**TINSAL-T2D Form CONMED**
**Concomitant Medication Log**

Clinic CLINIC | Participant ID PATIENT | CMPAGENO | Page No. ⇐ If this is the first time a log entry has been made for this participant, enter 01. If this page is an addition to a log that already exists, enter the next sequential page number.

Nickname CMNICKNA

*Instructions: At the screening visit, list all concomitant medications that the participant is currently taking. At all other visits, update this log with all concomitant medications that the participant has taken since the previous visit, or is currently taking.*

## A. Concomitant Medications

| | Category (a) | Start Date OR Date of change in dose or frequency (mm/dd/yyyy) | End Date OR Last date at this dose and frequency (mm/dd/yyyy) | Dose | Unit | Route (a) |
|---|---|---|---|---|---|---|
| 1. | CMCATEG1 | / / CMSTADT1 | / / CMENDDT1 | CMDOSE1 . | CMUNIT1 | CMROUTE1 |
| | Medication: | | | | CMMEDIC1 | |
| CMFREQ1 | Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h ☐7 Other (specify): | | | | CMFREQS1 | |
| 2. | CMCATEG2 | / / CMSTADT2 | / / CMENDDT2 | CMDOSE2 . | CMUNIT2 | CMROUTE2 |
| | Medication: | | | | CMMEDIC2 | |
| CMFREQ2 | Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h ☐7 Other (specify): | | | | CMFREQS2 | |
| 3 | CMCATEG3 | / / CMSTADT3 | / / CMENDDT3 | CMDOSE3 | CMUNIT3 | CMROUTE3 |
| | Medication: | | | | CMMEDIC3 | |
| CMFREQ3 | Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h ☐7 Other (specify): | | | | CMFREQS3 | |

**(a)** For Category and Route codes, refer to the lists on the next page.

**TINSAL-T2D Form CONMED**
**Concomitant Medications**

| Medication | Category |
|---|---|
| **Antihypertensive agents** (Loop diuretics, thiazide diuretics, K-sparing diuretic agents, potassium supplements, ARBs, ACE inhibitors, dihydropyridine calcium channel blockers, non-dihydropyridine calcium channel blockers, peripheral alpha-blockers, central alpha-adrenergic agonists, beta-blockers, vasodilators, reserpine, etc.) | 01 |
| **Cardiovascular drugs** (digitalis, anti-arrhythmics, nitrates, etc.) | 02 |
| **Lipid-lowering drugs** (Bile acid sequestrants, HMG CoA reductase inhibitors (statins), fibrates, cholesterol absorption inhibitors, niacin, nicotinic acid, etc.) | 03 |
| Oral anticoagulants (warfarin, coumadin, etc). **This is an exclusionary medication. If the participant has not been randomized, discontinue his or her participation in the study. If this is a follow-up visit, STOP study medication. Fill out MEDLOG.** | 04 |
| Heparins. **This is an exclusionary medication. If the participant has not been randomized, discontinue his or her participation in the study. If this is a follow-up visit, STOP study medication. Fill out MEDLOG.** | 05 |
| Inhibitors of platelet aggregation (except aspirin) | 06 |
| Cox-2 inhibitor | 07 |
| Aspirin | 08 |
| Progestins | 09 |
| Estrogens (excluding vaginal creams) | 10 |
| Thyroid agents | 11 |
| Oral asthma drugs (except steroids) | 12 |
| Inhaled steroids for asthma | 13 |

| Medication | Category |
|---|---|
| Antidepressant | 14 |
| Antipsychotic | 15 |
| Erectile dysfunction drugs | 16 |
| Weight loss drug | 17 |
| Steroids | 18 |
| Any other prescribed medication | 19 |
| Vitamins and/or nutritional supplements | 20 |
| Over-the-counter medications | 21 |
| Herbal/alternative therapies | 22 |

| Route | Code |
|---|---|
| Intravenous | IV |
| Intramuscular | IM |
| By mouth | PO |
| Subcutaneous | SC |
| Other | OTH |
| Vagina | PV |
| Each eye | OU |
| Rectal | PR |
| Sublingual | SL |
| Inhaled | INH |
| Topical | TOP |
| Left eye | OD |
| Right eye | OD |

**TINSAL-T2D Form CONSENT**
**Informed Consent Permissions**

Clinic CLINIC | Participant ID PATIENT | Date of Form CONSENT completion (mm/dd/yyyy) CNVISIDT

1. Nickname CNNICKNA

2. Staff ID CNSTAFFI

*Instructions: Indicate which permissions have been given by the participant on his or her informed consent form.*

## Genetic Study Permissions

3. Participant gives permission for his or her DNA and RNA to be collected. ☐1 Yes ☐2 No CNDNARNA

4. Participant gives permission for researchers to make a living line for study. ☐1 Yes ☐2 No CNLIVING

5. Participant gives permission for his or her samples to be sent to the NIDDK Central Repositories. ☐1 Yes ☐2 No CNNIDDK

***(Applicable to Carl T. Hayden VA Medical Center and the University of Nebraska VA Medical Center only.)***

Check one of the following:
CNVAMED

☐1 Participant agrees to allow his or her genetic sample to be studied for genes related to any major disease or health condition or risk factor.

☐2 Participant agrees to allow his or her genetic sample to be studied only for genes related to diabetes, obesity, inflammation, blood pressure, blood cholesterol abnormalities, heart disease, or other risk factors for heart disease or for diabetes or complications of diabetes.

☐3 Participant agrees to allow his or her genetic samples to be used only for this study.

☐4 Participant declines permission to collect his or her DNA and RNA for a genetic sample.

6. Date of participant's signature (mm/dd/yyyy) / / CNSIGNDT

**TINSAL-T2D Form EXERCISE**
**Exercise Questionnaire**

EXVISITI

| Clinic | Participant ID | Visit ID |
|---|---|---|
| CLINIC | PATIENT | |

**BAS=Visit 3**
**W14=Visit 7**
**W26=Visit 9**

| | | |
|---|---|---|
| Nickname | EXNICKNA | |
| Visit date (mm/dd/yyyy) | EXVISITD | / / |
| Staff ID | EXSTAFFI | |

*Instructions: The participant completes this form during Visit 3 (baseline), and during Visit 7 (Stage 1) or Visit 9 (Stage 2)*

1. Which category best describes your main occupation? (check only one) EXOCCUPA
   - ☐ 1 Clerical work, driving, shopkeeping, teaching, studying, housework, medical practice, any occupation requiring a university education
   - ☐ 2 Factory work, plumbing, carpentry, farming (not requiring a university education)
   - ☐ 3 Dock work, construction work, sports (not requiring a university education)

2. How often do you sit at work? EXSIT
   - ☐ 1 Never
   - ☐ 2 Seldom
   - ☐ 3 Sometimes
   - ☐ 4 Often
   - ☐ 5 Always

3. How often do you stand at work? EXSTAND
   - ☐ 1 Never
   - ☐ 2 Seldom
   - ☐ 3 Sometimes
   - ☐ 4 Often
   - ☐ 5 Always

4. How often do you walk at work? EXWALKW
   - ☐ 1 Never
   - ☐ 2 Seldom
   - ☐ 3 Sometimes
   - ☐ 4 Often
   - ☐ 5 Always

5. How often do you lift heavy loads at work?

EXLIFT

- ☐ 1 Never
- ☐ 2 Seldom
- ☐ 3 Sometimes
- ☐ 4 Often
- ☐ 5 Very often

6. How often are you tired after working?

EXTIRED

- ☐ 1 Very often
- ☐ 2 Often
- ☐ 3 Sometimes
- ☐ 4 Seldom
- ☐ 5 Never

7. How often do you sweat at work?

EXSWEATW

- ☐ 1 Very often
- ☐ 2 Often
- ☐ 3 Sometimes
- ☐ 4 Seldom
- ☐ 5 Never

8. In comparison with others of your own age, how much heavier or lighter do you think your work is?

EXHEAVIE

- ☐ 1 Much heavier
- ☐ 2 Heavier
- ☐ 3 As heavy
- ☐ 4 Lighter
- ☐ 5 Much lighter

9. Do you play sports? EXSPORT1 ☐ 1 Yes ☐ 2 No

***If YES,***

a. Which category best describes the sport you play most frequently? (check only one)

EXSPOR1

- ☐ 1 Billiards, sailing, bowling, golf
- ☐ 2 Badminton, cycling, dancing, swimming, tennis
- ☐ 3 Boxing, basketball, football, rugby, rowing, soccer

b. How many hours per week?

EXSPORH1

- ☐ 1 Less than 1 hour
- ☐ 2 Between 1 and 2 hours
- ☐ 3 Between 2 and 3 hours
- ☐ 4 Between 3 and 4 hours
- ☐ 5 More than 4 hours

c. How many months per year?

EXSPORM1

- ☐ 1 Less than 1 month
- ☐ 2 Between 1 and 3 months
- ☐ 3 Between 4 and 6 months
- ☐ 4 Between 7 and 9 months
- ☐ 5 More than 9 months

d. Do you play a second sport?

EXSPORT2

- ☐ 1 Yes
- ☐ 2 No

***If YES,***

i. Which category best describes the sport? (check only one)

EXSPORC2

- ☐ 1 Billiards, sailing, bowling, golf
- ☐ 2 Badminton, cycling, dancing, swimming, tennis
- ☐ 3 Boxing, basketball, football, rugby, rowing, soccer

ii. How many hours per week?

EXSPORH2

- ☐ 1 Less than 1 hour
- ☐ 2 Between 1 and 2 hours
- ☐ 3 Between 2 and 3 hours
- ☐ 4 Between 3 and 4 hours
- ☐ 5 More than 4 hours

iii. How many months per year?

EXSPORM2

- ☐ 1 Less than 1 month
- ☐ 2 Between 1 and 3 months
- ☐ 3 Between 4 and 6 months
- ☐ 4 Between 7 and 9 months
- ☐ 5 More than 9 months

10. How do you think your physical activity during leisure time compares to others of your own age?

EXACTIVI

- ☐ 1 Much more
- ☐ 2 More
- ☐ 3 The same
- ☐ 4 Less
- ☐ 5 Much less

11. How often do you sweat during leisure time?

EXSWEATL

- ☐ 1 Very often
- ☐ 2 Often
- ☐ 3 Sometimes
- ☐ 4 Seldom
- ☐ 5 Never

12. How often do you play sports during leisure time?

EXSPORTL

- ☐ 1 Very often
- ☐ 2 Often
- ☐ 3 Sometimes
- ☐ 4 Seldom
- ☐ 5 Never

13. How often do you watch television or use a computer during leisure time?

EXWATCH

- ☐ 1 Very often
- ☐ 2 Often
- ☐ 3 Sometimes
- ☐ 4 Seldom
- ☐ 5 Never

14. How often do you walk during leisure time?

EXWALKL

- ☐ 1 Very often
- ☐ 2 Often
- ☐ 3 Sometimes
- ☐ 4 Seldom
- ☐ 5 Never

15. How often do you cycle during leisure time?

EXCYCLE

- ☐ 1 Very often
- ☐ 2 Often
- ☐ 3 Sometimes
- ☐ 4 Seldom
- ☐ 5 Never

16. How many minutes do you walk and/or cycle per day to and from work, school or shopping?

EXWALKDY

- ☐ 1 Less than 5 minutes
- ☐ 2 Between 5 and 15 minutes
- ☐ 3 Between 15 and 30 minutes
- ☐ 4 Between 30 and 45 minutes
- ☐ 5 More than 45 minutes

**TINSAL-T2D Form Health History and ROS**
**Health History and Review of Systems**

HHVISIT
HH2VISIT

SCR=Visit 1
RUN=Visit 2
BAS=Visit 3
W02=Visit 4
W04=Visit 5
W08=Visit 6
W14=Visit 7
W16=Visit 8 (Stage 1)
W20=Visit 8 (Stage 2)
W26=Visit 9
W28=Visit 10

Clinic [ ][ ] CLINIC

Participant ID [ ][ ][ ][ ][ ] PATIENT

Visit ID [ ][ ][ ]

1. Nickname [ ][ ][ ][ ][ ][ ][ ] HHNICKNA
2. Staff ID [ ][ ][ ] HHSTAFF

## A. Medical and Health History

*Instructions:*

***If this is the participant's first visit,*** *check all conditions with which the participant has ever been diagnosed by a health care provider. If the participant has been diagnosed with the condition more than once, enter the date of the first diagnosis and the end date of the last episode.*

***If this is not the participant's first visit:***
*(a ) Check all conditions with which a health care provider has diagnosed the participant since the previous visit. For these conditions, enter the date of diagnosis. Also, enter the end date, or check the "check here if continuing" box.*
*(b) Consult the Health History and ROS forms from the participant's previous visits. Ask the participant about conditions that were marked as continuing. If the condition has resolved, enter the end date below. For follow-up visits, complete the Relationship to Drug, Action Taken, Severity, Outcome and Treatment columns as well. If the condition has not resolved, do not make an entry.*

***3. (Not applicable to SCR – Visit 1)***

I verify that I have consulted Section A of the Health History and ROS forms from the participant's previous visits. The participant has confirmed that each condition previously listed, if any, is continuing, unless noted below. The participant also confirms that no new conditions have been diagnosed, other than those listed below.

Staff ID: [ ][ ][ ] HH1ASTAF

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

**TINSAL-T2D Form Health History and ROS**
**Health History and Review of Systems**

Clinic | Participant ID | Visit ID

## A. Medical and Health History

| Check all that apply | Date of onset (a) | End date (a) OR check here if continuing | Relationship to Drug (b) | Action Taken (c) | Sev-erity (d) | Out-come (e) | Treat-ment (f) |
|---|---|---|---|---|---|---|---|
| 4. Eyes, ears, nose and throat | | | Note: for these vars, combine the prefix of the condition with the following numeric suffix | | | | |
| a. Retinopathy requiring laser treatment HHARETI1 | / / HHRETI2 | / HHARETI3 | 4 | 5 | 6 | 7 | 8 | 9 |
| b. Other HHAEYEO1 | / / HHAEYEO2 | / HHAEYEO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 5. Respiratory HHARESP1 | / / HHARESP2 | / HHARESP3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 6. Cardiovascular HHAHIGH1 | | | | | | | | |
| a. High blood pressure | / / HHAHIGH2 | / HHAHIGH3 | 4 | 5 | 6 | 7 | 8 | 9 |
| b. High LDL (>140 mg/dL) HHAHLDL1 | / / HHAHLDL2 | / HHAHLDL3 | 4 | 5 | 6 | 7 | 8 | 9 |
| c. High triglycerides (>150 mg/dL) HHAHTRI1 | / / HHAHTRI2 | / HHAHTRI3 | 4 | 5 | 6 | 7 | 8 | 9 |
| d. Low HDL (males: <40; females: <50 mg/dL) HHALHDL1 | / / HHALHDL2 | / HHALHDL3 | 4 | 5 | 6 | 7 | 8 | 9 |
| e. MI HHAMI1 | / / HHAMI2 | / HHAMI3 | 4 | 5 | 6 | 7 | 8 | 9 |
| f. Angina HHAANGI1 | / / HHAANGI2 | / HHAANGI3 | 4 | 5 | 6 | 7 | 8 | 9 |

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

Clinic | Participant ID | Visit ID

## A. Medical and Health History (continued)

| Check all that apply | Date of onset (a) | End date (a) OR check here if continuing | Relationship to Drug (b) | Action Taken (c) | Severity (d) | Outcome (e) | Treatment (f) |
|---|---|---|---|---|---|---|---|
| g. CABG/PTCA HHACABG1 | HHACABG2 | HHACABG3 | 4 | 5 | 6 | 7 | 8 | 9 |
| h. Other HHACARO1 | HHACARO2 | HHACARO3 | HHACAR4 5 | 6 | 7 | 8 | 9 |
| 7. Gastrointestinal HHAUPPE1 | | | HAUPPE5 | | HAUPPE7 | | HHAUPPE9 |
| a. Upper GI bleed | HHAUPPE2 | HHAUPPE3 | HAUPPE4 | HAUPPE6 | | HAUPPE8 | |
| b. Lower GI bleed HHALOWE1 | HHALOWE2 | HHALOWE3 | 4 | 5 | 6 | 7 | 8 | 9 |
| c. Other HHAGASO1 | HHAGASO2 | HHAGASO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 8. Musculoskeletal HHAMUSC1 | HHAMUSC2 | HHAMUSC3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 9. Neurological | | | | | | | | |
| a. Peripheral neuropathy HHAPERI1 | HHAPERI2 | HHAPERI3 | 4 | 5 | 6 | 7 | 8 | 9 |
| b. Autonomic neuropathy HHAAUTO1 | HHAAUTO2 | HHAAUTO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| c. Other HHANEUO1 | HHANEUO2 | HHANEUO3 | 4 | 5 | 6 | 7 | 8 | 9 |

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

**Health History and Review of Systems**

Clinic | Participant ID | Visit ID

## A. Medical and Health History (continued)

| Check all that apply | Date of onset (a) | End date (a) OR check here if continuing | | Relationship to Drug (b) | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | Action Taken (c) | Sev-erity (d) | Out-come (e) | Treat-ment (f) | |
| 10. Endocrine (other than diabetes) | HHAENDO1 / / HHAENDO2 | / HHAENDO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 11. Hematopoietic / lymphatic | HHAHEMA1 / / HHAHEMA2 | / HHAHEMA3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 12. Dermatologic | ☐ HHADERM1 / / HHADERM2 | / HHADERM3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 13. Psychological | | | | | | | | |
| a. Depression requiring hospitalization | HHADEPR1 / / HHADEPR2 | / HHADEPR3 | 4 | 5 | 6 | 7 | 8 | 9 |
| b. Other HHAPSYO1 | ☐ / / HHAPSYO2 | / HHAPSYO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| 14. Genitourinary | | | | | | | | |
| a. Proteinuria HHAPROT1 | / / HHAPROT2 | / HHAPROT3 | 4 | 5 | 6 | 7 | 8 | 9 |
| b. Other HHAGENO1 | ☐ / / HHAGENO2 | / HHAGENO3 | 4 | 5 | 6 | 7 | 8 | 9 |

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

Clinic | Participant ID | Visit ID

## A. Medical and Health History (continued)

| Check all that apply ⇓ | Date of onset (a) | End date (a) OR check here if continuing ⇓ | | Relationship to Drug (b) ⇓ | Action Taken (c) | Sev-erity (d) | Out-come (e) | Treat-ment (f) |
|---|---|---|---|---|---|---|---|---|
| 15. Other | | | | | | | | |
| a. Specify diagnosis #1 | HHDIAG11 | | | | | | | |
| | / / HHDIAG12 | / / HHDIAG13 | 14 | 15 | 16 | 17 | 18 | 19 |
| b. Specify diagnosis #2 | HHDIAG21 | | | | | | | |
| | / / HHDIAG22 | / / HHDIAG23 | 24 | 25 | 26 | 27 | 28 | 29 |
| c. Specify diagnosis #3 | HHDIAG31 | | | | | | | |
| | / / HHDIAG32 | / / HHADIAG33 | 34 | 35 | 36 | 37 | 38 | 39 |

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

| Clinic | Participant ID | Visit ID |
|---|---|---|
| | | |

## B. Interim History / Review of Symptoms

*Instructions:*

***If this is the participant's first visit,*** *check all symptoms that the participant has experienced within the past 6 months. If the participant has experienced the symptom more than once, enter the onset date of the first episode and the end date of the last episode.*

***If this is not the participant's first visit:***
*(a ) Check all new symptoms that the participant has experienced since the previous visit. For these symptoms, enter the date of onset. Also, enter the end date, or check the "check here if continuing" box.*
*(b) Consult the Health History and ROS forms from the participant's previous visits. Ask the participant about symptoms that were marked as continuing. If the symptom has resolved, enter the end date below. For follow-up visits, complete the Relationship to Drug, Action Taken, Severity, Outcome and Treatment columns as well. If the condition has not resolved, do not make an entry.*

***16. (Not applicable to SCR – Visit 1)***

I verify that I have consulted Section B of the Health History and ROS forms from the participant's previous visits. The participant has confirmed that each symptom previously listed, if any, is continuing, unless noted below. The participant also confirms that no new symptoms have been experienced, other than those listed below.

Staff ID: HH2BSTAF

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

Clinic | Participant ID | Visit ID

## B. Interim History / Review of Symptoms

| Check all that apply | Date of onset (a) | End date (a) OR check here if continuing | | Relationship to Drug (b) | Action Taken (c) | Sev-erity (d) | Out-come (e) | Treat-ment (f) |
|---|---|---|---|---|---|---|---|---|
| 17. Eyes HHBLURR1 | | | | | | | | |
| a. Blurry vision ☐ | HHBLURR2 | HHBLURR3 | 4 | 5 | 6 | 7 | 8 | 9 |
| b. Loss of vision HHLOSSO1 | HHLOSSO2 | HHLOSSO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| c. Dots / flashes HHDOTSF1 | HHDOTSF2 | HHDOTSF3 | 4 | 5 | 6 | 7 | 8 | 9 |
| d. Other HHBEYEO1 ☐ | HHBEYEO2 | HHBEYEO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) HHBEYEOS | | | | | | | | |
| 18. Ears | | | | | | | | |
| a. Earaches HHBEARA1 ☐ | HHBEARA2 | HHBEARA3 | 4 | 5 | 6 | 7 | 8 | 9 |
| b. Infections HHBINFE1 ☐ | HHBINFE2 | HHBINFE3 | 4 | 5 | 6 | 7 | 8 | 9 |
| c. Ringing in the ears HHBRING1 | HHBRING2 | HHBRING3 | 4 | 5 | 6 | 7 | 8 | 9 |
| d. Other HHBEARO1 ☐ | HHBEARO2 | HHBEARO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) HHBEAROS | | | | | | | | |

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

Clinic | Participant ID | Visit ID

## B. Interim History / Review of Symptoms (continued)

| Check all that apply | Date of onset (a) | End date (a) OR check here if continuing | | Relationship to Drug (b) | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Action Taken (c) | Sev-erity (d) | Out-come (e) | Treat-ment (f) |
| **19. Nose / sinuses** | | | | | | | | |
| a. Frequent colds HHBFREQ1 | HHBFREQ2 | HHBFREQ3 | 4 | 5 | 6 | 7 | 8 | 9 |
| b. Stuffiness HHBSTUF1 | HHBSTUF2 | HHBSTUF3 | 4 | 5 | 6 | 7 | 8 | 9 |
| c. Nose bleeds HHBNOSE1 | HHBNOSE2 | HHBNOSE3 | 4 | 5 | 6 | 7 | 8 | 9 |
| d. Runny nose HHRUNN1 | HHBRUNN2 | HHBRUNN3 | 4 | 5 | 6 | 7 | 8 | 9 |
| e. Other HHBNOSO1 ☐ | HHBNOSO2 | HHBNOSO3 | 4 | NNBNOSO5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) | | | | HHBNOSOS | | | | |
| **20. Mouth / throat** | | | | | | | | |
| a. Mouth sores HHBMOUS1 | HHBMOUS2 | HHBMOUS3 | 4 | 5 | 6 | 7 | 8 | 9 |
| b. Hoarseness HHBHOAR1 | HHBHOAR2 | HHBHOAR3 | 4 | 5 | 6 | 7 | 8 | 9 |
| c. Bleeding gums HHBBLEE1 | HHBBLEE2 | HHBBLEE3 | 4 | 5 | 6 | 7 | 8 | 9 |
| d. Other HHBMOUO1 ☐ | HHBMOUO2 | HHBMOUO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) | | | | HHBMOUOS | | | | |

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

Clinic | Participant ID | Visit ID

## B. Interim History / Review of Symptoms (continued)

| Check all that apply | Date of onset (a) | End date (a) OR check here if continuing | Relationship to Drug (b) | Action Taken (c) | Severity (d) | Outcome (e) | Treatment (f) |
|---|---|---|---|---|---|---|---|
| 21. Neck | | | | | | | |
| a. Pain or stiffness HHBNECP1 | HHBNECP2 | HHBNECP3 | HHPNECP5 | HHPNECP6 | HHPNECP7 | HHPNECP8 | HHPNECP9 |
| b. Swollen glands HHBSWOL1 | HHBSWOL2 | HHBSWOL3 | 4 5 | 6 | 7 | 8 | 9 |
| c. Other HHBNECO1 ☐ | HHBNECO2 | HHBNECO3 | 4 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) | | HHBNECOS | | | | | |
| 22. If female | | | | | | | |
| a. Change in cycle HHBCHAN1 | HHBCHAN2 | HHBCHAN3 | 4 5 | 6 | 7 | 8 | 9 |
| b. Other HHBFEMO1 ☐ | HHBFEMO2 | HHBFEMO3 | 4 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) | | HHBFEMOS | | | | | |
| 23. Breasts | | | | | | | |
| a. Lumps HHBLUMP1 ☐ | HHBLUMP2 | HHBLUMP3 | 4 5 | 6 | 7 | 8 | 9 |
| b. Nipple discharge HHBNIPP1 | HHBNIPP2 | HHBNIPP3 | 4 5 | 6 | 7 | 8 | 9 |
| c. Other HHBBREO1 ☐ | HHBBREO2 | HHBBREO3 | 4 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) | | HHBBREOS | | | | | |

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

Clinic | Participant ID | Visit ID

## B. Interim History / Review of Symptoms (continued)

| Check all that apply | Date of onset (a) | End date (a) OR check here if continuing | Relationship to Drug (b) | Action Taken (c) | Severity (d) | Outcome (e) | Treatment (f) |
|---|---|---|---|---|---|---|---|
| 24. Respiratory | | | | | | | |
| a. Frequent cough HHBFREC1 | HHBFREC2 | HHBFREC3 | 4 5 | 6 | 7 | 8 | 9 |
| b. Asthma HHBASTH1 | HHBASTH2 | HHBASTH3 | 4 5 | 6 | 7 | 8 | 9 |
| c. Shortness of breath with exercise HHBSHOE1 | HHBSHOE2 | HHBSHOE3 | 4 HHBSHO5 6 | | HHSHOE7 | 8 | 9 |
| d. Shortness of breath at rest HHBSHOR1 | HHBSHOR2 | HHBSHOR3 | 4 5 | 6 | 7 | 8 | 9 |
| e. Other HHBRESO1 | HHBRESO2 | HHBRESO3 | 4 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) HHBRESOS | | | | | | | |
| 25. Cardiac | | | | | | | |
| a. Palpitations (irregular heart beats) HHBPALP1 | HHBPALP2 | HHBPALP3 | 4 5 | 6 | 7 | 8 | 9 |
| b. Chest pain or discomfort HHBCHES1 | HHBCHES2 | HHBCHES3 | 4 5 | 6 | 7 | 8 | 9 |
| c. Trouble breathing at night HHBTROU1 | HHBTROU2 | HHBTROU3 | 4 5 | 6 | 7 | 8 | 9 |
| d. Swelling in legs or feet HHBSWEL1 | HHBSWEL2 | HHBSWEL3 | 4 5 | 6 | 7 | 8 | 9 |

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

Clinic | Participant ID | Visit ID

## B. Interim History / Review of Symptoms (continued)

| Check all that apply | Date of onset (a) | End date (a) OR check here if continuing | Relationship to Drug (b) | Action Taken (c) | Severity (d) | Outcome (e) | Treatment (f) |
|---|---|---|---|---|---|---|---|
| e. Other HHBCARO1 ☐ | / / HHBCARO2 | / / HHBCARO3 | 4 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) HHBCAROS | | | | | | | |
| 26. Gastrointestinal | | | | | | | |
| a. Heartburn HHBHEAR1 ☐ | / / HHBHEAR2 | / / HHBHEAR3 | 4 5 | 6 | 7 | 8 | 9 |
| b. Trouble swallowing HHBTROS1 | / / HHTROS2 | / / HHBTROS3 | 4 5 | 6 | 7 | 8 | 9 |
| c. Nausea HHBNAUS1 ☐ | / / HHBNAUS2 | / / HHBNAUS3 | 4 5 | 6 | 7 | 8 | HHBAUS9 |
| d. Vomiting HHBVOMI1 ☐ | / / HHBVOMI2 | / / HHBVOMI3 | 4 5 | 6 | 7 | 8 | 9 |
| e. Diarrhea HHBDIAR1 ☐ | / / HHBDIAR2 | / / HHBDIAR3 | 4 HHBIAR5 | 6 | 7 | 8 | 9 |
| f. Bloody stools HHBBLOO1 | / / HHBBLOO2 | / / HHBBLOO3 | 4 5 | 6 | 7 | 8 | 9 |
| g. Constipation HHBCONS1 | / / HHBCONS2 | / / HHBCONS3 | 4 5 | 6 | 7 | 8 | 9 |
| h. Hemorrhoids HHBHEMO1 | / / HHBHEMO2 | / / HHBHEMO3 | 4 5 | 6 | HHBHEOM7 | 8 | 9 |
| i. Excessive thirst or hunger HHBEXCE1 | / / HHBEXCE2 | / / HHBEXCE3 | 4 5 | 6 | 7 | 8 | 9 |
| j. Dark tarry stools HHBDARK1 | / / HHBDARK2 | / / HHBDARK3 | HHBDAR4 5 | 6 | 7 | 8 | 9 |

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

Clinic | Participant ID | Visit ID

## B. Interim History / Review of Symptoms (continued)

| Check all that apply | Date of onset (a) | End date (a) OR check here if continuing | | Relationship to Drug (b) | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | Action Taken (c) | Sev-erity (d) | Out-come (e) | Treat-ment (f) |
| k. Change in bowel habit HHCHAG1 | HHBCHAG2 | HHBCHAG3 | 4 | 5 | 6 | 7 | 8 | 9 |
| l. Other HHBGASO1 ☐ | HHBGASO2 | HHBGASO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) HHBGASOS | | | | | | | | |
| 27. Urinary | | | | | | | | |
| a. Excessive frequency HHBEXCF1 | HHBEXCF2 | HHBEXCF3 | 4 | 5 | 6 | 7 | 8 | 9 |
| b. Bloody urine HHBBLOY1 | HHBBLOY2 | HHBBLOY3 | 4 | 5 | 6 | 7 | 8 | 9 |
| c. Burning or pain on urination HHBBURN1 | HHBBURN2 | HHBBURN3 | 4 | 5 | 6 | 7 | 8 | 9 |
| d. Urgency HHBURGE1 ☐ | HHBURGE2 | HHBURGE3 | 4 | 5 | 6 | 7 | 8 | 9 |
| e. Incontinence HHBINCO1 | HHBINCO2 | HHBINCO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| f. Infections HHBINFC1 | HHBINFC2 | HHBINFC3 | 4 | 5 | 6 | 7 | 8 | 9 |
| g. Waking at night to urinate HHBWAKE1 | HHBWAKE2 | HHBWAKE3 | 4 | 5 | 6 | 7 | 8 | 9 |
| h. Other HHBURIO1 ☐ | HHBURIO2 | HHBURIO3 | 4 | 5 | 6 | 7 | 8 | 9 |

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

Clinic | Participant ID | Visit ID

## B. Interim History / Review of Symptoms (continued)

| Check all that apply ⇓ | Date of onset (a) | End date (a) OR check here if continuing ⇓ | ⇓ | Relationship to Drug (b) Action Taken (c) | Severity (d) | Outcome (e) | Treatment (f) |
|---|---|---|---|---|---|---|---|
| Specify (list additional symptoms in Question 32 if necessary) HHBURIOS | | | | | | | |
| 28. Musculoskeletal | | | | | | | |
| a. Stiffness HHBSTIF1 ☐ | / / HHBSTIF2 | / / HHBSTIF3 | 4 5 | 6 | 7 | 8 | 9 |
| b. Muscle or joint pains HHBMUSC1 | / / HHBMUSC2 | / / HHBMUSC3 | 4 5 | 6 | 7 | 8 | 9 |
| c. Arthritis HHBARTH1 ☐ | / / HHBARTH2 | / / HHBARTH3 | 4 5 | 6 | 7 | 8 | 9 |
| d. Backache HHBBACK1 ☐ | / / HHBBACK2 | / / HHBBACK3 | 4 5 | 6 | 7 | 8 | 9 |
| e. Other HHBMUSO1 ☐ | / / HHBMUSO2 | / / HHBMUSO3 | 4 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) HHBMUSOS | | | | | | | |
| 29. Neurological | | | | | | | |
| a. Fainting / blackouts HHBFAIN1 | / / HHBFAIN2 | / / HHBAIN3 | 4 5 | 6 | 7 | 8 | 9 |
| b. Numbness or tingling HHBNUMB1 | / / HHBNUMB2 | / / HHBNUMB3 | 4 5 | 6 | 7 | HHBNUM8 | HHBNUM9 |
| c. Seizures HHBSEIZ1 ☐ | / / HHBSEIZ2 | / / HHBSEIZ3 | 4 5 | 6 | 7 | 8 | 9 |
| d. Hand tremors HHBHAND1 | / / HHBHAND2 | / / HHBHAND3 | 4 5 | 6 | 7 | 8 | 9 |

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

Clinic | Participant ID | Visit ID

## B. Interim History / Review of Symptoms (continued)

| Check all that apply | | Date of onset (a) | End date (a) OR check here if continuing | | Relationship to Drug (b) Action Taken (c) | Severity (d) | Outcome (e) | Treatment (f) |
|---|---|---|---|---|---|---|---|---|
| e. Nervousness | HHBNERV1 | HHBNERV2 | HHBNERV3 | 4 | 5 | 6 | 7 | 8 | 9 |
| f. Depression | HHBDEPR1 | HHBDEPR2 | HHBDEPR3 | 4 | HHPDEPR5 | HHPDEPR6 | HHPDEPR7 | HHPDEPR8 | HHPDEPR9 |
| g. Other | HHBNEUO1 | HHBNEUO2 | HHBNEUO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) | | HHBNEUOS | | | | | | | |
| 30. Hematologic | | | | | | | | | |
| a. Easy bruising or bleeding | HHBEASY1 | HHBEASY2 | HHBEASY3 | 4 | 5 | 6 | 7 | 8 | 9 |
| b. Other | HHBHEAO1 | HHBHEAO2 | HHBHEAO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) | | HHBHEAOS | | | | | | | |
| 31. General | | | | | | | | | |
| a. Dizzy | HHBDIZZ1 | HHBDIZZ2 | HHBDIZZ3 | 4 | 5 | 6 | 7 | 8 | 9 |
| b. Weakness or fatigue | HHBWEAK1 | HHBWEAK2 | HHBWEAK3 | 4 | 5 | 6 | 7 | 8 | 9 |
| c. Other | HHBGENO1 | HHBGENO2 | HHBGENO3 | 4 | 5 | 6 | 7 | 8 | 9 |
| Specify (list additional symptoms in Question 32 if necessary) | | HHBGENOS | | | | | | | |

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

Clinic | Participant ID | Visit ID

## B. Interim History / Review of Symptoms (continued)

| Check all that apply ⇓ | Date of onset (a) | End date (a) OR check here if continuing ⇓ | Relationship to Drug (b) ⇓ | Action Taken (c) | Sev-erity (d) | Out-come (e) | Treat-ment (f) |
|---|---|---|---|---|---|---|---|

***Use the following question to list additional symptoms from Questions 17 through 31.***

32. Other

HHQUESTA

a. Number of the question above (Questions 17 – 31) to which this symptom applies:

Specify symptom: HHSYMPTA

HHBSYMA2 / / HHBSYMA3 / / 4 5 6 7 8 9

b. Number of the question above (Questions 17 – 31) to which this symptom applies: HHQUESTB

Specify symptom: HHSYMPTB

HHBSYMB2 / / HHBSYMB3 / / 4 5 6 7 8 9

**(a) – (f) Refer to the end of this form for explanation of reference marks and codes.**

| Clinic | Participant ID | Visit ID |
|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐☐ |

## C. Hypoglycemia

| | | Yes | No |
|---|---|---|---|
| 33. | ***(Not applicable to SCR – Visit 1)*** Since the last clinic visit, has the participant experienced episodes of hypoglycemia? HHEPISOD | ☐ | ☐ |
| | ***If YES,*** | | |
| a. | Was this repeated mild hypoglycemia? (blood glucose <60 more than twice/week or 5 times/month) HHREPEAT | ☐ | ☐ |
| b. | Did the participant require help from someone else to bring blood sugar back to normal? (3rd party assistance due to loss of consciousness, confusion or severe lethargy) HHRQHELP | ☐ | ☐ |
| | ➔ *If YES, complete form **SH, Severe Hypoglycemia*** | | |
| c. | How many episodes of hypoglycemia (mild or severe) have occurred since the last clinic visit? HHEPINUM ☐☐ episode(s) | | |

***Reference Marks and Codes:***

**(a) Dates:** Enter date in mm/dd/yyyy format. Enter 06 for month if unknown. Enter 15 for day if unknown. Do not enter date of diagnosis or onset for conditions or symptoms previously reported.

**(b) Relationship to Drug:** To be completed for baseline and follow-up visits only.
1-Definite
2-Probable
3-Possible
4-Unlikely
5-Unrelated

**(c) Action taken:** To be completed for baseline and follow-up visits only.
1-None
2-Discontinued
3-Reduced
4-Interrupted

**(d) Severity:** To be completed for baseline and follow-up visits only.
1- Mild: awareness of symptom but easily tolerated
2- Moderate: discomfort enough to cause interference with usual activity
3- Severe: incapacitating with inability to work or do usual activity

**(e) Outcome:** To be completed for baseline and follow-up visits only.
1-Recovered
2-Resolved, but sequelae / residual effect(s) remain
3-Still present
4-Death

**(f)Treatment:** To be completed for baseline and follow-up visits only.
1-None
2-Medication required; no hospitalization
3-Hospitalization required or prolonged; no medication required
4-Medication required; hospitalization required or prolonged
5-Other

**TINSAL-T2D Form INTERIM**
**Interim visit**

INVISIDT

Clinic (CLINIC) | Participant ID (PATIENT) | Visit date (mm/dd/yyyy)

1. Nickname INNICKNA
2. Staff ID MSTAFFID INSTAFF
3. Visit location INVISLOC ☐1 Phone ☐2 In clinic ☐3 Other medical facility
4. Does visit require physical examination? ☐1 Yes ☐2 No
   *If yes, fill out form PE* INREQPE

*Instructions: Complete at all non-scheduled visits after initial consent.*

## A. Reason for Visit

5. Reason for visit — **Check all that apply**

a. ☐1 Central laboratory test (blood or urine) INREASA
b. ☐1 Follow-up to local laboratory test (i.e., performed by PCP) INREASB
c. ☐1 Adverse event (or suspected AE) INREASC
d. ☐1 Medication dispensing INREASD
e. ☐1 Medical supplies (strips, monitors) INREASE
f. ☐1 Other (specify INREASFS _____) INREASF

## B. Vital Signs

6. Sitting blood pressure — Systolic / Diastolic

***Record BP reading 3 only if first 2 readings vary by more than 10%.***

a. BP reading 1 (after sitting 5 minutes) CSBP1/ INBPS1 ___ / ___ mm INBPD1
b. BP reading 2 (after waiting 1 minute) CSBP2/ INBPS2 ___ / ___ mm INBPD2
c. BP reading 3 (after waiting 1 minute) CSBP3/ INBPS3 ___ / ___ mm INBPD3

7. Heart rate INHEARTR ___ bpm

Clinic ☐☐ Participant ID ☐☐☐☐☐ Visit date (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

## C. Diabetes Medication and Rescue Therapy

8. Is there a change in diabetes therapy other than salsalate? ☐1 Yes ☐2 No INCHANGE

***If YES***,

a. Reason for change: INCHGRE
- ☐1 Adjusted based on home monitoring or by PCP
- ☐2 Met protocol criteria for rescue therapy
- ☐3 Hyperglycemia
- ☐4 Hypoglycemia
- ☐5 Other (specify INCHGRES _____)

b. Date of change in therapy: ☐☐/☐☐/☐☐☐☐ INCHGDT

c. What medication is the participant currently taking?

Metformin ☐1 Yes ☐2 No INMETF

Dose: ☐☐☐☐ mg INMETFD

Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h INMETFF

☐7 Other (specify): ☐☐☐☐☐ INMETFFS

---

Insulin secretagogue ☐1 Yes ☐2 No ININSE

Dose: ☐☐☐☐ mg ININSED

Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h ININSEF

☐7 Other (specify): ☐☐☐☐☐ ININSEFS

---

Insulin ☐1 Yes ☐2 No ININSU

Type: ☐1 Glargine ☐2 NPH/Lente ☐3 Regular
☐4 Humalog /Novalog ☐5 Ultralente ☐6 Other ININSUT

Dose: ☐☐☐ total units per day ININSUD

Clinic ☐☐ Participant ID ☐☐☐☐☐ Visit date (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

## C. Diabetes Medication and Rescue Therapy (continued)

Other ☐1 Yes ☐2 No INOTHE

Specify: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ INOTHES

Dose: ☐☐☐☐ mg INOTHED

Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h INOTHEF

☐7 Other (specify): ☐☐☐☐☐ INOTHEFS

**TINSAL-T2D Form MEDLOG**
**Study Medication Log**

MEPAGENO

Clinic
CLINIC

Participant ID
PATIENT

Page No. ⇐

If this is the first time a log entry has been made for this participant, enter 01. If this page is an addition to a log that already exists, enter the next sequential page number.

Nickname MENICKNA

| Date (mm/dd/yyyy) | Staff ID | Action | Adjust /Stop Reason | Stop Perma-nently? | Total Daily Dose |
|---|---|---|---|---|---|
| 1. / / MEDATE1 | MESTAFF1 | ☐ Start ☐ Adjust ☐ Stop MEACTI1 | MEADJU1 | ☐ Yes ☐ No MESTOP1 | ☐ number of tablets METOTAL1 |
| 2. / / MEDATE2 | MESTAFF2 | ☐ Start ☐ Adjust MEACTI2 | MEADJU2 | ☐ Yes ☐ No MESTOP2 | ☐ number of tablets METOTAL2 |
| 3. / / MEDATE3 | MESTAFF3 | ☐ Start ☐ Adjust MEACTI3 | MEADJU3 | ☐ Yes ☐ No MESTOP3 | ☐ number of tablets METOTAL3 |
| 4. / / MEDATE4 | MESTAFF4 | ☐ Start ☐ Adjust MEACTI4 | MEADJU4 | ☐ Yes ☐ No MESTOP4 | ☐ number of t METOTAL4 |
| 5. / / MEDATE5 | MESTAFF5 | ☐ Start ☐ Adjust MEACTI5 | MEADJU5 | ☐ Yes ☐ No MESTOP5 | ☐ number of tablets METOTAL5 |

Reasons for adjustment:
01 – tinnitus
02 – headache
03 – GI side effects
04 – other side effects

Reasons for discontinuation:
05 – evidence of allergy to medication
06 – acute change in renal function
07 – intolerable adverse event
08 – pregnancy
09 – intercurrent illness (may be transient if condition resolves)
10 – new diagnosis of exclusionary medical condition
11 - other

**TINSAL-T2D Form MH**
**Mild Hypoglycemia**

Clinic CLINIC | Participant ID PATIENT | Date of form completion (mm/dd/yyyy) MHCOMPDT / | Hypoglycemic event number MHNUMBER

If only one MH form is completed for this participant on this date, enter 1.
For multiple forms completed for this participant on this date, use additional MH forms and label 1, 2, 3, etc.

*Instructions: Complete this form each time a participant experiences a mild or moderate hypoglycemia episode.*

1. Nickname MHNICKNA
2. Staff ID MHSTAFFI
3. Date of occurrence or recognition of hypoglycemic event (mm/dd/yyyy) MHOCCUDT /
   a. If date uncertain, check here ⇒ MHUNCERT ☐1
4. Date reported to clinic (mm/dd/yyyy) MHREPODT /

## A. Clinical Manifestation

5. The hypoglycemia was
   a. associated with symptoms. MHSYMPTO ☐1
   b. detected by routine blood glucose monitoring. MHMONITO ☐1

***If ASSOCIATED WITH SYMPTOMS,***

Check all that apply:

i. Hunger MHHUNGER ☐1
ii. Anxiousness MHANXIOU ☐1
iii. Sweating MHSWEAT ☐1
iv. Shakiness MHSHAKIN ☐1
v. Heart pounding MHHEARTP ☐1
vi. Dizziness MHDIZZIN ☐1
vii. Trouble concentrating MHTROCON ☐1
viii. Trouble remembering words MHTROREM ☐1
ix. Other: MHOTHER ☐1

1. Specify: MHOSPE

Note that symptom "Blackout" removed from form; Variable=MHBLACKO

**TINSAL-T2D Form MH**
**Mild Hypoglycemia**

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | Hypoglycemic event number |
|---|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐/☐☐/☐☐☐☐ | ☐ |

## A. Clinical Manifestation (Continued)

x. Were the low sugar symptoms that the participant had while participating in the TINSAL-T2D study similar to previous symptoms? ☐1 Yes ☐2 No MHSIMIL

***If NO,***

1. Describe how the hypoglycemia episode during the study was different from the participant's past experience(s): MHDIFFDE

_____

_____

_____

_____

_____

## B. Blood Glucose Determination

6. Was the blood sugar documented near the time of the hypoglycemia? ☐1 Yes ☐2 No MHBMEAS

***If YES,***

a. What was the glucose value? ☐☐☐ MHGLVALU mg/dl

*If documented more than once, enter the lowest value.*

MHGLTIME
- ☐1 before treating
- ☐2 after treating
- ☐3 unknown

## C. Potential Contributing Factors

7. Note any extenuating circumstances:

a. Missed meal MHMISSME ☐1

b. Greater than usual exercise MHEXERC ☐1

c. Increased dose of medications MHINMEDS ☐1

i. Specify which medications: MHIMSPEC

_____

_____

d. None MHNONE ☐1

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | Hypoglycemic event number |
|---|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐/☐☐/☐☐☐☐ | ☐ |

## C. Potential Contributing Factors (continued)

8. Has the participant previously had hypoglycemic events requiring the assistance of others? ☐1 Yes ☐2 No **MHASSIST**

***If YES,***

a. How many times has the participant needed the help of others? **MHASTIME** ☐☐ times

b. When was the most recent episode of low sugar requiring assistance? **MHASDATE** ☐☐/☐☐/☐☐☐☐

*(mm/dd/yyyy – use 06 if the month is unknown; use 15 if the day is unknown.)*

9. Has the participant had low sugar reactions that did not require the help of others? ☐1 Yes ☐2 No **MHLSREAC**

***If YES,***

a. Did the participant have symptoms in the past with low sugar reactions? ☐1 Yes ☐2 No **MHLSSYMP**

b. Did the participant have low sugar reactions detected by blood glucose monitoring without symptoms? ☐1 Yes ☐2 No **MHLSMONI**

c. About how often has the participant had low sugar reactions in the past 6 months? **MHLSOFTE** ☐☐ times

**MHLSOFTS** ☐1 per week ☐2 per month

10. Did you contact the primary care physician? ☐1 Yes ☐2 No **MHPCP**

a. What was the result? **MHPCPRES**

_____

_____

_____

_____

_____

**TINSAL-T2D Form PD**
**Protocol Deviation**

PDCOMPDT

PDNUMBER

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | Protocol deviation number |
|---|---|---|---|
| CLINIC | PATIENT | / / | |

If only one PD form is completed for this participant on this date, enter 1.
For multiple forms completed for this participant on this date, use additional PD forms and label 1, 2, 3, etc.

1. Nickname PDNICKNA
2. Staff ID MMSTFFID PDSTAFFI

*Instructions: Complete this form for each protocol deviation.*

## Protocol deviation

3. Date of protocol deviation (mm/dd/yyyy) / / PDDEVIDT
4. Nature of deviation (check at least one):
   a. An ineligible participant was randomized without permission from the medical monitor. ☐1 PDRNDWOP
   b. An ineligible participant was randomized with permission from the medical monitor. ☐1 PDRNDWIP
   c. An incorrect dosage was given to the participant. ☐1 PDINCORR
   d. The participant's treatment assignment became unmasked to the clinician(s). ☐1 PDUNMASC
   e. The participant's treatment assignment became unmasked to the participant. ☐1 PDUNMASP
   f. Other (e.g., lab tests not performed, informed consent not signed) ☐1 PDOTHER
5. Details of protocol deviation (include assessment of participant harm, if any):

PDDETAIL

PDDETAI2

**TINSAL-T2D Form PE**
**Physical Examination**

PEVISITD

Clinic (CLINIC) | Participant ID (PATIENT) | Visit date (mm/dd/yyyy)

| | | | |
|---|---|---|---|
| 1. Nickname MSTAFFID | PENICKNA | | |
| 2. Visit ID | PEVISITI | | RUN=Visit 2<br>W14=Visit 7<br>W26=Visit 9<br>INT=Interim |
| 3. Staff ID MSTAFFID | PESTAFFI | | |

*Instructions: Complete physical exam form at run-in, at interim visits (optional) and at the final study visit (Week 14 of Stage 1 or Week 26 of Stage 2).*

## A. General Physical Exam

| | | Normal | Abnormal, not clinically significant | Abnormal, clinically significant |
|---|---|---|---|---|
| 4. HEENT | PEHEENT | ☐ | ☐ | ☐ |
| 5. Thyroid | PETHYROI | ☐ | ☐ | ☐ |
| 6. Lungs | PELUNGS | ☐ | ☐ | ☐ |

a. Auscultation of lungs PEAUSCUL

☐ Normal ☐ Basilar rales only ☐ Rales greater than basilar ☐ Wheezing

| | | Normal | Abnormal, not clinically significant | Abnormal, clinically significant |
|---|---|---|---|---|
| 7. Heart | PEHEART | ☐ | ☐ | ☐ |

a. ***If ABNORMAL, CLINICALLY SIGNIFICANT, specify*** PEHEARTS _____

| | | | | |
|---|---|---|---|---|
| 8. Abdomen | PEABDOME | ☐ | ☐ | ☐ |

a. ***If ABNORMAL,*** hepatomegaly present ☐ Yes ☐ No PEHEPATO

***If this is not a run-in visit, skip to Question 9.***

b. Stool guaiac PESTOOLG ☐ Digital Rectal Exam ☐ Hemoccult card

c. Stool guaiac results PESTOOLR ☐ Normal ☐ Abnormal

***If stool guaiac ABNORMAL,***

d. Specify cause PESTOOLS _____

**TINSAL-T2D Form PE**
**Physical Examination**

Clinic ☐☐ Participant ID ☐☐☐☐☐ Visit date (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐

## A. General Physical Exam (continued)

| | | Normal | Abnormal, not clinically significant | Abnormal, clinically significant |
|---|---|---|---|---|
| 9. Skin | PESKIN | ☐ | ☐ | ☐ |

***If skin ABNORMAL,***

| | | | |
|---|---|---|---|
| a. Acanthosis nigricans | ☐ Yes ☐ No | PEACANTH | |
| b. Rash MRASH | ☐ Yes ☐ No | PERASH | |
| ***If YES,*** | | | |
| i. Possibly drug related? MRASHRX | ☐ Yes ☐ No | PEPOSSIB | |
| ii. Infectious? | ☐ Yes ☐ No | PEINFECT | |

*Excluded if i or ii present at run-in visit*

## B. Edema Exam

| | Left Foot (mark one only) | | Right Foot (mark one only) | |
|---|---|---|---|---|
| 10. Grade pre-tibial edema based on today's visit | ☐ None<br>☐ Trace<br>☐ 2+ | PEEDEMA1 | ☐ None<br>☐ Trace<br>☐ 2+ | PEEDEMA2 |

## C. Foot Exam

| | Left Foot | | | | Right Foot | | | |
|---|---|---|---|---|---|---|---|---|
| 11. Ulceration | PEULCERL ☐ Present | ☐ Absent | | | ☐ Present | ☐ Absent | | PEULCERR |
| 12. Ankle reflexes | PEANKLEL ☐ Present | ☐ Present/ Reinforcement | ☐ Absent | | ☐ Present | ☐ Present/ Reinforcement | ☐ Absent | PEANKLER |
| 13. 10gm filament | PE10GMFL ☐ Present (≥ 8) | ☐ Reduced (1–7) | ☐ Absent (0) | | ☐ Present (≥ 8) | ☐ Reduced (1–7) | ☐ Absent (0) | PE10GMFR |

**TINSAL-T2D Form SAE**
**Serious Adverse Event**

SACOMPDT

SANUMBER

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | SAE number |
|---|---|---|---|
| CLINIC | PATIENT | | |

**If only one SAE form is completed for this participant on this date, enter 1.**
**For multiple forms completed for this participant on this date, use additional SAE forms and label 1, 2, 3, etc.**

1. Nickname SANICKNA
2. Staff ID SASTAFFI

*Instructions: Complete this form within 24 hours of each serious adverse event.*

## Serious Adverse Event Information

3. Event – short description SASDESCR
4. Date reported to clinic (mm/dd/yyyy) SAREPODT
5. Date of onset (mm/dd/yyyy) SAONSEDT
6. Date of resolution (mm/dd/yyyy) SARESODT

or continuing 1 SACONTIN

7. Was SAE anticipated? 1 Yes 2 No SAANTICI
8. Type of adverse event *(check all that apply)*

- 1 Death SATDEATH
- 1 A life-threatening event SATLIFET
- 1 Inpatient hospitalization or prolongation of existing hospitalization SATINPAT
- 1 A persistent or significant disability/incapacity SATPERSI
- 1 A congenital anomaly or birth defect SATCONGE
- 1 Important medical event based upon appropriate medical judgement SATIMPOR

**TINSAL-T2D Form SAE**
**Serious Adverse Event**

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | SAE number |
|---|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐/☐☐/☐☐☐☐ | ☐ |

## Serious Adverse Event Information (continued)

9. Outcome *(check all that apply)*

SAODEC ☐ 1 Deceased

*If Deceased,*

SAODECDT a. Date of death ☐☐/☐☐/☐☐☐☐

SAODECLO b. Location of death

SAOHOSPI ☐ 1 Required or prolonged hospitalization

SAODISAB ☐ 1 Resulted in permanent or severe disability

SAOINTER ☐ 1 Required intervention to prevent permanent damage or disability

10. Relationship to study intervention *(check one)*

☐ 1 Not related

SARELATI ☐ 2 Unlikely

☐ 3 Suspected (reasonable possibility)

☐ 4 Probable

11. Body system affected *(check all that apply)*

SABCIRCU ☐ 1 Circulatory system

☐ 1 Respiratory system SABRESPI

SABNERVO ☐ 1 Nervous system

☐ 1 Musculoskeletal system SABMUSCU

SABSKIN ☐ 1 Skin or subcutaneous tissue

☐ 1 Digestive system SABDIGES

SABGENIT ☐ 1 Genitourinary system

☐ 1 Unknown SABUNKNO

SABOTHE ☐ 1 Other (specify) → SABOTHES

**TINSAL-T2D Form SAE**
**Serious Adverse Event**

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | SAE number |
|---|---|---|---|
| | | / / | |

## Serious Adverse Event Information (continued)

12. Action taken/corrective therapy *(check all that apply)*

SAANONE ☐ 1 None

SAASELFT ☐ 1 Self treatment or OTC therapy

SAAOFFIC ☐ 1 Office, clinic, ER, or outpatient visit

SAAINPAT ☐ 1 Inpatient visit, hospital admission

SAAPRESC ☐ 1 Prescription medication

SAAPROCE ☐ 1 Procedure performed

SAAOTHE ☐ 1 Other *(specify)* → SAAOTHES

13. Action taken regarding coded study medication

SASTUDYM

☐ 1 N/A, previously discontinued ☐ 2 No action taken ☐ 3 Dose reduced

☐ 4 Dose increased ☐ 5 Interrupted ☐ 6 Drug stopped

*If coded study medication stopped for ≥ 72 hours, complete Form **MEDLOG, Coded Study Medication Log***

14. Recovery *(check one)* SARECOVE

☐ 1 Recovered / resolved

☐ 2 Recovering / resolving with no sequelae

☐ 3 Not recovered / not resolved

☐ 4 Recovering / resolving with sequelae

☐ 5 Fatal

☐ 6 Unknown

15. Description of event

SALDESCR

SALDESC2

**TINSAL-T2D Form SAE**
**Serious Adverse Event**

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | SAE number |
|---|---|---|---|
| | | / / | |

## Serious Adverse Event Information (continued)

16. Relevant history *(including preexisting medical conditions)*

SAHISTOR

SAHISTO2

17. List concomitant medications (excluding study medication) taken at the time the event occurred.

| | Medication | Dose | Frequency |
|---|---|---|---|
| a. | SAMEDICA | SADOSEA | SAFREQA |
| b. | SAMEDICB | SADOSEB | SAFREQB |
| c. | SAMEDICC | SADOSEC | SAFREQC |
| d. | SAMEDICD | SADOSED | SAFREQD |

**TINSAL-T2D Form SCREEN**
**Screening and Patient History Form**

Clinic (CLINIC) ☐☐ Participant ID (PATIENT) ☐☐☐☐☐

| | | |
|---|---|---|
| 1. Nickname | SCNICKNA | ☐☐☐☐☐☐ |
| 2. Visit date (mm/dd/yyyy) | SCVISIDT | ☐☐/☐☐/☐☐☐☐ |
| 3. Staff ID | SCSTAFF | ☐☐☐ |

*Instructions: This form is to be completed to assess eligibility for the run-in after the participant has signed the consent for screening. Checking a shaded box indicates that the participant is ineligible. Complete all items on the form even if the participant is ineligible. However, if it is determined that the participant is ineligible before screening labs are drawn, do not collect screening labs or measure vital signs. Leave questions 36-39 blank.*

## A. Demographic Eligibility Criteria

4. Was informed consent signed and dated? SCCONSEN ☐ 1 Yes ☐ 2 No

➔ ***IF NO, STOP.***

5. Age eligibility

a. Date of birth (mm/dd/yyyy) SCDOB ☐☐/☐☐/☐☐☐☐

b. Age: SCAGE ☐☐ years

c. Age 18-74? SCAGE18 ☐ 1 Yes ☐ 2 No

6. Gender SCGENDER ☐ 1 Male ☐ 2 Female

## B. Diabetes Eligibility Criteria

7. Date of diabetes diagnosis (mm/dd/yyyy – mark day as 15 if unknown) ☐☐/☐☐/☐☐☐☐ SCDIAGDT

8. Does the participant have type 1 diabetes (by medical history)? ☐ 1 Yes ☐ 2 No SCTYPE1

9. Has the participant ever experienced ketoacidosis? ☐ 1 Yes ☐ 2 No SCKETOAC

10. Is the participant currently taking insulin, or has the participant used insulin for > 30 days within the past year? ☐ 1 Yes ☐ 2 No SCINSU30

Clinic ☐☐ Participant ID ☐☐☐☐☐

## B. Diabetes Eligibility Criteria (continued)

11. What diabetes medication is the participant currently taking?

Metformin ☐1 Yes ☐2 No SCMETF

Dose: ☐☐☐☐ mg SCMETFD

Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h SCMETFF

☐7 Other (specify): ☐☐☐☐☐ SCMETFFO

---

Insulin secretagogue ☐1 Yes ☐2 No SCINSS

Specify: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ SCINSSS

Dose: ☐☐☐☐ mg SCINSSD

Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h SCINSSF

☐7 Other (specify): ☐☐☐☐☐ SCINNSFO

---

Alpha-glucosidase inhibitor ☐1 Yes ☐2 No SCAGIN

Type: ☐1 Acarbose ☐2 Miglitol SCAGINT

Dose: ☐☐☐☐ mg SCAGIND

Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h SCAGINF

☐7 Other (specify): ☐☐☐☐☐ SCAGINFO

---

DPP-4 inhibitor (Januvia™) ☐1 Yes ☐2 No SCDPP

Dose: ☐☐☐☐ mg SCDPPD

Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h SCDPPF

☐7 Other (specify): ☐☐☐☐☐ SCDPPFO

Clinic ☐☐ Participant ID ☐☐☐☐☐

## B. Diabetes Eligibility Criteria (continued)

Other ☐1 Yes ☐2 No SCOTHE

Specify: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ SCOTHES

Dose: ☐☐☐☐ mg SCOTHED

Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h SCOTHEF

☐7 Other (specify): ☐☐☐☐☐ SCOTHEFS

12. Has the participant taken rosiglitazone (Avandia), pioglitazone (Actos), or extendin-4 (Byetta) in the last 6 months? 1 Yes 2 No SCOTHRX

13. Is the participant on any diabetes therapy other than the following? 1 Yes 2 No SCDBTHER

- Diet and exercise therapy **OR**
- Monotherapy with metformin, an insulin secretagogue, or an alpha-glucosidase inhibitor **OR**
- Low-dose combination of these at ≤ 50% of maximal dose (see "Appendix: Recommended Dosing of Diabetic Medication" in the TINSAL-T2D Protocol) **OR**
- Combination of two of these at ≤ 100% of maximal dose for each **OR**
- Sitagliptin (Januvia™) and metformin

***If NO,***

a. Has dosing been stable for 8 weeks prior to screening? 1 Yes 2 No SCSTABLE

b. Is the participant on combination therapy consisting of two of the following: metformin, an insulin secretagogue, or an alpha-glucosidase inhibitor, **AND** one or both doses are > 50% of maximal dose? 1 Yes 1 No SCMAXDOS

Clinic ☐☐ Participant ID ☐☐☐☐☐

## C. Medical/Historical Eligibility Criteria

*Checking a shaded box indicates that the participant is ineligible.*

| | Yes | No | |
|---|---|---|---|
| 14. The participant is male. ***OR*** The participant is female without child-bearing potential. ***OR*** The participant is female with child-bearing potential and has agreed to use an appropriate contraceptive method (hormonal, IUD, or diaphragm). | 1 | 2 | SCCONTRA |
| 15. History of severe diabetic neuropathy including autonomic neuropathy, gastroporesis, or lower limb ulceration or amputation. | 1 | 2 | SCNEURO |
| 16. Pregnancy or lactation. | 1 | 2 | SCPREGNA |
| 17. Participant requires oral corticosteroids within 3 months or recurrent continuous oral corticosteroid treatment (more than 2 weeks). | 1 | 2 | SCSTER |
| *Note: inhaled or topical corticosteroids are acceptable in moderation at the discretion of the site investigator, with exclusion for excessive use, including suspected adrenal suppression or cushinoid appearance.* | | | |
| 18. Use of weight loss drugs (e.g., Xenical (orlistat), Meridia (sibutramine), Acutrim (phenylpropanol-amine), or similar over the counter medications) within 3 months of screening. | 1 | 2 | SCWTRX |
| 19. Intentional weight loss of ≥ 10 lbs in the previous 6 months. | 1 | 2 | SCWTLOSS |
| 20. Surgery within 30 days of screening. | 1 | 2 | SCSURG |
| 21. History of chronic liver disease including hepatitis B or C. | 1 | 2 | SCLIVER |
| 22. History of peptic ulcer or endoscopy demonstrated gastritis. | 1 | 2 | SCULCER |
| 23. History of acquired immune deficiency syndrome or human immunodeficiency virus (HIV). | 1 | 2 | SCHIV |
| 24. History of malignancy, except participants who have been disease-free for greater than 10 years, or whose only malignancy has been basal or squamous cell skin carcinoma. | 1 | 2 | SCMALIG |

Clinic | Participant ID

## C. Medical/Historical Eligibility Criteria (continued)

| | Yes | No | |
|---|---|---|---|
| 25. New York Heart Association Class III or IV cardiac status or hospitalization for congestive heart failure. | 1 | 2 | SCCHD |
| 26. History of unstable angina, myocardial infarction, cerebrovascular accident, transient ischemic attack or any revascularization – any of these within 6 months. | 1 | 2 | SCCV |
| 27. Uncontrolled hypertension (defined as systolic BP >150 mmHg or diastolic BP >95 mmHg on three or more assessments on more than one day) | 1 | 2 | SCHIBP |
| *Participant may be treated for hypertension and invited to re-screen once in control.* | | | |
| 28. History of drug or alcohol abuse, or current weekly alcohol consumption >10 units/week (1 unit = 1 beer, 1 glass of wine, 1 cocktail containing 1 oz alcohol). | 1 | 2 | SCDRUGS |
| 29. Poor mental function or any other reason to expect participant difficulty in complying with the requirements of the study. | 1 | 2 | SCCOMPLY |
| 30. Previous allergy to aspirin. | 1 | 2 | SCALLERG |
| 31. Chronic or continuous use (daily for more than 7 days) of nonsteroidal anti-inflammatory drugs within the past 2 months. | 1 | 2 | SCNSAID |
| 32. Use of warfarin (Coumadin), clopidogrel (Plavix), dipyridamole (Persantine), heparin or other anticoagulants | 1 | 2 | SCANTICO |
| 33. Use of probenecid (Benemid, Probalan), sulfinpyrazone (Anturane) or other uricosuric agents. | 1 | 2 | SCPROBEN |
| 34. Patient able to complete the study protocol in the opinion of the investigator. | 1 | 2 | SCCOMPLE |
| 35. History of chronic tinnitus. | 1 | 2 | SCTINNIT |

Clinic: ☐☐ Participant ID: ☐☐☐☐☐

## D. Weight and Vital Signs

36. Sitting blood pressure Systolic / Diastolic

**Record BP reading 3 only if first 2 readings vary by more than 10%.**

a. BP reading 1 (after sitting 5 minutes) SCSBP1 ☐☐☐/☐☐☐ mmHg SCDBP1

b. BP reading 2 (after waiting 1 minute) SCSBP2 ☐☐☐/☐☐☐ mmHg SCDBP2

c. BP reading 3 (after waiting 1 minute) SCSBP3 ☐☐☐/☐☐☐ mmHg SCDBP3

*Participants with uncontrolled hypertension (defined as systolic blood pressure >150 mmHg or diastolic blood pressure >95 mmHg on three or more assessments on more than one day) are not eligible.*

37. Heart rate ☐☐☐ bpm SCHEARTR

*If Dinamap® is used for both BP and heart rate, record first heart rate measurement.*

38. Anthropometrics

**For weight, record Measure 3 only if first 2 measurements are not within 0.2 kilograms.**

a. Weight ☐☐☐.☐ kg SCWEIGH1 ☐☐☐.☐ kg SCWEIGH2 ☐☐☐.☐ kg SCWEIGH3

Clinic ☐☐ Participant ID ☐☐☐☐☐

## E. If participant meets all above requirements, proceed with eligibility laboratory screening.

| | Yes | No | |
|---|---|---|---|
| 39. Participant meets laboratory eligibility criteria as follows. | ☐ 1 | ☐ 2 | SCLABEL |

- Serum creatinine ≤1.4 for women and ≤1.5 for men AND eGFR ≥60
  - eGFR (ml/min/1.73m$^2$)=186 x ($S_{cr}$)$^{-1.154}$ x (age)$^{-0.203}$ x (0.742 if female) x (1.210 if African American) (conventional units)
- Hemoglobin ≥12 (males) or ≥10 (females) g/dL
- Platelets ≥100,000 cu mm
- AST (SGOT) ≤ 2.50 x ULN and ALT (SGPT) ≤ 2.50 x ULN
- Total bilirubin ≤1.5 x ULN
- Triglycerides ≤500 mg/dL
- FPG ≤ 225 mg/dL
- HbA1c ≥ 7.5% and ≤ 9.5% (Participant is on combination therapy consisting of two of the following: metformin, an insulin secretagogue, or an alpha-glucosidase inhibitor, **AND** one or both doses are > 50% of maximal dose)
- HbA1c ≥ 7% and ≤ 9.5% (All other participants)
- Urine creatinine ≤300 mcg/mg Cr

a. Date verification received from laboratory (mm/dd/yyyy) ☐☐/☐☐/☐☐☐☐ SCLABDT

## F. Eligibility for Run-in

| | Yes | No | |
|---|---|---|---|
| 40. Participant meets eligibility for run-in ***(All shaded boxes must be blank)*** | ☐ 1 | ☐ 2 | SCELIG |

## G. Participant's Ethnicity

41. Is the participant Spanish/Hispanic/Latino? ☐ 1 Yes ☐ 2 No SCLATIN

**TINSAL-T2D Form SCREEN**
**Screening and Patient History Form**

Clinic

Participant ID

## H. Participant's Race

42. What is the participant's race? ***Mark one or more races to indicate what this person considers himself/herself to be.***

a. ☐ 1 White SCWHITE

b. ☐ 1 Black or African American SCBLACK

c. ☐ 1 American Indian or Alaska Native SCAIAN

d. ☐ 1 Asian SCASIAN

e. ☐ 1 Hawaiian or Pacific Islander SCHIPI

f. ☐ 1 Some other race. SCORACE
***Print race*** ⇒ SCORACES

## I. Family History

43. Is there a history of any of the following conditions in the participant's biological father?

| | Yes, before age 60 | Yes, age 60 or older | Yes, age unknown | No | Unknown | |
|---|---|---|---|---|---|---|
| a. Coronary heart disease, heart attack, or stroke | 1 | 2 | 3 | 4 | 5 | SCFHXCVD |
| b. Type 1 diabetes | 1 | 2 | 3 | 4 | 5 | SCFHXT1D |
| c. Type 2 diabetes | 1 | 2 | 3 | 4 | 5 | SCFHXT2D |

Clinic ☐☐ Participant ID ☐☐☐☐☐

## I. Family History (continued)

44. Is there a history of any of the following conditions in the participant's biological mother?

| | Yes, before age 60 | Yes, age 60 or older | Yes, age unknown | No | Unknown | |
|---|---|---|---|---|---|---|
| a. Coronary heart disease, heart attack, or stroke | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SCMHXCVD |
| b. Type 1 diabetes | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SCMHXT1D |
| c. Type 2 diabetes | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SCMHXT2D |

45. Is there a history of any of the following conditions in the participant's biological siblings?

| | Yes. Occurred in at least one sibling before age 60 | Yes. Did not occur in any sibling before age 60 | Yes, age(s) unknown | No | Unknown | |
|---|---|---|---|---|---|---|
| a. Coronary heart disease, heart attack, or stroke | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SCSHXCVD |
| b. Type 1 diabetes | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SCSHXT1D |
| c. Type 2 diabetes | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SCSHXT2D |

**TINSAL-T2D Form SF-36 (English)**
**Health Status Survey**

SFVISIT

**Clinic** CLINIC | **Participant ID** PATIENT | **Visit ID**

**BAS=Visit 3**
**W14=Visit 7**
**W26=Visit 9**

| | | | |
|---|---|---|---|
| 1. | Nickname | SFNICKNA | |
| 2. | Visit date (mm/dd/yyyy) WVISDT | SFVISITD | / / |
| 3. | Staff ID WSTAFFID | SFSTAFFI | |

*Instructions: The following pages are to be completed by the patient.*



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**TINSAL-T2D Form SF-36 (English)**
**Health Status Survey**

| Clinic | Participant ID | Visit ID |
|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐☐ |

**BAS=Visit 3**
**W14=Visit 7**
**W26=Visit 9**

# Your Health and Well-Being

*Instructions: This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities. Thank you for completing this survey!*

*For each of the following questions, please mark an ☒ in the one box that best describes your answer.*

1. In general, would you say your health is: SFHEALTH

- ☐ 1 Excellent
- ☐ 2 Very Good
- ☐ 3 Good
- ☐ 4 Fair
- ☐ 5 Poor

2. Compared to one year ago, how would you rate your health in general now? SFLASTYR

- ☐ 1 Much better now than one year ago
- ☐ 2 Somewhat better now than one year ago
- ☐ 3 About the same as one year ago
- ☐ 4 Somewhat worse now than one year ago
- ☐ 5 Much worse now than one year ago



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**TINSAL-T2D Form SF-36 (English)**
**Health Status Survey**

| Clinic | Participant ID | Visit ID |
|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐☐ |

**BAS=Visit 3**
**W14=Visit 7**
**W26=Visit 9**

3. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

| Activities: | Yes, limited a lot | Yes, limited a little | No, not limited at all | |
|---|---|---|---|---|
| a. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports | 1 | 2 | 3 | SFVIGORO |
| b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf | 1 | 2 | 3 | SFMODERA |
| c. Lifting or carrying groceries | 1 | 2 | 3 | SFLIFTIN |
| d. Climbing several flights of stairs | 1 | 2 | 3 | SFCLIMBS |
| e. Climbing one flight of stairs | 1 | 2 | 3 | SFCLIMB1 |
| f. Bending, kneeling, or stooping | 1 | 2 | 3 | SFBENDIN |
| g. Walking more than a mile | 1 | 2 | 3 | SFWALK1M |
| h. Walking several hundred yards | 1 | 2 | 3 | SFWALKSB |
| i. Walking one hundred yards | 1 | 2 | 3 | SFWALK1B |
| j. Bathing or dressing yourself | 1 | 2 | 3 | SFBATHIN |



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4. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time | |
|---|---|---|---|---|---|---|
| a. Cut down the amount of time you spent on work or other activities | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SF4CUTDO |
| b. Accomplished less than you would like | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SF4ACCOM |
| c. Were limited in the kind of work or other activities | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SF4LIMIT |
| d. Had difficulty performing the work or other activities (for example, it took extra effort) | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SF4DIFFI |

5. During the past 4 weeks, how much of the time have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time | |
|---|---|---|---|---|---|---|
| a. Cut down the amount of time you spent on work or other activities | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SF5CUTDO |
| b. Accomplished less than you would like | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SF5ACCOM |
| c. Did work or other activities less carefully than usual | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SF5LESSC |



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6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

- ☐ 1 Not at all
- ☐ 2 Slightly
- ☐ 3 Moderately
- ☐ 4 Quite a bit
- ☐ 5 Extremely

SFSOCIEX

7. How much bodily pain have you had during the past 4 weeks?

- ☐ 1 None
- ☐ 2 Very mild
- ☐ 3 Mild
- ☐ 4 Moderate
- ☐ 5 Severe
- ☐ 6 Very severe

SFPAIN



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8. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?

| | | |
|---|---|---|
| 1 | Not at all | |
| 2 | A little bit | SFINTERF |
| 3 | Moderately | |
| 4 | Quite a bit | |
| 5 | Extremely | |

9. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks -

| | All of the time | Most of the time | Some of the time | A Little of the time | None of the time | |
|---|---|---|---|---|---|---|
| a. Did you feel full of life? | 1 | 2 | 3 | 4 | 5 | SFFULPEP |
| b. Have you been very nervous? | 1 | 2 | 3 | 4 | 5 | SFNERVOU |
| c. Have you felt so down in the dumps that nothing could cheer you up? | 1 | 2 | 3 | 4 | 5 | SFDUMPS |
| d. Have you felt calm and peaceful? | 1 | 2 | 3 | 4 | 5 | SFCALM |
| e. Did you have a lot of energy? | 1 | 2 | 3 | 4 | 5 | SFENERGY |



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(SF-36v2 Standard, US Version 2.0)

| Clinic | Participant ID | Visit ID |
|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐☐ |

**BAS=Visit 3**
**W14=Visit 7**
**W26=Visit 9**

| | All of the time | Most of the time | Some of the time | A little of the time | None of the time | |
|---|---|---|---|---|---|---|
| f. Have you felt downhearted and depressed? | 1 | 2 | 3 | 4 | 5 | SFBLUE |
| g. Did you feel worn out? | 1 | 2 | 3 | 4 | 5 | SFWORN |
| h. Have you been a happy person? | 1 | 2 | 3 | 4 | 5 | SFHAPPY |
| i. Did you feel tired? | 1 | 2 | 3 | 4 | 5 | SFTIRED |

10. During the <u>past 4 weeks</u>, how much of the time have your <u>physical health or emotional problems</u> interfered with your social activities (like visiting with friends, relatives, etc.)?

- ☐ 1 All of the time
- ☐ 2 Most of the time
- ☐ 3 Some of the time — SFSOCITM
- ☐ 4 A little of the time
- ☐ 5 None of the time



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(SF-36v2 Standard, US Version 2.0)

**TINSAL-T2D Form SF-36 (English)**
**Health Status Survey**

| Clinic | Participant ID | Visit ID |
|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐☐ |

**BAS=Visit 3**
**W14=Visit 7**
**W26=Visit 9**

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

| | Definitely True | Mostly True | Don't Know | Mostly False | Definitely False | |
|---|---|---|---|---|---|---|
| a. I seem to get sick a little easier than other people | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SFSICK |
| b. I am as health as anybody I know | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SFHELTHY |
| c. I expect my health to get worse | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SFWORSE |
| d. My health is excellent | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | SFEXCELL |

***THANK YOU FOR COMPLETING THESE QUESTIONS!***



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(SF-36v2 Standard, US Version 2.0)

**TINSAL-T2D Form SH**
**Severe Hypoglycemia**

SHCOMPDT

SHNUMBER

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | Hypoglycemic event number |
|---|---|---|---|
| CLINIC | PATIENT | | |

If only one SH form is completed for this participant on this date, enter 1.
For multiple forms completed for this participant on this date, use additional SH forms and label 1, 2, 3, etc.

*Instructions: Complete this form each time a participant experiences a severe hypoglycemia episode requiring assistance as specified in Chapter 8 of the Manual of Operations.*

1. Nickname SHNICKNA
2. Staff ID SHSTAFFI
3. Date of occurrence or recognition of hypoglycemic event (mm/dd/yyyy) SHOCCUDT
   a. If date uncertain, check here ⇒ ☐1 SHUNCERT
4. Date reported to clinic (mm/dd/yyyy) SHREPODT

## A. Clinical Manifestation

5. Check all symptoms or signs which occurred:

| | | | |
|---|---|---|---|
| a. | SHSLOSSC | ☐1 | Loss of consciousness |
| b. | SHSSEIZU | ☐1 | Seizure |
| c. | SHSSUSPE | ☐1 | Suspected seizure |
| d. | SHSUNUSU | ☐1 | Unusual difficulty in awakening |
| e. | SHSIRRAT | ☐1 | Irrational |
| f. | SHSUNCON | ☐1 | Uncontrollable behavior |
| g. | SHSCONFU | ☐1 | Confusion |
| h. | SHSMEMOR | ☐1 | Memory loss |
| i. | SHSOTHE | ☐1 | Other, specify: SHSOTHES _____ _____ _____ |
| j. | SHSNONE | ☐1 | None |

**TINSAL-T2D Form SH**
**Severe Hypoglycemia**

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | Hypoglycemic event number |
|---|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐/☐☐/☐☐☐☐ | ☐ |

## B. Blood Glucose Determination

6. Was the blood glucose measured BEFORE treatment? SHBMEASD ☐1 Yes ☐2 No ☐3 Unknown

***If YES***,

a. By whom? SHBBYWHO
☐1 Participant
☐2 Medical care personnel
☐3 Other

b. Record measurement ☐☐☐ mg/dl SHBMEAST
OR, if UNKNOWN, check here ⇒ ☐1 SHBUNKNO

c. Method used SHBMETHO
☐1 Blood glucose monitoring -- meter
☐2 Lab determination (plasma)

7. Was the blood glucose measured AFTER treatment? SHAMEASD ☐1 Yes ☐2 No ☐3 Unknown

***If YES***,

a. By whom? SHABYWHO
☐1 Participant
☐2 Medical care personnel
☐3 Other

b. Record measurement ☐☐☐ mg/dl SHAMEAST
OR, if UNKNOWN, check here ⇒ ☐1 SHAUNKNO

c. Method used SHAMETHO
☐1 Blood glucose monitoring -- meter
☐2 Lab determination (plasma)

**TINSAL-T2D Form SH**
**Severe Hypoglycemia**

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | Hypoglycemic event number |
|---|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐/☐☐/☐☐☐☐ | ☐ |

## C. Treatment of Clinical Manifestation

8. Did the symptoms reverse without treatment? SHREVERS ☐1 Yes ☐2 No ☐3 Unknown

9. Was the participant hospitalized or treated in an emergency room or other medical facility? SHHOSPIT ☐1 Yes ☐2 No ☐3 Unknown

10. Treatment administered: (check all that apply)

a. SHTINTRA ☐1 Intravenous glucose

b. SHTGLUCA ☐1 Glucagon

c. SHTORALC ☐1 Oral carbohydrates

d. SHTOTHE ☐1 Other, describe: SHTOTHES

_____

_____

## D. Associated Events

11. Did any of the following occur with the hypoglycemic event described above? ☐1 Yes ☐2 No SHDEVENT

***If YES***, check all that apply:

a. SHDDEATH ☐1 Death

b. SHDNEURO ☐1 Neurological insult requiring hospitalization

c. SHDMYOCA ☐1 Myocardial infarction

d. SHDSTROK ☐1 Stroke

e. SHDINPAR ☐1 Injury to the participant requiring hospitalization

f. SHDINPER ☐1 Injury to another person

g. SHDPROPE ☐1 Property damage

h. SHDTRAFF ☐1 Traffic violation

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | Hypoglycemic event number |
|---|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐/☐☐/☐☐☐☐ | ☐ |

## E. Diurnal Frequency

12. Indicate the time of the onset of the episode (best estimate):

a. Indicate the period in which the episode began SHEPERIO

- ☐1 12:00 a.m. – 3:59 a.m.
- ☐2 4:00 a.m. – 7:59 a.m.
- ☐3 8:00 a.m. – 11:59 a.m.
- ☐4 12:00 p.m. – 3:59 p.m.
- ☐5 4:00 p.m. – 7:59 p.m.
- ☐6 8:00 p.m. – 11:59 p.m.
- ☐7 Unknown

b. If KNOWN, record the time ☐☐:☐☐ o'clock SHETIME

☐1 a.m. ☐2 p.m. SHEAMPM

OR, if UNKNOWN, check here ⇒ ☐1 SHEUNKNO

13. Onset of hypoglycemia occurred while participant was ☐1 Asleep ☐2 Awake SHEONSET

## F. Description of the Event

14. Participant's location at onset of episode: SHFLOCA

- ☐1 Home
- ☐2 Work
- ☐3 School
- ☐4 Automobile
- ☐5 Unknown
- ☐6 Other, specify: SHFLOCAS

_____

_____

_____

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | Hypoglycemic event number |
|---|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐/☐☐/☐☐☐☐ | ☐ |

## F. Description of the Event (continued)

15. If participant was awake,

a. Were warning signs or symptoms present prior to the episode? SHFWARNI ☐1 Yes ☐2 No ☐3 Unknown

***If YES***,

b. Were these recognized as symptoms of hypoglycemia by the participant? ☐1 Yes ☐2 No ☐3 Unknown SHFREPAR

c. Another person? ☐1 Yes ☐2 No ☐3 Unknown SHFREPER

## G. Potential Contributing Factors

16. Characterize the participant's exercise preceding the hypoglycemic event:

a. Exercise during the same four-hour period in Item 12a SHGXSAME

☐1 None
☐2 Sedentary
☐3 Moderate
☐4 Strenuous
☐5 Unknown

b. Was this unusual for this participant? SHGXSAMU ☐1 Yes ☐2 No ☐3 Unknown

c. Exercise during the previous 24 hours excluding the four-hour period in Item 12a SHGXPREV

☐1 None
☐2 Sedentary
☐3 Moderate
☐4 Strenuous
☐5 Unknown

d. Was this unusual for this participant? SHGXPREU ☐1 Yes ☐2 No ☐3 Unknown

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) | Hypoglycemic event number |
|---|---|---|---|
| ☐☐ | ☐☐☐☐☐ | ☐☐/☐☐/☐☐☐☐ | ☐ |

## G. Potential Contributing Factors (continued)

17. Characterize the participant's diet preceding this hypoglycemic event: (check all that apply)

a. During the same four-hour period in Item 12a

| | Meal | Snack | Unknown |
|---|---|---|---|
| Missed | ☐ SHG04MIM | ☐ SHG04MIS | ☐1 SHG04MIU |
| Delayed | ☐ SHG04DEM | ☐ SHG04DES | ☐1 SHG04DEU |
| Ate less than usual | ☐ SHG04ATM | ☐ SHG04ATS | ☐1 SHG04ATU |

b. During the previous 24 hours excluding the four-hour period in Item 12a

| | Meal | Snack | Unknown |
|---|---|---|---|
| Missed | ☐ SHG24MIM | ☐ SHG24MIS | ☐1 SHG24MIU |
| Delayed | ☐ SHG24DEM | ☐ SHG24DES | ☐1 SHG24DEU |
| Ate less than usual | ☐ SHG24ATM | ☐ SHG24ATS | ☐1 SHG24ATU |

18. Any alcohol or other recreational drug consumption preceding hypoglycemic event?

a. During the same four-hour period in Item 12a SHGALC04 ☐1 Yes ☐2 No ☐3 Unknown

b. During the previous 24 hours excluding the four-hour period in Item 12a SHGALC24 ☐1 Yes ☐2 No ☐3 Unknown

19. Were other potentially contributing factors present? SHGOTHE ☐1 Yes ☐2 No ☐3 Unknown

***If YES,*** specify _____

SHGOTHES

_____

_____

**TINSAL-T2D Form STATUS**
**Participant Study Status**

| Clinic | Participant ID | Date of form completion (mm/dd/yyyy) |
|---|---|---|
| CLINIC | PATIENT | STCOMPDT |

1. Nickname STNICKNA

2. Date of change of status or death (mm/dd/yyyy) STCHANDT

3. Staff ID STSTAFFI

*Instructions: Update this form each time the participant changes study status beginning with run-in. If coded study medications are stopped for ≥ 72 hours, complete form* ***MEDLOG.***

## Status change information

4. Updated status STUPDATE

1 Withdrawal (e.g., actively and formally withdrew consent, unwilling to continue)

2 Deceased → *Complete* ***SAE Tracker*** *on the TINSAL-T2D website*

***If withdrawal (status=1), continue. Otherwise, STOP.***

5. Primary reason for withdrawal status: ***(Check one)*** STREASON

1 Side effects of treatment(s)

2 Participant discomfort with returning to study, discomfort or conflict with study staff

3 Study burden

4 Transportation

5 Family issues

6 School issues

7 Jail or other residential treatment facility

8 Safety for participant or staff (e.g., inappropriate behavior, alcohol or drug abuse)

9 Moved, unable to continue with TINSAL-T2D or no forwarding address

10 Pregnancy

11 Other (specify: _____ STSPECIF _____ )

**TINSAL-T2D Form VISIT**
**Run-In, Baseline and Follow-Up Visits**

| Clinic | Participant ID | VVISID Visit ID |
|---|---|---|
| CLINIC | PATIENT | |

RUN=Visit 2
BAS=Visit 3
W02=Visit 4
W04=Visit 5
W08=Visit 6
W14=Visit 7
W16=Visit 8 (Stage 1)
W20=Visit 8 (Stage 2)
W26=Visit 9
W28=Visit 10

1. Nickname VNICKNA
2. Visit date (mm/dd/yyyy) VVISIDT __/__/____
   a. or, check here if the visit was missed: ☐1 VMISS
3. Staff ID VSTAFF
4. For visit W16 only, check here if conducted over the phone ☐1 VLOC

*Instructions: Complete this form for all participants for all run-in, baseline and follow-up visits. If a participant misses a visit, provide the information above, other than "visit date", and leave the fields below blank.*

5. ***(Not applicable to Run-in, Visit 2)*** Did the participant present to the site after an overnight fast? ☐1 Yes ☐2 No VFAST

   *If NO, do not collect a blood sample. Reschedule the blood draw within 3 days. When the blood sample is collected, update this form with the date of the blood draw.*

   Date of blood draw (mm/dd/yyyy) VRESCHED __/__/____

## A. Height, Weight and Vital Signs

6. Sitting blood pressure Systolic / Diastolic

***Record BP reading 3 only if first 2 readings vary by more than 10%.***

a. BP reading 1 (after sitting 5 minutes) VSYS1 ___/___ mmHg VDIA1
b. BP reading 2 (after waiting 1 minute) VSYS2 ___/___ mmHg VDIA2
c. BP reading 3 (after waiting 1 minute) VSYS3 ___/___ mmHg VDIA3

7. Heart rate VHR ___ bpm

***If Dinamap® is used for both BP and heart rate, record first heart rate measurement***

Clinic ☐☐ Participant ID ☐☐☐☐☐ Visit ID ☐☐☐

## A. Height, Weight and Vital Signs (continued)

8. Anthropometrics

***For weight, record Measure 3 only if first 2 measurements are not within 0.2 kilograms.***

a. Weight

| VWEIGHT1 | VWEIGHT2 | VWEIGHT3 |
|---|---|---|
| ☐☐☐.☐ kg | ☐☐☐.☐ kg | ☐☐☐.☐ kg |

***For height, record Measure 3 only if first 2 measurements are not within 0.5 centimeters. Record height at baseline visit only (Visit 3).***

b. Height

| VHEIGHT1 | VHEIGHT2 | VHEIGHT3 |
|---|---|---|
| ☐☐☐.☐ cm | ☐☐☐.☐ cm | ☐☐☐.☐ cm |

***Waist circumference is measured until 2 values are not more than 1 centimeter apart. Record measurements until two of the values differ by no more than 1 centimeter. Circle the two values. Record waist at baseline and final visits only (Visits 3 and 7 for Stage 1; Visits 3 and 9 for Stage 2).***

c. Waist circumference

| | VWAIST2 | VWAIST3 |
|---|---|---|
| VWAIST1 ☐☐☐.☐ cm | ☐☐☐.☐ cm | ☐☐☐.☐ cm |
| VWAIST4 ☐☐☐.☐ cm | ☐☐☐.☐ cm | VWAIST5 |

9. Examiner IDs a. BP: ☐☐☐ VBPID b. HR: ☐☐☐ VHRID c. Anthropometrics: ☐☐☐ VANTHID

## B. Diabetes Medication and Rescue Therapy

10. Is there a change in diabetes therapy other than salsalate? ☐1 Yes ☐2 No VNEWRX

***If YES***,

a. Reason for change: VREASON

- ☐1 Adjusted based on home monitoring or by PCP
- ☐2 Met protocol criteria for rescue therapy
- ☐3 Hyperglycemia
- ☐4 Hypoglycemia
- ☐5 Other (specify VREASONS _____)

b. Date of change in therapy: ☐☐/☐☐/☐☐☐☐ VCHGTHDT

Clinic ☐☐ Participant ID ☐☐☐☐☐ Visit ID ☐☐☐

## B. Diabetes Medication and Rescue Therapy (continued)

c. What medication is the participant currently taking?

Metformin ☐1 Yes ☐2 No VMETFO

Dose: ☐☐☐☐ mg VMETFOD

Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h VMETFOF

☐7 Other (specify): ☐☐☐☐☐ VMETFOFS

---

Insulin secretagogue ☐1 Yes ☐2 No VINSUS

Dose: ☐☐☐☐ mg VINSUSD

Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h VINSUSF

☐7 Other (specify): ☐☐☐☐☐ VINSUSFS

---

Insulin ☐1 Yes ☐2 No VINSUL

Type: ☐1 Glargine ☐2 NPH/Lente ☐3 Regular VINSULT

☐4 Humalog /Novalog ☐5 Ultralente ☐6 Other

Dose: ☐☐☐ total units per day VINSULD

---

Other ☐1 Yes ☐2 No VCHOTH

Specify: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ VCHOTHS

Dose: ☐☐☐☐ mg VCHOTHD

Frequency: ☐1 QD ☐2 BID ☐3 TID ☐4 PRN ☐5 QID ☐6 Q4h VCHOTHF

☐7 Other (specify): ☐☐☐☐☐ VCHOTHFS

| Clinic | Participant ID | Visit ID |
|---|---|---|
| | | |

## C. Medication Dispensation

11. ***(Not applicable to Run-in, Visit 2)*** Number of tablets returned: ☐☐☐ tablets VTABRET

***Note: If the medication dose has changed, complete Form MEDLOG.***

12. ***(Not applicable to Run-in, Visit 2)*** Medication adherence rate: ☐☐☐ % VADHER

$$\frac{(\#\ \text{capsules dispensed} - \#\ \text{capsules returned}) * 100}{\#\ \text{of pills that should have been taken}}$$

*If < 80% on baseline visit, then participant is ineligible.*

a. If the participant has completed a 2-week extension of the run-in period as described in the MOP, enter the 2-week adherence rate here: ☐☐☐ % VADHER2

*If < 90% during 2-week extension, then participant is ineligible.*

13. ***(Not applicable to W14, Visit 7, or W16, Visit 8, for Stage 1. Not applicable to W26, Visit 9, or W28, Visit 10, for Stage 2)***

a. Number of tablets dispensed on this visit: ☐☐☐ tablets VTABDISP

b. ***(Applicable to Run-in, Visit 2, only)*** Bottle number: ☐☐☐☐ VBOTTLE

c. ***(Not applicable to Run-in, Visit 2)*** Kit ID from which tablets were dispensed: ☐☐☐ V_KITID