# 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	<u>I /</u>	IDEN	HEICA	<u> </u>

	Part	<u>I /</u>	IDENTIFICATION					
/	۹. <u>F</u>	ar	ticipant Identification					
		1.	Clinic number					CLINIC
	2	2.	Participant number					PATID
	;	3.	Participant's initials			first	last	INITS
	4	4.	Participant's date of birth	mont	h	day	year	DOB
	ţ	5.	Participant's sex				Male 1 Female 2	SEX
E	3. <u>\</u>	/isi	t Information					
		1.	Date of visit	mont	h	day	year	AVSTDT replaced with DAYSRAND
	2	2.	Week of visit					AVSTWK
	;	3.	Type of visit				Clinic 1  e Visit 2	AVSTTYP
	4	4.	Outcome visit					VISIT
	ţ	5.	End of Study				Yes 1	AVEOS
(	C. <u>l</u> i	nst	ructions for Form F02 Completion				No 2	
			ease refer to the instructions above each section for further emplete all sections of Form F02 with the following exceptions:  Sections D.4 - skin-fold thickness and D.5 - sagittal diameter at 12 and End of Study visits.  Section E.2 - supine ankle-arm systolic blood pressure is complicated, and End of Study visits.  Part IV - Local Laboratory Results is completed for participants pharmacological treatment.	re con leted a	npl at E	End-m	onths 12 a	
	I	niti	als of person reviewing completed form first last	m ente	ere	d in co	omputer?	
	5	Sigi	nature of P.I.	Da	te:			_

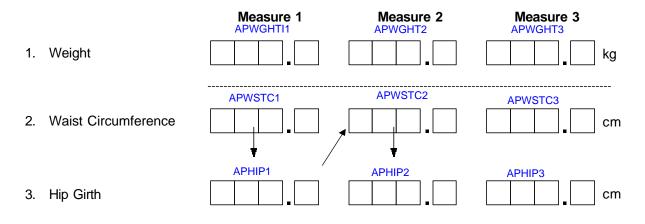
Particip	ant's initials	Date of b	oirth		Date o	f visit		DPP FORM F02.3
			ľ					January 2002 Page 2 of 6
first	last	month	day	vear	month	day	vear	· ·

### Part II / PHYSICAL AND HISTORY

## Troglitazone participants only complete question D1.

## D. Anthropometrics

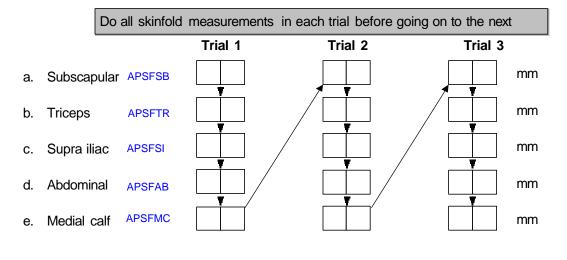
- For D.1 Weight, record Measure 3 only if first 2 measurements are not within 0.2 kilograms.
- For D.2 Waist Circumference, and D.3 Hip Girth, record measure 1 for each before completing Measure 2 and only record Measure 3 if first 2 measurements are not within 0.5 cm.

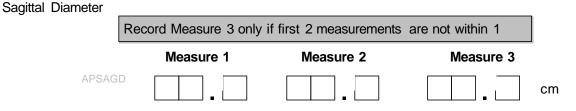


If this is the End-month 12 or the End of Study visit, CONTINUE.

If not, SKIP to Section E - Blood Pressure.

### 4. Skin-fold Thickness





Troglitazone participants only complete question E1.  E. Blood Pressure  1. Seated Arm Blood Pressure Reading 1 (after sitting 5 minutes)  b. Blood Pressure Reading 2 (after waiting 30 seconds)  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  Right arm APSS Left arm  Pressure
Troglitazone participants only complete question E1.  E. Blood Pressure  1. Seated Arm Blood Pressure  2. Supine Ankle/Arm Systolic Blood Pressure  Right arm to be used unless left arm pressure, and enter the repeat result as the first arm  2. Supine Arm  APSSEP  To Diastolic  Diastolic  Diastolic  Diastolic  Diastolic  Diastolic  APSBP1  APDBP1  MmHg  APSBP1  APDBP1  MmHg  APSBP1  APSSBP  MmHg  APSSBP  MmHg  APSSBP  MmHg  Right arm  APSSBP
E. Blood Pressure  1. Seated Arm Blood Pressure  2. Supine Ankle/Arm Systolic Blood Pressure  Systolic Diastolic  APSBP1 APDBP1 APDBP1  APDBP1 APDBP2  APDBP2 APDBP2  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  APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP mmHg Right arm APSSBP
1. Seated Arm Blood Pressure  a. Blood Pressure Reading 1 (after sitting 5 minutes)  b. Blood Pressure Reading 2 (after waiting 30 seconds)  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
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b. Blood Pressure Reading 2 (after waiting 30 seconds)  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
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<ul> <li>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     </li> <li>a. Arm</li> </ul> APSSBP mmHg Right arm Right arm APSSBP
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   Right arm   Right arm   APSSBP   Right arm   Right arm   APSSBP   Right arm   APSSBP   Right arm   Right arm   APSSBP   Right arm   APSSBP
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   Right arm   Right arm   APSSBP   Right arm   Right arm   APSSBP   Right arm   APSSBP   Right arm   Right arm   APSSBP   Right arm   APSSBP
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 Right arm  APSSBP mmHg
seconds, repeat left arm pressure, and enter the repeat result as the first arm  a. Arm  APSSBP   mmHq   Right arm   APSSBP   APSSBP   mmHq   Right arm   Right arm   APSSBP   mmHq   Right arm   Right arm   APSSBP   mmHq   Right arm   Right ar
a. Arm  APSSBP mmHa Right arm  APSS
a. Arm APSSEP       mmHg 🖵 S APSS
a. Arm APSSEP       mmHg 🖵 S APSS
b. Right dorsalis pedis  APADORR mmHg
c. Right tibialis posterior APAPOSR mmHg
c. Right tibialis posterior APAPOSR mmHg
d. Left dorsalis pedis APADORL mmHg
e Left tibialis posterior APADOSL mmHa
e. Left tibialis posterior  APADOSL   mmHg
f. Arm (same arm as 2.a)  APSSBPF mmHg
f. Arm (same arm as 2.a)  APSSBPF mmHg

		Participant's initials  first last	Date of birth	Date of vi	sit day ye	ear		P FORM F02.3 January 2002 Page 4 of 6
Co	m	olete Section F for all p	participants.					
F.	<u>A</u>	dverse Events				YES	NO	
	1.	Interval History Ques	stionnaire (Form Q08) comp	oleted?		1	2	APQOB
	2.	_	nce the last visit, has the p ns, injuries, illness or side sting conditions?	•		1	2	APAEQ
		If YES to F.2, ar	n Adverse Event Report (Fo	orm E01) MUST	be comple	ted.		
Co	mn	ulata Saction C for all w	roman who are accioned to	and activoly t	okina Mo <del>tt</del>	iormin		
			vomen who are assigned to					
G. J	₽re	egnancy Questions - co	omplete only for women par	ticipants assign	ed to and a	YES	NO NO	
	1.	Does the participant	have reproductive potential	?		1	2	APREM
		If YES, review menstri If NO, SKIP to Part III	ual diary and confirm use a - Medications.	and form of conti	raception a	and CONT	INUE.	
	2.	Date of last menstrua	al period		month	day y	rear	APDOLM
		a. Menstrual period	more than one week late?			YES 1	NO 2	AP1WK
			a is YES, a pregnancy test O, skip to question G.5.	must be perform	ed.			
	3.	Date of pregnancy te	st		month	day y	 rear	APDOPT
	4.	Result of pregnancy	test			Positive Negative	2	APREG
			, Metformin must be disco Confirmation Report (Form		•			
	5.	Does the participant	plan on becoming pregnant	within the next	3 months?	YES	NO 2	APLAN
			If YES, Metformin must be	discontinued.				

Participant's initials D	ate of birth	Date of visit	year	DPP FORM F02.3 January 2002 Page 5 of 6
Part III / MEDICATIONS				
Complete Section H if the partic	ipant is assigned to Metfor	rmin.		
H. <u>Metformin</u>			YES N	O
1. Has the participant take	n any METFORMIN since	the last visit?	1 2	AMTAKM
If YES, a. Daily dose of METF	ORMIN per protocol	850 m	ֿרס <sup>ֿ</sup>	OOSE
a. Daily dood of MET	Craviii v por protocor			
b. What is your best e	stimate of the participant's	s level of	80% 1	
exposure to metform				СОМРМ
	di	d not return pill conta	iner 3	
c. For the most recent	typical week, what is the p	participant's		
estimate of	of the <u>number of days</u> when were taken	n the	day	AMDAYSM
metformin pills	were taken	as		3
Dispensing of Medication	1			
, ,		MIN LABEL		
	Remove label from medi		-	
	2b. If no	t dispensed, check h	ere 1 AMNOM	IE I
	2c. METFOR	MIN LABEL		
	Remove label from medi 2d. If no	cation before dispens t dispensed, check h	_	:

Date of visit

Participant's initials

Date of birth

	Participant's initials	Date of birth		Date of v	risit		DPP FORM F02.3
					1		January 2002 Page 6 of 6
	first last	month day y	year	month	day	year	C .
Comp	olete Section I for all pa	rticipants.					
I. <u>Co</u>	oncomitant Medications					YES	NO
1.	Is the participant curr	ently taking any PRE	SCRIPTION			1	2 AMRXDQ
	medications other tha	in the coded metform	in?				
	If YES, list below:	Medicine Descrip	tion			Route	
	AMRXDAM						
	a						
	b. AMRXDBM						
	AMRXDCM					$\mathbf{H}$	
	C. AWIKADOW					$\Box$	
	d. AMRXDDM						
					_		
	e. AMRXDEM						
	AMRXDFM						
	f.						
	g. AMRXDGM						
	AMRXDHM						
	h					$\mathcal{H}$	
	i. AMRXDIM						
					<u> </u>		
	j. AMRXDJM						
		gents, beta blockers,			ng/day		
	(or equival	ent dose of SSRI) ar	e discourage	d.			
						_	
Part I\	/ / LOCAL LABORATOR	RY RESULTS					
	participant is assigned		IDD THE CRO	O DECLII	TC		
	; STOP.	to Metiornin, RECO	ND THE CO	J KESUL	_13.		
J. C	omplete Blood Count						
			AL	HGLOB			
1	. Hemoglobin						g/dL
2	2. Hematocrit		AL	LHCRIT			0/
_							%
_	N DI A LA COLLA			DI ATE			
3	B. Platelet Count		AL	PLATE			x10³/ml