

**TODAY Form VISIT, Clinical Visit Inventory**

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Release Participant ID

 RELEASEID 
  

Release Visit Number

 MVISIT 

1. Days since randomization

   

DAYS

*Instructions: This form is completed for all participants at all scheduled visits after the Baseline visit (M02, M04, etc...).*

**Physical Exam Measurements**

2. Seated arm blood pressure

a. Systolic Blood Pressure

   mmHg

SBP

b. Diastolic Blood Pressure

   mmHg

DBP

c. Was TODAY BP cuff CAS 740-1 MAXNIBP used?

<sub>1</sub> Yes <sub>0</sub> No

BPCUFF

3. Anthropometrics

a. BMI

<sub>1</sub> ≤28.0000   .     <sub>3</sub> >46.0000

BMI

b. BMI Percentile

<sub>1</sub> ≤98.5   .  <sub>3</sub> >99.5

BMIPCT

c. BMI Z-score

<sub>1</sub> ≤1.8000   .     <sub>3</sub> >2.7000

BMIZ

i. Was TODAY Seca Scale 882 used to collect weight?

<sub>1</sub> Yes <sub>0</sub> No

SECA

**Complete d. and e. (waist circumference and abdominal height) only at M06 and M24 visits.**

d. Waist circumference

<sub>1</sub> ≤95.0 cm    .   cm <sub>3</sub> >130.0 cm

WASTCIRC

e. Abdominal height

<sub>1</sub> ≤21.0 cm    .   cm <sub>3</sub> >30.0 cm

ABDHGHT

**Concomitant Medications**

4. Has the participant had any of the following medications, treatments, or procedures since the last visit?

<sub>1</sub> Yes <sub>0</sub> No

MEDS

**If YES, continue. If NO, skip to question 5**

a. Antihypertensives (study and non-study drug)?

<sub>1</sub> Yes <sub>0</sub> No

ANTIHYP

b. Lipid lowering medications (study and non-study drug)?

<sub>1</sub> Yes <sub>0</sub> No

LIPLOW

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c. Diabetes medication (other than study medication or insulin)?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="text" value="DIABMED"/>
d. Steroids?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="text" value="STER"/>
e. Weight loss treatments?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="text" value="WHTSUP"/>
f. Other prescription medications?	<input type="checkbox"/>	Yes	<input type="checkbox"/>	No	<input type="text" value="OTHERRX"/>

**Interval History**

5. Outside the TODAY study, since the last clinic visit, how many times has the participant:

a. Called a health care provider for a specific medical issue/concern?	<input type="text"/> <input type="text"/> time(s)	<input type="text" value="JCALLHCP"/>
b. Had a regularly scheduled outpatient visit(s)?	<input type="text"/> <input type="text"/> time(s)	<input type="text" value="JSCHEDOV"/>
c. Had urgent care visit(s) (i.e. doctor's office, clinic, not to emergency room)?	<input type="text"/> <input type="text"/> time(s)	<input type="text" value="JUCARE"/>
d. Had an emergency room visit?	<input type="text"/> <input type="text"/> time(s)	<input type="text" value="JERVISIT"/>
e. Had an overnight hospital stay?	<input type="text"/> <input type="text"/> time(s)	<input type="text" value="JINPATNT"/>

6. Since the last clinic visit, how many days has the participant missed from school, work, or household activities, due to illness, injury, or medical care? Include visits related to his/her diabetes. **DO NOT** include scheduled TODAY visits. Round to nearest half day.

a. School	<input type="text"/> <input type="text"/> . <input type="text"/> day (s)	<input type="text" value="JLSTSCH1"/>
b. Work	<input type="text"/> <input type="text"/> . <input type="text"/> day (s)	<input type="text" value="JLSTWRK1"/>
c. Household activities	<input type="text"/> <input type="text"/> . <input type="text"/> day (s)	<input type="text" value="JLSTHOU1"/>

7. Since the last clinic visit, how many days has the participant missed from school, work, or household activities while attending scheduled TODAY visits, including TLP visits? Round to nearest half day.

a. School	<input type="text"/> <input type="text"/> . <input type="text"/> day (s)	<input type="text" value="JLSTSCH2"/>
b. Work	<input type="text"/> <input type="text"/> . <input type="text"/> day (s)	<input type="text" value="JLSTWRK2"/>
c. Household activities	<input type="text"/> <input type="text"/> . <input type="text"/> day (s)	<input type="text" value="JLSTHOU2"/>

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8. Is the participant in school? <sub>1</sub> Yes <sub>0</sub> No

**If YES,**

a. What grade?   grade

JSTUDENT

JGRADE

9. Is the participant employed outside the home? <sub>1</sub> Yes <sub>0</sub> No

**If YES,**

a. How many hours per week?   hours/week

10. Is the participant in a formal weight loss program outside of TODAY? (Examples are programs such as Weight Watchers or Jenny Craig.) <sub>1</sub> Yes <sub>0</sub> No

JEMPLOY

JHRWKS

JWTLOSS

**Study Medication Status**

11. Was the participant supposed to have taken study medication since the last visit? <sub>1</sub> Yes <sub>0</sub> No

**If YES, continue. If NO, skip to question 12.**

a. Number of pills taken since the last visit?    pills

b. Number of pills taken from late returns?    pills

12. Has the participant missed any doses of study medication? <sub>1</sub> Yes <sub>0</sub> No

JMEDS

JRXNMBR

JLATENBR

JMISSRX

**If YES,**

What has gotten in the way with taking study medication as prescribed?

**Check All That Apply**

a. Permanently discontinued study medication <sub>1</sub>

b. Temporarily stopped study medication due to intercurrent illness or other protocol-specified break <sub>1</sub>

c. Forgets to take pills in general <sub>1</sub>

d. Tends to forget to take a particular dose <sub>1</sub>

**If YES,**

Which dose? <sub>1</sub> Morning <sub>2</sub> Evening

e. GI reaction to pills <sub>1</sub>

JDISCRX

JTEMPBRK

JFORGET

JMISSDOS

JMISSPEC

JGIREACT

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f. Believes pills cause weight gain or edema	<input type="checkbox"/> <sub>1</sub>	JWGHTGN
g. Disruption of regular routine due to new personal or family issues	<input type="checkbox"/> <sub>1</sub>	JDISRPT
h. Depressed mood or other psychiatric issue	<input type="checkbox"/> <sub>1</sub>	JDEPRSS
i. Lost/misplaced pills	<input type="checkbox"/> <sub>1</sub>	JLOSTRX
j. Size of pill is a problem	<input type="checkbox"/> <sub>1</sub>	JSIZERX
k. Lack of family support to remember pills	<input type="checkbox"/> <sub>1</sub>	JLACKSUP
l. Sometimes spends a few days away from home	<input type="checkbox"/> <sub>1</sub>	JAWAY
m. No specific reason given	<input type="checkbox"/> <sub>1</sub>	JNOSPEC
13. What strategies has participant used to help remember to take study medication as prescribed?		
<b>Check All That Apply</b>		
a. Taking pills at scheduled time	<input type="checkbox"/> <sub>1</sub>	JSCHEDTM
b. Taking pills at the same time as other activity (e.g., brushing teeth)	<input type="checkbox"/> <sub>1</sub>	JSCHDACT
c. Reminder device	<input type="checkbox"/> <sub>1</sub>	JREMIND
d. Family help with remembering pills	<input type="checkbox"/> <sub>1</sub>	JFAMILY
e. Change in type and/or frequency of TODAY staff communication	<input type="checkbox"/> <sub>1</sub>	JCHGTYP
f. No strategy used	<input type="checkbox"/> <sub>1</sub>	JNOSTRAT