Diabetes Prevention Program

BRIDGE PERIOD - MAJOR FOLLOW-UP VISIT INVENTORY

This form is completed for all 3-arm and Troglitazone participants at Major follow-up visits: annual follow-up visits (End-months 12, 24, . . .).
Form F02 records the following: anthropometrics, arm/ankle blood pressures, adverse events, pregnancy information, coded and concomitant medications and local CBC results.

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 [1] Female [2] SEX

B. Visit Information

1. Date of visit [ ][ ] / [ ][ ] / [ ][ ] AVSTDT replaced with DAYSRAND (month day year)
2. Week of visit [ ][ ][ ] AVSTWK
3. Type of visit In Clinic [1] Home Visit [2] AVSTTYP
4. Outcome visit [ ][ ][ ] VISIT
5. End of Study Yes [1] No [2] AVEOS

C. Instructions for Form F02 Completion

Please refer to the instructions above each section for further details.
Complete all sections of Form F02 with the following exceptions:

- Sections D.4 - skin-fold thickness and D.5 - sagittal diameter are completed at End-month 12 and End of Study visits.
- Section E.2 - supine ankle-arm systolic blood pressure is completed at End-months 12 and 36, and End of Study visits.
- Part IV - Local Laboratory Results is completed for participants assigned to the pharmacological treatment.

Initials of person reviewing completed form [ ][ ][ ][ ] (first last) Form entered in computer? [ ]

Signature of P.I. _____ Date: _____

Part II / PHYSICAL AND HISTORY

Troglitazone participants only complete question D1.

D. Anthropometrics

- For D.1 - Weight, record Measure 3 only if first 2 measurements are not within 0.2 kilograms.
- For D.2 - Waist Circumference, and D.3 - Hip Girth, record measure 1 for each before completing Measure 2 and only record Measure 3 if first 2 measurements are not within 0.5 cm.

	Measure 1	Measure 2	Measure 3	
1. Weight	APWGHTI1	APWGHT2	APWGHT3	kg
2. Waist Circumference	APWSTC1	APWSTC2	APWSTC3	cm
3. Hip Girth	APHIP1	APHIP2	APHIP3	cm

If this is the End-month 12 or the End of Study visit, CONTINUE.
If not, SKIP to Section E - Blood Pressure.

4. Skin-fold Thickness

Do all skinfold measurements in each trial before going on to the next

	Trial 1	Trial 2	Trial 3	
a. Subscapular APSFSB				mm
b. Triceps APSFTR				mm
c. Supra iliac APSFSI				mm
d. Abdominal APSFAB				mm
e. Medial calf APSFMC				mm

5. Sagittal Diameter

Record Measure 3 only if first 2 measurements are not within 1

	Measure 1	Measure 2	Measure 3	
APSAGD				cm

Participant's initials (first last) | Date of birth (month day year) | Date of visit (month day year)

Troglitazone participants only complete question E1.

E. Blood Pressure

1. Seated Arm Blood Pressure

	Systolic	Diastolic	
a. Blood Pressure Reading 1 (after sitting 5 minutes)	APSBP1	APDBP1	mmHg
b. Blood Pressure Reading 2 (after waiting 30 seconds)	APSBP2	APDBP2	mmHg

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

If this is the End-months 12 or 36 or the End of Study visit, CONTINUE.
If not, SKIP to Section F - Adverse Events.

2. Supine Ankle/Arm Systolic Blood Pressure

Right arm to be used unless left arm is ≥ 10 mmHg higher, in which case wait 30 seconds, repeat left arm pressure, and enter the repeat result as the first arm

a. Arm	APSSBP	mmHg	1 Right arm, 2 Left arm — APSSBPA
b. Right dorsalis pedis	APADORR	mmHg	
c. Right tibialis posterior	APAPOSR	mmHg	
d. Left dorsalis pedis	APADORL	mmHg	
e. Left tibialis posterior	APADOSL	mmHg	
f. Arm (same arm as 2.a)	APSSBPF	mmHg	

Initials of data collector completing pages 2 and 3 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.

F. Adverse Events

	YES	NO	
1. Interval History Questionnaire (Form Q08) completed?	1	2	APQOB
2. 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?	1	2	APAEQ

If YES to F.2, an Adverse Event Report (Form E01) MUST be completed.

Complete Section G for all women who are **assigned to and actively taking Metformin**.

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

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

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) APDOLM

	YES	NO	
a. Menstrual period more than one week late?	1	2	AP1WK

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) APDOPT

4. Result of pregnancy test — Positive 1, Negative 2 — APREG

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

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

If YES, Metformin must be discontinued.

Part III / MEDICATIONS

Complete Section H if the participant is assigned to Metformin.

H. Metformin

	YES	NO	
1. Has the participant taken any METFORMIN since the last visit?	[1]	[2]	AMTAKM

If YES,

	850 mg	1700 mg	
a. Daily dose of METFORMIN per protocol	[1]	[2]	AMDOSE

b. What is your best estimate of the participant's level of exposure to metformin per protocol?	< 80% [1]	AMCOMPM
	≥ 80% [2]	
	did not return pill container [3]	

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 AMDAYSM

2. Dispensing of Medication

2a. METFORMIN LABEL

Remove label from medication before dispensing and affix here.

2b. If not dispensed, check here [1] AMNOMET

2c. METFORMIN LABEL

Remove label from medication before dispensing and affix here.

2d. If not dispensed, check here [1] AMNOME2

Participant's initials (first, last) | Date of birth (month, day, year) | Date of visit (month, day, year)

Complete Section I for all participants.

I. Concomitant Medications

1. Is the participant currently taking any PRESCRIPTION medications other than the coded metformin? If YES, list below:

YES [1] NO [2] AMRXDQ

	Medicine Description	Route
a.	AMRXDAM	
b.	AMRXDBM	
c.	AMRXDCM	
d.	AMRXDDM	
e.	AMRXDEM	
f.	AMRXDFM	
g.	AMRXDGM	
h.	AMRXDHM	
i.	AMRXDIM	
j.	AMRXDJM	

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

Part IV / LOCAL LABORATORY RESULTS

If the participant is assigned to Metformin, RECORD THE CBC RESULTS.
If not, STOP.

J. Complete Blood Count

1. Hemoglobin — ALHGLOB [ ][ ].[ ] g/dL
2. Hematocrit — ALHCRIT [ ][ ].[ ] %
3. Platelet Count — ALPLATE [ ][ ][ ] x10³/ml