEMENT

G. Blood Pressure

- | | | | |
|---|--|--|------|
| 1. Seated Arm Blood Pressure | JISBP1
Systolic | JISBP1
Diastolic | |
| a. Blood Pressure Reading 1
(after sitting 5 minutes) | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | mmHg |
| b. Blood Pressure Reading 2
(after waiting 30 seconds) | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | / <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | mmHg |
| | JISBP2 | JIDBP2 | |

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