

# Diabetes Prevention Program Outcomes Study F02 ANNUAL VISIT INVENTORY

Form F02	This Form is interviewer-administered for all participants at an in-clinic annual visit year 13 and on (13A, 14A, 15A). Form F02 records the following: anthropometrics, blood pressure, adverse events, study metformin status, concomitant medications, nutritional supplements, and diabetes monitoring.										
A. <u>Parti</u>	icipant Identification										
1.	Clinic number										
2.	Participant number										
3.	Nickname										
4.	Date of randomization		month day	year							
5.	Sex		Male 1	Female <sup>2</sup>							
6.	Outcome visit		VISIT								
7.	Date of visit	AVSTDT replaced with DAYSRAND	month day	year							

### APFORMIN

Identification code of person reviewing completed form		Form entered in computer?

Participant ID	Nick	Nickname					Outcome Visi			

# PART II / PHYSICAL AND HISTORY

Complete Part II for all participants								
B. <u>Blood Pressure</u>								
1. Seated Arm Blood Press	ure							
a. Blood Pressure Read (after sitting 5 minute		APSBP1	Systolic Diastolic	CAPDBP1				
b. Blood Pressure Read (after waiting 30 sec		APSBP2		APDBP mmHg				
	petes follow the JNCP guidelines er 6 of the Manual of Operations PCP.							
C. <u>Anthropometrics</u>								
For C.2 – Waist Circumference	asure 3 only if first 2 measurements e, record Measure 3 only if first usure 3 only if first 2 measurement	2 measurements are	not within 0.5 cm.					
1. Weight	Measure 1	Measure 2	Measure 3	kg				
Complete waist circumferer	nce at 13A, 14A, 16A, and 18A v	isits only.						
2. Waist Circumference	APWSTC1	APW\$TC2	cm APWSTC3	cm				
Complete height at 15A and	d 18A visits only.							
3. Height		APHGHT2	cm APHGHT3	•cm				
D. Events and Procedures								
<ul> <li>Query the participant for any events or procedures experienced since the last contact or visit.</li> <li>At the visit during which a participant is queried for eye, gastric reduction, renal failure, and kidney transplant procedures for the first time, ask the participant if s/he underwent any of these procedures since randomization in DPP.</li> <li>At subsequent visits, query for procedures done since the last contact or visit.</li> <li>Eye procedures to be queried are: laser/intravitreal treatment for diabetic retinopathy or diabetic macular edema, or other retinal procedures/surgeries.</li> <li>Gastric reduction surgeries include reversals of prior surgeries.</li> </ul>								
1. Since the last contact o	r visit, has the participant ex	perienced any of t	he following?					
	M	ARK WITH AN 'X' A	LL THAT APPLY					

a.	Any acute life threatening event?	APACTT	. 1 -	٦	
	Permanent or severe disability?	APDISA	1		lf marked, complete E08 for each event.
С.	Required or prolonged hospitalization?	APHOSP	1	ſ	E08 for each event.

Participant ID				Nickname					Outcome Visit			

	If 'Required or prolonged hospitalization' is selected, mark any events that caused or occurred during the hospitalization.								
	1. Infection (including nosocomial)?	1							
	2. Fracture?	1							
	3. Joint replacement?	1							
d.	Pregnancy resulting in congenital abnormality or birth defect?	1							
e.	APTSAE Required intervention or treatment to prevent serious adverse event?	1							
f.	Possible CVD event?	1		lf marked, cor E08 for each e					
g.	Renal failure?	1							
h.	APKIDTRNS Kidney transplant?	1							
i.	Eye procedure?	1		Complete E09					
j.	APGAS Gastric reduction surgery?	1 -		Complete E11					
k.	APCAN	1 -		Complete E12					
If any of options ah. are marked, complete a separate E08 for each event. For multiple CVD events that may occur during the same hospitalization, complete an E08 for the first CVD diagnosis and report subsequent events (from the same hospitalization) on the same E08 form. If option c.1 is marked, complete the E14 form. If option c.2 is marked, complete the E15 form. If option c.3 is marked, complete the E16 form.									

# E. <u>History</u>

1. Since the last annual visit, did the participant experience any of the following?

			Yes	No
a.	APSTON Frequent stomach pains, bloating, nausea, diarrhea, or loss of appetite?	M	1	2
b.	Unexplained weight loss?	SN	1	2
C.	APSPRN		1	2
d.	A fall and landed on the floor, ground, OR has fallen and hit an object like APFAL a table or chair?	1	2	
	If YES, complete an R25 Falls Report.			

Participant ID				Nickname					Outcome Visi								

2. Did a health care provider (outside the DPPOS) diagnose the participant with a new onset of the following since the last annual visit?

a. Diabetes (sugar in blood or urine)?	APDIAB	Yes 1	<b>No</b>
If YES, complete an E10 Outside PCP Diabetes Diagnosis Event Report form.			
b. High blood pressure?	APHYPER	1	2
c. Any lipid abnormality (high cholesterol, high triglycerides, etc.)?	APLIPID	1	2
d. Dementia?		1	2
e. Alzheimer's disease?	APALZDS	1	2
f. Hearing loss?	APHEAR	1	2

# PART III/MEDICAL HISTORY

# F. CHD Status

C	omplete this section at 14A, 16A, and 18A visits only.		
1.	Does the participant have atherosclerotic vascular disease including coronary disease, cerebrovascular disease, or peripheral vascular disease? (NOTE: abnormal ABI does not define PVD in the absence of signs or symptoms)	Yes 1	NO APATHER
2.	Family history of premature CHD (any event or CVD procedure before age 55 in father or other first-degree male relative, or before age 65 in mother or other first-degree female relative)	Yes 1	No APHIST

# G. Interval Cardiovascular History

Ask the participant to think about the last 12 months when answering the following questions:									
1. Have you had any pain or discomfort in your chest?	APPAIN	Yes 1	No <sup>2</sup>						
2. Have you had any pressure or heaviness in your chest?	APPRES	Yes 1	No <sup>2</sup>						
If Questions 1 AND 2 are NO, skip to section I. If either are YES, contin	nue.								
a. Do you get it when you walk uphill or hurry?	APHURF	Yes 1	No <sup>2</sup>						
b. Do you get it when you walk at an ordinary pace on the	e level? APLEVE	L <sub>Yes</sub>	No <sup>2</sup>						
c. When you get it in your chest, what do you do?		APDO	Stop 1						
		Slov	v down						
Continue at same pace									

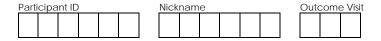
Part	icipa	nt ID		Nick	name			0	utcome	e Visit							PPOS <b>F</b> June 2 Page 5	018
		d. E	Does it g	lo away	y when <u>y</u>	you sta	and st	till?						Ye	1 S		STILL	2
		<b>lf</b> 1.	<b>YES</b> , How s	soon?										APSC			n. or le n 10 mi	2
		e. V	Where do	o you g	jet this p	bain or	disco	omf	ort:									
		1.	Sternu	um (cei	ntral che	est)?							APSTE	R Ye	1 S		Ν	2 Io
		2.	Left a	nterior	chest?								APLCHS	ST <sub>Yes</sub>	1 S		Ν	2 Io
		3.	Left a	rm?									APLARM	Ye	1 S		Ν	2 Io
			ave you or half ar				ain a	CrO	oss the	front	of your	chest la Al	asting P30MIN	Ye	1 S		Ν	2
H.	. <u>Stro</u>	oke / <sup>·</sup>	TIA															
	1.										en feeling ot, or fac		mbness, APNOFEE	L Ye	1 S		Ν	2 Io
		If YES	<b>b</b> ,															
		a. F	How long	g did th	ie symp	toms la	ast?							A	PNOF	LT	< 1 ho	ur 1
																1-2	4 hour	(s) <sup>2</sup>
	2.		ng the p oss of use							sudde	en attac	ks of pa	aralysis,	Ye	S 1		24 hou P <mark>ARL</mark> <sub>N</sub>	urs 10
		If YES	<b>,</b>															
		a. F	How long	g did th	ie symp <sup>.</sup>	toms la	ast?							,	APPA	RLT	< 1 ho	ur
																1-2	4 hour	(S) 2 3
																	24 hou	urs
	3.		ng the p ring of vi							sudde	en loss of	f eyesig	jht or	Ye	s	APB	LUR N	lo
		If YES	<b>5</b> ,															
		a. F	How long	g did th	ie symp	toms la	ast?							ŀ	PBLU	JRT	< 1 ho	ur
																1-2	4 hour	(s) 2
																>	24 hou	urs 3

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4	During the past 12 months, have you had any sudden attacks of change In speech, loss of speech or inability to say words for more than two minutes?	s Yes APLUR NO 2
	If YES,	
	a. How long did the symptoms last?	APLURT < 1 hour
		1-24 hour(s) $\left  \begin{array}{c} 2 \\ \end{array} \right $
		> 24 hours <sup>3</sup>
_		
5	. During the past 12 months, have you had any spells of dizziness, difficulty walking, lightheadedness or loss of balance?	in <sub>Yes</sub> APDIZY <sub>No</sub> <sup>2</sup>
	If YES,	
	a. How long did the symptoms last?	APDIZYT < 1 hour
		1-24 hour(s)
		> 24 hours
6	. Since your last annual visit has your doctor diagnosed you with a new onset of Transient ischemic attack (TIA)?	Yes APTIA No 2
PART	IV / INTERVAL DRINKING, SMOKING, ANTI-INFLAMMATORY MEDICATION, & R	DUTINE CARE HISTORY
I. <u>Dri</u>	inking Status	
1		
	. During the past 12 months, have you consumed an average of at least c alcoholic beverage per week?	ne <sub>Yes</sub> <sup>1</sup> APWK <sub>No</sub> <sup>2</sup>
	alcoholic beverage per week?	ne Yes APWK No 2
	<ul><li>alcoholic beverage per week?</li><li>If YES, for the most recent normal (i.e., usual) week:</li><li>a. How many 12 oz. bottles of beer did you consume during the past 7</li></ul>	
	<ul> <li>alcoholic beverage per week?</li> <li>If YES, for the most recent normal (i.e., usual) week:</li> <li>a. How many 12 oz. bottles of beer did you consume during the past 7 days?</li> <li>b. How many 4 oz. glasses of wine did you consume during the past 7</li> </ul>	APBEER 12 oz Bottles APWINE 4 oz Glasses
2	<ul> <li>alcoholic beverage per week?</li> <li>If YES, for the most recent normal (i.e., usual) week: <ul> <li>a. How many 12 oz. bottles of beer did you consume during the past 7 days?</li> </ul> </li> <li>b. How many 4 oz. glasses of wine did you consume during the past 7 days?</li> <li>c. How many 1.5 oz. shots of hard liquor or mixed drinks did you consume during the past 7 days?</li> </ul>	e APBEER 12 oz Bottles APWINE 4 oz Glasses APMIXD 1.5 oz Shots
2	<ul> <li>alcoholic beverage per week?</li> <li>If YES, for the most recent normal (i.e., usual) week: <ul> <li>a. How many 12 oz. bottles of beer did you consume during the past 7 days?</li> </ul> </li> <li>b. How many 4 oz. glasses of wine did you consume during the past 7 days?</li> <li>c. How many 1.5 oz. shots of hard liquor or mixed drinks did you consume during the past 7 days?</li> <li>During the past 12 months, have you ever consumed 7 or more alcoholic beverages (including mixed drinks, shots, beer, and/or wine) within a 24-</li> </ul>	e APBEER 12 oz Bottles APWINE 4 oz Glasses APMIXD 1.5 oz Shots Yes 1 APBINGE 2
2	<ul> <li>alcoholic beverage per week?</li> <li>If YES, for the most recent normal (i.e., usual) week: <ul> <li>a. How many 12 oz. bottles of beer did you consume during the past 7 days?</li> </ul> </li> <li>b. How many 4 oz. glasses of wine did you consume during the past 7 days?</li> <li>c. How many 1.5 oz. shots of hard liquor or mixed drinks did you consume during the past 7 days?</li> <li>During the past 12 months, have you ever consumed 7 or more alcoholic beverages (including mixed drinks, shots, beer, and/or wine) within a 24-hour period?</li> <li>a. About how often is this (that you have had 7 or more drinks within a 2 hour period?</li> </ul>	e APBEER 12 oz Bottles APWINE 4 oz Glasses APMIXD 1.5 oz Shots Yes 1 APBINGE 2 No 2

1-3 times per month	
	_

Once a week or more



## J. Smoking Status

1. During the past 30 days, have you smoked any cigarettes?

## If YES,

a. On average, how many cigarettes per day?

## K. Physical Activity Status

- 1. Over the past seven days, how many total minutes did you participate in activities that were at least moderate in intensity (like a brisk walk)?
- L. Anti-inflammatory Medication Status

1.	During an average week, how often do you take one or more aspirin	
	tablets regardless of dosage?	

Yes	NOK No	2
SDAY	cigs per	day

AP

			mins
AP	7D	١Y	

APNSAID No

Yes

APASPIR Never	1
Less than 1 day per week	2
1 or 2 days per week	3
3 to 4 days per week (includes every other day)	4
5 or 6 days per week	5
Every day	6

### If you take aspirin (options 2-6)

Type of aspirin	Do you take this type of aspirin?	If, YES, 1. On days you use aspirin, what is the total number of pills you take?
baby-strength aspinn (ormg)	APASPBABY	
Regular-strength aspirin (325mg)	<sup>1</sup> APASPREG	. APASPREGNO
Extra-strength aspirin (500mg)		
		type of aspirin?Type of aspirinYesNoBaby-strength aspirin (81mg)1APASPBABYRegular-strength aspirin (325mg)1APASPREG

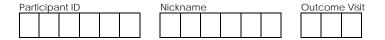
2. Has the participant taken a non-prescription non-steroidal anti-inflammatory drug (NSAID) other than aspirin in the past month? (Many pain relievers are NSAIDs, including ibuprofen, Advil, Motrin, and Aleve)

		Do you take NSAID?	e this	If YES, 1. On average how many days in the past	2. On days you use the NSAID, what is the total number of pills you	
	Type of NSAID	Yes	No	month?	take?	
a.	Ibuprofen (e.g. Advil, Motrin, Nuprin) APNSAIDIB	1	2	APIBDAY days	pills AP	IBNO

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b.	Naproxen (e.g. Aleve, Anaprox, Naprosyn, Naprelan) APNSAIDN	1 2	APNADAY days		NO
C.	Other APNSAIDOTH	1 2	APOTHDAY days		HNO
	3. If OTHER, specify:	APNSAIDSP			

M. Diabetes Management

Com	plete this section for participants with	diabetes	s only.						
1.	During the <b>past month</b> , did you <u>rou</u>	<u>utinely</u> r	monitor your blood glu	ucose? Ye	s APMNTBG 2 No 2				
I	If YES,								
ä	a. On average, how many days per week did you monitor your blood glucose?								
ł	b. On days that you monitored your blood glucose, on average, how many <u>times</u> APMNTDY time(s)/day								
2.	Total number of insulin formulation	ns taker	n in the past 2 weeks		APINSNO				
	If number of insulin formulations is greater than zero, a. Type of insulin regimen?								
	API	NSFO		APINSTM	Infusion pump				
	Insulin formulation description APINSDES	Form	APINSUNT If injection (option 1), i. Number of units per injection (inj)?	If Injection (option 1), ii. Number of times per day?	If Infusion pump (option 2), APINSTD iii. Average total daily dose				
1			units/inj	times/day	units				
2			units/inj	times/day	units				
3			units/inj	times/day	units				
4			units/inj	times/day	units				
5			units/inj	times/day	units				
6			units/inj	times/day	units				
7			units/inj	times/day	units				
8			units/inj	times/day	units				



### N. Routine Medical Care

- 1. During the past 3 months, how many times have you, outside the DPPOS: (none=0)
  - a. called a health care provider (for a specific issue/concern)?
  - had electronic communication other than a phone call (i.e. email, text, online portal message) with a health care provider (for a specific issue/concern?)
  - c. had a regularly scheduled out-patient visit(s)?
  - d. had urgent care visit(s) (i.e. doctor's office, clinic; not to emergency room)?
  - e. had an emergency room visit(s)?
- During the past 3 months, how many days have you lost from school, work, or household activities due to illness or injury or medical services received <u>not</u> including visits related to the DPPOS? Do not include any time that you are taking off for this visit today. (round to nearest half day)

#### PART V / MLS PARTICIPANT SECTION

Complete sections O and P for all MLS participants		
O. <u>Metformin Status</u>		AMTAKM
1. Has the participant taken any STUDY METFORMIN since the last visit?	Yes 1	No 2
If YES, complete the F08 Metformin Safety & Adherence Form for this participant.		
P. <u>Dispensing of Metformin</u>		

Complete the Metformin Safety and Adherence Checklist for all participants receiving study metformin before metformin in	is
dispensed.	

1. How many months of metformin was dispensed (0. 3. 6)?....

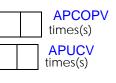
METFORMIN LABELS:

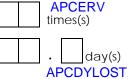
Remove label from metformin before dispensing and affix here.

Remove label from metformin before dispensing and affix here.

If metformin is NOT dispensed for reasons other than a previously reported permanent condition, a Metformin Discontinuation Form (Form F07) must be completed.







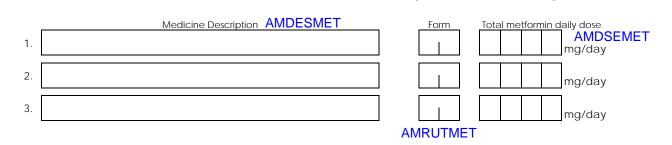
APDISE

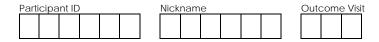
Participant ID		Nickname				Outo	come	e Visit			

## PART VI / CONCOMITANT MEDICATIONS / NUTRITIONAL SUPPLEMENTS / CANCER SCREENINGS

Complete this section for all participants.	
Q. <u>Concomitant Medications</u>	AMRXDQ
1. Has the participant taken any <b>PRESCRIPTION</b> medications within the past weeks (excluding study metformin)?	2 Yes 1 No 2
If YES,	
<ul> <li>Total number of medications taken (including any medications listed on additional sheets)</li> </ul>	AMTOTMED
b. List all medications without metformin below:	
Medicine Description AMDRUG1-30	Form AMROUTE
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	
11.	
12.	
13.	

c. List all medications that include metformin below (list the total daily dose of metformin only):





# R. <u>Nutritional Supplements</u>

there a	Multivitamins are identified by the word multivitamin in the bottle label or if the number of active ingredients are 5 or more. If here are fewer than 5 active ingredients in a supplement, include them in Question S3. Multivitamins should exclude B-Complex and instead the relevant B-vitamins should be included in the specific supplement list in Question R3.							
1.	Has the participant taken any non-prescription oral multivitamins at leastonce a week in the past 12 months?AMMULTIV	Yes 1	No 2					
2.	Has the participant received any Vitamin B12 shots in the past 12 months?	Yes 1	No 2					
	If YES,	AMSHOTNO						
	a. Number of shots received in the past 12 months		shots					
3.	Has the participant taken any <b>non-prescription</b> oral supplements other than multivitamins at least once a week in the past 12 months? AMSUP	Yes 1	No 2					

#### If YES,

	Type of supplement	this supplement?		If YES, 1. Number of months used in the past 12	
		Yes	No	months?	
AMOMEGA <sub>a.</sub>	Omega 3 (fish oil)	1	2	months	AMOMEGAMO
AMVITA b.	Vitamin A (not Beta-carotene)	1	2	months	AMVITAMO
AMVITB6 <sub>C.</sub>	Vitamin B6	1	2	months	AMVITB6MO
AMVITB12 <sub>1.</sub>	Vitamin B12	1	2	months	AMVITB12MO
AMVITC e.	Vitamin C (with or without rose hips)	1	2	months	АМVITСМО
AMVITD f.	Vitamin D	1	2	months	AMVITDMO
AMVITE g.	Vitamin E	1	2	months	AMVITEMO
AMCAL h.	Calcium	1	2	months	AMCALMO
AMCHROi.	Chromium	1	2	months	AMCHROMO
AMFOL j.	Folate (Folic Acid)	1	2	months	AMFOLMO
	Iron	1	2	months	AMIRONMO
AMMAG.	Magnesium	1	2	months	AMMAGMO

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AMPOT m.	Potassium	1	2	months	ΑΜΡΟΤΜΟ
AMSEL n.	Selenium	1	2	months	AMSELMO
AMZINC <sub>O.</sub>	Zinc	1	2	months	AMZINCMO

# S. Cancer Screening Assessment

Screening questions should be completed for any cancer screening test(s) the participant has had in the past year.

Со	mplete questions 1-3 for female pa	articipants only.					
			Have ye past ye		this tes	t in the	If YES, a. Date of last test or biopsy
Тур	be of test		Yes	No	know	N/A	(month/year)
1.	Pap smear	<b>\PPAP</b>	1	2	3	4	
2.	Mammogram	APMAM	1	2	3	4 A	PMAIVIVO APMAN
3.	Breast biopsy	PBRST	1	2	3	4 AP	BR\$TINO APBRS
Со	mplete questions 4-5 for male par	icipants only.					
			Have ye past ye		this tes	t in the	If YES, a. Date of last test or biopsy
Тур	be of test		Yes	No	know	N/A	(month/year)
4.	A blood test for prostate can specific antigen (PSA)	cer, prostate APPSA	1	2	3	4	APPSAMO APPSAYR
5.	Prostate biopsy	APPROST	1	2	3	4	APFROSTMO APPROSTYR
Со	mplete questions 6-9 for all partici	pants.	<u> </u>				
			Have y		this tes	t in the	
			past ye	ar?	Don't		If YES, a. Date of last test or biopsy
Typ	be of test		Yes	No	know	N/A	(month/year)
6.	Fecal occult blood test	APFOBT	1	2	3	4	APFOBTMO APFOBTYR
7.	Sigmoidoscopy	APSIG	1	2	3	4	AFSIGMO APSIGYR
8.	Colonoscopy	APCOL	1	2	3	4	
9.	Other cancer screening test	APOTHTS		2	3	4	APSCRMO APSCR
	If YES, specify: APCOT	HSP					]