Manual of Procedures (MOP)
Section 15. Data Management
Appendix 2. Sample e-CRFs and Completion Guidelines

Table of Contents

Subject Form 3
Visit Date Form 3
Screening Inclusion Exclusion Criteria 4
Baseline Inclusion/Exclusion Criteria Form 7
Consent and Enrollment Form 9
Demographics Form 12
Visit Other Data Forms 15
- Screening Visit Other Data 15
- Baseline Visit Other Data 16
- M03 Visit Other Data 19
- Annual Visit Other Data 20
- Unscheduled-Confirmatory Other Data 24

Vital Signs Form 26
Medical History Form 27
Physical Examination Form 29
Concomitant Medications 30
Local Laboratory Forms 32
- Screening Local Laboratory Form 32
- Safety Local Laboratory 34

Central Laboratory Forms 35
- Baseline and Annual Central Laboratory Form 35
- M03 Central Laboratory 37
- Semi Annual Central Laboratory Form 38
- Central Laboratory Confirmatory Tests 39
- Central Laboratory Upload 41

Physical Activity Questionnaire Form 42
Quality of Life 49

PROMIS-29 49
Study Pill Distribution 52
Discontinuation of Study Pills 53
Non-Visit Contact 54
Scheduled Contact 55
End of Study Telephone Contact 56
Call Log 57
Study Completion 58
Adverse Events 59
Diabetes Adjudication 63
Diabetes Outcome 66

Subject Form

Participant Initials ☐

If previously screened under different enrollment ID, enter prior ID number: ☐

Please confirm that you would like to enroll participant in the D2d Study before you SAVE this form. The Enrollment ID number will be generated by the system after this form is Saved.

Enrollment ID

A participant who is screened 6 months after the initial screening visit should be entered as a new participant and receive a new ID number. Enter original 6 digit screening ID here.

Visit Date Form

The Visit Date Form must be completed prior to entering any other visit data.

Visit Date ☐ / ☐ ▼ / ☐

dd MMM yyyy

Encounter Type ❍ Visit ❍ Non-visit encounter

Screening Inclusion Exclusion Criteria

If the Screening visit ended early due to meeting an exclusion criterion, fill in as much information as is known, leaving the rest blank. This will help the CC determine why people are excluded. Select "No" for participant eligibility at the end of the form.

Inclusion Criteria

Meets D2d protocol or site-specific glycemic inclusion criteria? ❍ Yes ❍ No

Age ≥ 30 years (25 if American-Indian, Alaska Native, Native Hawaiian or Other Pacific Islander) ❍ Yes ❍ No

Body Mass Index ≥ 24.0 (22.5 kg/m^2 for Asians) and ≤ 42.0 kg/m^2 ❍ Yes ❍ No

Provision of signed and dated written informed consent prior to any study procedures ❍ Yes ❍ No

Exclusion Criteria

Diabetes or hyperglycemia based on either of the following criteria. If yes, indicate which of the following applies: ❍ Yes ❍ No

A. History (past 1 year) of hypoglycemic pharmacotherapy (oral or injectable medications approved by the FDA for type 2 diabetes) used for any condition (e.g. pre-diabetes, diabetes, polycystic ovarian syndrome) ☐

B. Meets glycemic criteria for diabetes OR exceeds site-specific glycemia inclusion criteria ☐

History (past 3 years) of hyperparathyroidism, nephrolithiasis or hypercalcemia ❍ Yes ❍ No

Any medical condition (past 3 years) that in the opinion of the site investigator may increase risk for nephrolithiasis or hypercalcemia during the trial (e.g. sarcoidosis) ❍ Yes ❍ No

Use of tanning devices within 12 weeks of the baseline visit and unwilling to stop use of tanning devices for the duration of the study ❍ Yes ❍ No

Medications and Supplements

Use of supplements containing vitamin D at total doses higher than 1000 IU/day and unwillingness to limit vitamin D supplementation dosage to no higher than 1000 IU/day for the duration of the study. ❍ Yes ❍ No

Use of supplements containing calcium at total doses higher than 600 mg/day within 1 week of the baseline visit and unwillingness to limit calcium supplementation dosage to no more than 600 mg/day for the duration of the study. ❍ Yes ❍ No

Current use of medications or conditions (e.g. untreated celiac disease) that would interfere with absorption or metabolism of vitamin D. ❍ Yes ❍ No

See MOP section 8 for list.

Current use of medications approved by the FDA for weight management. ❍ Yes ❍ No

See MOP section 8 for list.

Use of thiazide diuretics at a total dose greater than 37.5 mg/day. ❍ Yes ❍ No

Use of anticonvulsant drug started within 6 months of screening. Stable regimen of anticonvulsants is allowed. ❍ Yes ❍ No

History of intolerance to vitamin D supplements or allergy to any study pill ingredient. ❍ Yes ❍ No

Current use of any other excluded medication (as listed in MOP 8)? ❍ Yes ❍ No

Other Medical History

Severe symptomatic cardiovascular disease based on history and physical examination (unstable angina, dyspnea on exertion, paroxysmal nocturnal dyspnea, arrhythmia, congestive heart failure NYHA class II or higher, claudication) ❍ Yes ❍ No

History (past 1 year) of myocardial infarction, percutaneous coronary intervention or coronary artery bypass graft. ❍ Yes ❍ No

History (past 1 year) of cerebrovascular disease (stroke, transient ischemic attack). ❍ Yes ❍ No

Any type of cancer (past 5 years) except for basal cell skin cancer. Prostate cancer (for men over age 55) or well-differentiated thyroid cancer that are not expected to require treatment (except for suppression with thyroid hormone) over the next 4 years, or squamous cell cancer of the skin which was completely excised and with no evidence of metastases are not exclusions. ❍ Yes ❍ No

History (past 6 months) of treatment with oral (for > 7 days) or intravenous glucocorticoids or disease likely to require oral or intravenous glucocorticoid therapy during the study (inhaled glucocorticoids are not excluded). Epidural or intra-articular glucocorticoid injections are not exclusions. Volunteers with ❍ Yes ❍ No

adrenal insufficiency treated with physiologic doses of glucocorticoids who are otherwise stable are not excluded.

History (past 1 year) of substance abuse or unstable psychiatric disorder that in the opinion of the site investigator would impede competence or adherence with study procedures or hinder completion of the study or increase risk. ❍ Yes ❍ No

History of bariatric surgery (e.g. Roux-en-Y gastric bypass, gastric sleeve) or planned bariatric surgery in the next 4 years. Participants with gastric banding more than 2 years ago with self-reported weight stability [defined as weight change no greater than 3 kg during the prior 6 months] are *not excluded*. ❍ Yes ❍ No

A life-threatening event within 30 days of screening or currently planned major surgery. ❍ Yes ❍ No

Any other unstable active medical condition (including but not limited to liver disease, wasting illness, AIDS, tuberculosis, oxygen-dependent chronic obstructive pulmonary disease, organ transplant, Cushing's syndrome) that in the opinion of the site investigators would impede competence or adherence with study procedures or increase risk. ❍ Yes ❍ No

Uncontrolled hypertension (systolic blood pressure > 160 mmHg or diastolic blood pressure > 100 mmHg). ❍ Yes ❍ No

Poor venous access. ❍ Yes ❍ No

Laboratory Evaluation

Serum liver transaminase higher than 3 times the normal range for the clinical site's laboratory. ❍ Yes ❍ No

Anemia (hematocrit < 32 for women, < 36 for men), whole blood transfusion (within 6 months of screening or chronic requirement), whole blood donation (within 3 months of screening) or other condition (hemolysis, hemoglobinopathy) rendering HbA1c results unreliable as indicator of chronic glycemia. ❍ Yes ❍ No

Low platelet count (< 50,000). ❍ Yes ❍ No

Chronic kidney disease, defined as estimated glomerular filtration rate GFR < 50 mL/min, measured at the clinical site's laboratory. ❍ Yes ❍ No

Hypercalcemia, defined as serum calcium concentration greater than or equal to the upper limit of normal, measured at the clinical site's laboratory. ❍ Yes ❍ No

Other

Participation (within 30 days of screening) in another interventional research study. ❍ Yes ❍ No

Previous randomization in the D2d study. ❍ Yes ❍ No

Any other reason that in the opinion of the site investigator would impede adherence with study procedures or hinder completion of the study or increase risk. ❍ Yes ❍ No

Women Only

For male participants, all "Women Only" questions must be answered "Not Applicable".

Pregnancy (past 1 year by report or positive pregnancy test at screening), intent to become pregnant in the next 4 years or unprotected intercourse. *(History of gestational diabetes is not an exclusion criterion.)* ❍ Yes ❍ No ❍ Not Applicable

Currently breastfeeding. ❍ Yes ❍ No ❍ Not Applicable

Use of oral contraceptives or menopausal hormone therapy started within 3 months of baseline. *(Stable regimen of oral contraceptives or any other hormonal method of contraception (e.g. implantable) is allowed.)* ❍ Yes ❍ No ❍ Not Applicable

If oral contraceptives or menopausal hormone therapy has been started within 3 months, schedule the baseline visit to fall at the end of the 3 months.

==========

Did the participant meet all the Screening eligibility criteria? ❍ Yes ❍ No

If a participant is eligible after the baseline visit, the investigator must sign off on both the Screening Inclusion/Exclusion Criteria Form *and* Baseline Inclusion/Exclusion Criteria Form before being randomized.

Baseline Inclusion/Exclusion Criteria Form

Inclusion Criteria

Pre-diabetes defined by meeting 2-out-of-3, and not exceeding any of the following glycemic criteria measured at baseline by the Central Lab. If Yes, check all that apply: ❍ Yes ❍ No

Review Central Laboratory Upload form for results.

A. Fasting plasma glucose (FPG) 100-125 mg/dL, inclusive ☐

B. 2-hour plasma glucose (2hPG) 140-199 mg/dL, inclusive ☐

C. Hemoglobin A1c (HbA1c) 5.7-6.4%, inclusive ☐

Exclusion Criteria

Hypercalciuria, defined as a spot (morning void) calcium-creatinine ratio > 0.275, measured at baseline by the Central Lab. ❍ Yes ❍ No

Review Central Laboratory Upload form for results.

==========

Did the participant meet all the Baseline eligibility criteria? ❍ Yes ❍ No

If a participant is eligible after the baseline visit, the investigator must sign off on both the Screening Inclusion/Exclusion Criteria Form *and* Baseline Inclusion/Exclusion Criteria Form before being randomized.

Consent and Enrollment Form

Date the participant signed the D2d Informed Consent Form.

dd / MMM / yyyy

Only those participants who sign the Informed Consent Form *and* are seen for a screening visit are entered in EDC.

Protocol version participant enrolled under

. . .
1.4
1.5
1.6
1.7

Did the participant sign the consent for the Research Repository? ❍ Yes ❍ No

If Yes, enter the date dd / MMM / yyyy

Did the participant provide consent for future DNA genetic research? ❍ Yes ❍ No

If Yes, enter the date dd / MMM / yyyy

How did the participant find out about the study?

. . .
Participant responded to database-related outreach
Participant searched a research website
Referrals
Publicity and news stories (Public Relations)
Advertisement
Information from "Within" (medical centers and universities, e.g. employee newsletters, hospital TV, intranet, employee health services, bulletin boards)
In-person (health fairs, community events, community gathering places)

If participant responded to a database-related outreach or participant searched a research website or referrals or advertisement, select the database or website or referral or media uses:

These fields are dynamic (based on the response from the previous question) and need a few seconds for the dropdown options to activate.

Database-related outreach

. . .
Electronic medical record system
Local research participant database/registry
Public database list
Other

Participant searched a research website

. . .

Clinicaltrials.gov
ResearchMatch.org
Centerwatch.com
Search engine result (e.g. Google)
Social media (e.g. facebook)
Other

Referrals

. . .

From primary care providers or other clinicians
From other participant ("word of mouth")

Advertisement

. . .

<< |< *Back*| *1/2* |*Next*>| >>
Print media – Flyer
Print media – Newspaper
Print media – Newsletter
Print media – Public transportation (e.g. subway)
Print media – Mailer
Print media – Other
Web based – D2d
Web based – Craigslist
Web based – Google
Web based – Facebook

<< |< *Back*| *2/2* |*Next*>| >>
Web based – Twitter
Web based – Advertisement on internet
Web based – Other
AV Media – Radio
AV Media – TV
AV Media – Other

The options appear on *two* pages. Click "Next" at the top of the dropdown box to view additional options.

What was the mode of initial contact with the participant?

. . .

Participant contacted center
Center contacted participant
In-person screening

Select contact method:

Participant contacted center

. . .

Phone
Email/web-based

Center contacted participant

. . .

Phone
Email/web-based
Postal mail

In-person screening

. . . ▼
Community screening – Church Community screening – Health fair Community screening – Other community event Worksite Screening Medical Care Facility Screening Other

Demographics Form

Sex ❍ Female ❍ Male

Select sex by participant self-identification.

Date of Birth [ ] / [▼] / [ ]
dd MMM yyyy

Age (years) (calculated)

Ethnicity

Select ethnicity by participant self-identification.

. . .
Hispanic or Latino
Not Hispanic or Latino

If Hispanic or Latino, select subcategory. Otherwise, leave blank.

. . .
Mexican, Mexican American, Chicano/a
Puerto Rican
Cuban
Another Hispanic, Latino, or Spanish Origin

Primary Race

Select race by participant self-identification.

. . .
American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or Other Pacific Islander
White
Other

Specify Other Race

If Asian, Native Hawaiian or Other Pacific Islander, select subcategory. Otherwise, leave blank.

Asian

. . .
Asian Indian
Chinese
Filipino
Japanese
Korean
Vietnamese
Other Asian

Native Hawaiian or Other Pacific Islander

. . .
Native Hawaiian
Guamanian or Chamorro
Samoan
Other Pacific Islander

Secondary Race

. . .

None
American Indian or Alaska Native
Asian
Black or African American
Native Hawaiian or Other Pacific Islander
White
Other

If participant does not report a secondary race, select "None"

Specify Other Race

If Asian, Native Hawaiian or Other Pacific Islander, select subcategory. Otherwise, leave blank.

Asian

. . .

Asian Indian
Chinese
Filipino
Japanese
Korean
Vietnamese
Other Asian

Native Hawaiian or Other Pacific Islander

. . .

Native Hawaiian
Guamanian or Chamorro
Samoan
Other Pacific Islander

Highest level of education, including home schooling, you have completed?

. . .

No schooling
Elementary (grades 1-8)
High school (grades 9-12), no diploma
High school (grades 9-12), GED or equivalent diploma
Some post-high school education, no certificate or degree
Some post-high school education, Associate's degree (e.g. technical school certificate)
Bachelor's degree (e.g. BA, AB, BS)
Graduate or professional degree (master's, doctorate, PA, JD, MD, etc.)
Prefer not to answer

Do any relatives have diabetes ❍ Yes ❍ No

If participant does not know about family history of diabetes, select "No."

If Yes, select all family members that have been diagnosed with diabetes

If "Yes" is selected, at least one family member must be checked.

- ☐ Sister
- ☐ Brother
- ☐ Mother
- ☐ Father
- ☐ Maternal grandmother
- ☐ Maternal grandfather
- ☐ Paternal grandmother
- ☐ Paternal grandfather

Visit Other Data Forms

Screening Visit Other Data

Were vital signs collected? ❍ Yes ❍ No

Was the medical history completed? ❍ Yes ❍ No

Were the local laboratory tests collected? ❍ Yes ❍ No

The Vital Signs, Medical History, and Local Laboratory Forms will only appear in the Screening folder if these questions are answered "Yes."

Record current total daily dose of non-dietary vitamin D supplementation _____ international units

Record current total daily dose of non-dietary calcium supplementation _____ mg

Record the sum of vitamin D and calcium from all supplements taken. If none, enter "0."

Is the participant taking any anti-hypertensive medications? ❍ Yes ❍ No
If yes, record the medication on the concomitant medication form.

Is the participant taking any osteoporosis medications? ❍ Yes ❍ No
If yes, record the medication on the concomitant medication form.

Is the participant taking any weight-loss medications? ❍ Yes ❍ No
If yes, record the medication on the concomitant medication form.

Is the participant taking any lipid lowering medications? ❍ Yes ❍ No
If yes, record the medication on the concomitant medication form.

Baseline Visit Other Data

Did the participant report any adverse events? If yes, please record adverse event to Adverse Event folder. ❍ Yes ❍ No

Have there been any changes to the participant's diabetes, antihypertensive, osteoporosis, weight-loss, or lipid lowering medication(s)? If yes, record new medications or changes to existing medications on the concomitant medication form. ❍ Yes ❍ No

Record current total daily dose of non-dietary vitamin D supplementation ☐ international units

Record current total daily dose of non-dietary calcium supplementation ☐ mg

Record the sum of vitamin D and calcium from all supplements taken. If none, enter "0."

Was the Food Frequency Questionnaire completed? ❍ Yes ❍ No

If yes enter the FFQ serial number (found in the lower right hand corner of the FFQ, pg. 1): ☐

Was the D2d study lifestyle educational information provided to the participant? ❍ Yes ❍ No

Social History

What is your current marital status?

. . . ▼

- Single, never married
- Married / living with partner
- Separated
- Divorced
- Widowed
- Prefer not to answer

Please choose which of the following best describes your current employment status?

. . . ▼

- Homemaker, not working outside the home
- Employed (or self-employed) full-time
- Employed (or self-employed) part-time or seasonally employed
- Employed, but currently on leave
- Not employed, looking for work
- Not employed, full-time student
- Not working, on disability
- Retired
- Prefer not to answer

During the past year, your household income from all sources was?

. . .
- $0 to $10,000
- $11,000 to $15,000
- $16,000 to $20,000
- $21,000 to $35,000
- $36,000 to $50,000
- $51,000 to $75,000
- $75,001 or more
- Prefer not to answer

On average, over the last 1 year, how many hours per day did you spend outdoors in direct sunlight in the middle of the day, around 10 am to 4 pm - (including work, recreation, gardening, sports, etc.) during the following time periods?

Summer months, over the last 1 year

. . .
- Less than 30 minutes per day
- Between 30 minutes and 2 hours per day
- More than 2 hours but less than 5 hours per day
- More than 5 hours per day

Winter months, over the last 1 year

. . .
- Less than 30 minutes per day
- Between 30 minutes and 2 hours per day
- More than 2 hours but less than 5 hours per day
- More than 5 hours per day

Number of times in the past year you used an artificial tanning light or tanning booth?

. . .
- None
- 1-2 times per year
- 3-5 times per year
- 6-11 times per year
- 12-23 times per year
- 24 or more times per year

Have you used an artificial tanning light or tanning booth in the past 3 months (12 weeks)? ❍ Yes ❍ No

<u>Smoking History</u>

Have you smoked at least 100 cigarettes in your ENTIRE life?

. . .
- No
- Yes
- Don't know
- Prefer not to answer

If "No," do not complete remainder of smoking questions.

If No, Stop here, no need to answer the rest of question.
If Yes, don't know, or prefer not to answer, please complete the following questions.

Do you currently smoke?

. . .
No
Yes
Prefer not to answer

IF YES, How old were you when you started smoking regularly?

Or, if age not provided, please select one of the following

. . .
Don't know
Prefer not to answer

On average, how many cigarettes per day do you regularly smoke?

Or, if average not provided, please select one of the following:

. . .
Don't know
Prefer not to answer

IF NO, Did you ever smoke regularly? ❍ Yes ❍ No

If No, Stop here, no need to answer the rest of questions.
If Yes, please complete the following questions.

How old were you when you started smoking regularly?

Or, if age not provided, please select one of the following:

. . .
Don't know
Prefer not to answer

On average, how many cigarettes per day did you regularly smoke?

Or, if average not provided, please select one of the following:

. . .
Don't know
Prefer not to answer

How old were you when you last smoked cigarettes regularly?

Or, if age not provided, please select one of the following

. . .
Don't know
Prefer not to answer

M03 Visit Other Data

Was a physical examination performed? ❍ Yes ❍ No

Did the participant report any adverse events? If yes, please record adverse events to Adverse Event folder. ❍ Yes ❍ No

Have there been any changes to the participant's diabetes, antihypertensive, osteoporosis, weight-loss, or lipid lowering medication(s)? If yes, record new medications or changes to existing medications on the concomitant medication form. ❍ Yes ❍ No

Physical exam is performed only if warranted based on AE report and will only appear in visit folder if "Yes" is selected.

Record current total daily dose of non-dietary vitamin D supplementation ☐ international units

Record current total daily dose of non-dietary calcium supplementation ☐ mg

Record the sum of vitamin D and calcium from all supplements taken. If none, enter "0."

Annual Visit Other Data

Was a physical examination performed? ❍ Yes ❍ No

Did the participant report any adverse events? If yes, please record adverse events to Adverse Event folder. ❍ Yes ❍ No

Have there been any changes to the participant's diabetes, antihypertensive, osteoporosis, weight-loss, or lipid lowering medication(s)? If yes, record new medications or changes to existing medications on the concomitant medication form. ❍ Yes ❍ No

Physical exam is performed only if warranted based on AE report and will only appear in visit folder if "Yes" is selected.

Record current total daily dose of non-dietary vitamin D supplementation ☐ international units

Record current total daily dose of non-dietary calcium supplementation ☐ mg

Record the sum of vitamin D and calcium from all supplements taken. If none, enter "0."

Was the Food Frequency Questionnaire completed?

. . .
- Yes
- No
- No, participant has developed diabetes

Completed at M12 and M36 if participant has not been diagnosed with diabetes. If participant *has* been diagnosed with diabetes, select "No, participant has developed diabetes."

If yes enter the FFQ serial number (found in the lower right hand corner Of the FFQ, pg. 1): ☐

<u>Social History</u>

What is your current marital status?

. . .
- Single, never married
- Married / living with partner
- Separated
- Divorced
- Widowed
- Prefer not to answer

Please choose which of the following best describes your current employment status?

. . .
- Homemaker, not working outside the home
- Employed (or self-employed) full-time
- Employed (or self-employed) part-time or seasonally employed
- Employed, but currently on leave
- Not employed, looking for work
- Not employed, full-time student
- Not working, on disability
- Retired
- Prefer not to answer

During the past year, your household income from all sources was?

. . .
- $0 to $10,000
- $11,000 to $15,000
- $16,000 to $20,000
- $21,000 to $35,000
- $36,000 to $50,000
- $51,000 to $75,000
- $75,001 or more
- Prefer not to answer

On average, over the last 1 year, how many hours per day did you spend outdoors in direct sunlight in the middle of the day, around 10 am to 4 pm - (including work, recreation, gardening, sports, etc.) during the following time periods?

Summer months, over the last 1 year

. . .
- Less than 30 minutes per day
- Between 30 minutes and 2 hours per day
- More than 2 hours but less than 5 hours per day
- More than 5 hours per day

Winter months, over the last 1 year

. . .
- Less than 30 minutes per day
- Between 30 minutes and 2 hours per day
- More than 2 hours but less than 5 hours per day
- More than 5 hours per day

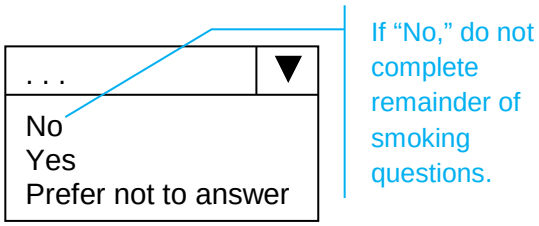
Number of times in the past year you used an artificial tanning light or tanning booth?

. . .
- None
- 1-2 times per year
- 3-5 times per year
- 6-11 times per year
- 12-23 times per year
- 24 or more times per year

Have you used an artificial tanning light or tanning booth in the past 3 months (12 weeks)? ❍ Yes ❍ No

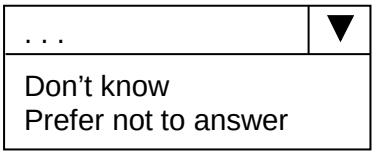
Smoking History

Do you currently smoke?



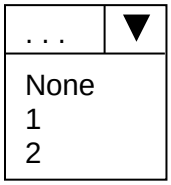
On average, how many cigarettes per day have you smoked during the past year? ☐

Or, if age not provided, please select one of the following



Support and Education Program Meeting Attendance

During the past twelve months, how many D2d Support and Education Program meetings did the participant attend?



Interim Visit Other Data

Was a physical examination performed? ❍ Yes ❍ No

Did the participant report any adverse events? If yes, please record adverse events to Adverse Event folder. ❍ Yes ❍ No

Have there been any changes to the participant's diabetes, antihypertensive, osteoporosis, weight-loss, or lipid lowering medication(s)? If yes, record new medications or changes to existing medications on the concomitant medication form. ❍ Yes ❍ No

Physical exam is performed only if warranted based on AE report and will only appear in visit folder if "Yes" is selected.

Record current total daily dose of non-dietary vitamin D supplementation ☐ international units

Record current total daily dose of non-dietary calcium supplementation ☐ mg

Record the sum of vitamin D and calcium from all supplements taken. If none, enter "0."

Unscheduled-Confirmatory Other Data

Please provide a reason for this Visit.

. . .

Adverse event
Safety laboratory confirmation
Diabetes diagnosed outside of study or symptoms of hyperglycemia
Outcome laboratory confirmation
Other

Other, specify

If Safety or Outcome laboratory Confirmation, select the visit that resulted in the need for an Unscheduled-Confirmatory visit?

. . .

<< |< *Back*| *1/2* |*Next*>| >>
Month 3
Month 6
Month 12
Month 18
Month 24
Month 30
Month 36
Month 42
Month 48
End of Study
<< |< *Back*| *1/2* |*Next*>| >>
Unscheduled-Confirmatory

Select the visit that prompted the need for the unscheduled visit.

The options appear on *two* pages. Click "Next" at the top of the dropdown box to view additional options.

If Safety or Outcome laboratory Confirmation, what was the date of the visit that resulted in the need for this Unscheduled -Confirmatory visit?

dd / MMM / yyyy

Was a physical examination performed? ❍ Yes ❍ No

Did the participant report any adverse events? If yes, please record adverse events to Adverse Event folder. ❍ Yes ❍ No

Physical exam is performed only if warranted based on AE report and will only appear in visit folder if "Yes" is selected.

Have there been any changes to the participant's diabetes, antihypertensive, osteoporosis, weight-loss, or lipid lowering medication(s)? If yes, record new medications or changes to existing medications on the concomitant medication form. ❍ Yes ❍ No

Were the safety laboratory tests collected? ❍ Yes ❍ No

Were blood or urine specimens collected to send to the Central Laboratory? ❍ Yes ❍ No

The Local Laboratory or Central Laboratory forms will only appear if "Yes" is checked here.

Record current total daily dose of non-dietary vitamin D supplementation

☐ international units

Record current total daily dose of non-dietary calcium supplementation

☐ mg

Record the sum of vitamin D and calcium from all supplements taken. If none, enter "0."

Vital Signs Form

Height ☐ cm

Weight ☐ kg

Body Mass Index (BMI) (calculated) kg/m^2

Heart Rate ☐ beats/min

Blood pressure must be measured twice, 5 minutes apart, while sitting in a chair.

Systolic Blood Pressure 1 ☐ mmHg

Diastolic Blood Pressure 1 ☐ mmHg

Systolic Blood Pressure 2 ☐ mmHg

Diastolic Blood Pressure 2 ☐ mmHg

Systolic Blood pressure average (calculated) mmHg

Diastolic Blood pressure average (calculated) mmHg

Arm used ❍ Left Arm ❍ Right Arm

For consistency, the same arm should be used throughout the study.

Blood pressure cuff size used ❍ Small Adult ❍ Adult ❍ Large Adult ❍ Adult Thigh

Waist Circumference ☐ cm

Enter to the tenths place (e.g. 151.0)

Enter to the tenths place (e.g. 56.0)

System will calculate

If there is a difference in values > 20 mmHg between 1st and 2nd measurements, system will ask for confirmation.

System will calculate

Enter to the tenths place (e.g. 68.0)

This question only appears at baseline

Medical History Form

Enter all relevant medical history below. For any yes response enter information on the medical condition or event in the log below:

Does the participant have a history related to the *Skin*?	❍ Yes	❍ No
Does the participant have a history related to the *HEENT*?	❍ Yes	❍ No
Does the participant have a history related to the *Respiratory* system?	❍ Yes	❍ No
Does the participant have a history related to the *Cardiovascular* system?	❍ Yes	❍ No
Does the participant have a history related to the *Musculoskeletal* system?	❍ Yes	❍ No
Does the participant have a history related to the *Gastrointestinal* system?	❍ Yes	❍ No
Does the participant have a history related to the *Gynecologic* system?	❍ Yes	❍ No
Does the participant have a history related to the *Urogenital Renal* system?	❍ Yes	❍ No
Does the participant have a history related to the *Endocrine/Metabolic* system?	❍ Yes	❍ No
Does the participant have a history related to the *Neurological* system?	❍ Yes	❍ No
Does the participant have a history related to the *Hematopoietic/Lymphatic* system?	❍ Yes	❍ No
Does the participant have a history related to *Psychiatric* or *Mental Health*?	❍ Yes	❍ No
Does the participant have a history of *Allergies*?	❍ Yes	❍ No

Is the participant Post-Menopausal? ❍ Yes ❍ No ❍ Not applicable - male

If yes, enter year of last menstrual period: ☐

All questions must be answered.

Each system with a "Yes" response requires further detail be entered in the log below.

Hypertension and hyperlipidemia are entered under the Cardiovascular system.

If participant is male, select "No."

Does the participant have a history of *Gestational Diabetes*? ❍ Yes ❍ No ❍ Not applicable - male

If yes, enter year of most recent diagnosis of gestational diabetes: ____

Medical History Log Form

Body System	Medical Condition or Event	Start Date	Ongoing	Resolved Date
. . . ▼ Skin HEENT Respiratory Cardiovascular Musculoskeletal Gastrointestinal Gynecologic Urogenital/Renal Endocrine/Metabolic Neurological Hematopoietic/Lymphatic Psychiatric or Mental Health Allergies		dd / MMM ▼ / yyyy	☐	dd / MMM ▼ / yyyy

Must be completed for each system that has a "Yes" response above.

Hit save between each log line entry.

Physical Examination Form

Date of Examination ____ / ____ / ____

dd MMM yyyy

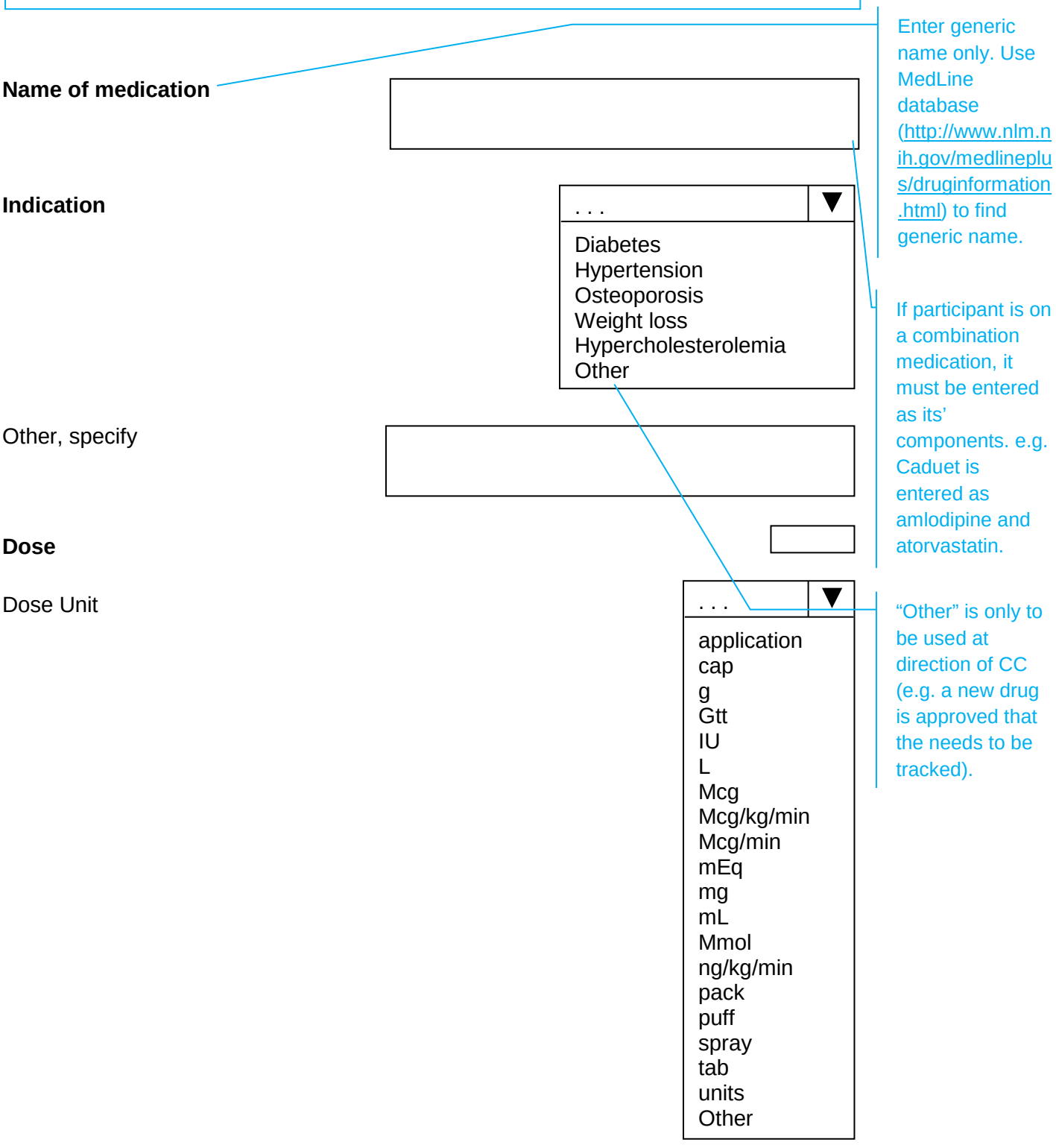
#	Body System Examined	Examination Result	Description of Abnormal Findings
1	General Appearance	. . . ▼ Normal Abnormal Not Examined	
2	Head / Eyes / Ears / Nose / Throat		
3	Neck		
4	Skin		
5	Heart		
6	Lungs		
7	Abdomen		
8	Lymph nodes		
9	Neurological		
10	Musculoskeletal		
11	Genitourinary		
12	Breast		
13	Psychological		

Need to enter an examination result for each category – none can be left bank.

If "Abnormal" is selected, description of the abnormal findings must be entered. If "Normal" is selected, no description should be entered.

Concomitant Medications

Only medications that fall into the 5 indications listed below (diabetes, hypertension, osteoporosis, weight loss, and hypercholesterolemia) should be entered in EDC, though *all* medications should be recorded in the source documents. "Other" will only be used if specified by the Coordinating Center.



Other, specify

Frequency

. . .
- once daily
- twice daily
- three times daily
- four times daily
- every other day
- every week
- every month
- as needed
- once
- unknown
- other

Route of Administration

. . .
- Oral
- Topical
- Subcutaneous
- Transdermal
- Intraocular
- Intramuscular
- Respiratory (Inhalation)
- Intralesional
- Intraperitoneal
- Nasal
- Vaginal

Start Date

dd / MMM / yyyy

End Date

dd / MMM / yyyy

Ongoing

If participant does not know specific start or end date, probe for more details. Otherwise, if necessary, enter UN for day and UNK for month. Year must be entered.

Local Laboratory Forms

Screening Local Laboratory Form

Date of required safety laboratory specimen collection ____ / ____ / ____ (dd / MMM / yyyy)

Date of glycemia (HbA1c and FPG) laboratory specimen collection ____ / ____ / ____ (dd / MMM / yyyy)

Was the participant fasting for at least 8 hours? ❍ Yes ❍ No

Estimated creatinine clearance (GFR) (calculated)

Was a pregnancy test done? ❍ Yes ❍ No ❍ Not Applicable

If yes, please record results ❍ Positive ❍ Negative

Check if glycemia (HbA1c and FPG) specimens Shipped to Central Laboratory for analysis ☐

Laboratory specimens 6 digit Kit ID barcode number (found on specimen collection kit labels) ____

Please print this form and place barcode label on the printout.

Date refrigerated specimens shipped to the Central Lab ____ / ____ / ____ (dd / MMM / yyyy)

Refrigerated specimen shipping tracking number ____

Date frozen specimens shipped to the Central Lab. ____ / ____ / ____ (dd / MMM / yyyy)

Frozen specimen tracking number ____

White blood cell count ____

Hemoglobin ____

Hematocrit ____

Platelet count ____

AST ____

System will calculate. Demographics Form must be completed for an accurate calculation.

For male participants, select "Not Applicable."

For female participants, pregnancy test must be done on all women of child-bearing potential. Select "Not Applicable" if woman is not of child-bearing potential.

Print completed eCRF, affix kit ID barcode label, and include as a packing slip when shipping refrigerated and frozen specimens.

Must enter date shipped *prior* to the end of the day of shipment

ALT

Serum calcium

Serum creatinine

Hemoglobin A1c

Fasting Plasma Glucose

When shipped to the Central Laboratory, lab results will upload to the Central Laboratory Upload form. Those results must then be transcribed into the Screening Local Laboratory form.

Safety Local Laboratory

Were the local (safety) laboratory tests collected

. . .

Yes
No
Not applicable – participant is no longer on study pills

Date of required safety laboratory specimen collection

dd / MMM / yyyy

Estimated creatinine clearance (GFR) (calculated)

System will calculate

Was a pregnancy test done? ❍ Yes ❍ No ❍ Not Applicable

For male participants, "Not Applicable" must be selected.

If yes, please record results ❍ Positive ❍ Negative

Serum calcium

Serum creatinine

For female participants, "No" is selected if participant is of child-bearing potential, but pregnancy test was not done. "Not Applicable" is selected if participant is not of child-bearing potential.

Central Laboratory Forms

Baseline and Annual Central Laboratory Form

Was urine specimen collected? ❍ Yes ❍ No

If Yes, volume of urine collected ____ mL

If No, explain: ____

Date and time of last food or drink other than plain water (24 hour clock 00:00-23:59) ____/____/____ ____:____
dd MMM yyyy hh mm

Date and time of fasting sample collection (24 hour clock 00:00-23:59) ____/____/____ ____:____
dd MMM yyyy hh mm

Note: Date of fasting sample collection must be the same as the visit date.

For each glycemia laboratory test sent to the Central Laboratory, the site will receive an email with whether the measure was positive or negative based on study criteria. Follow MOP section 18 to determine next steps.

Fasting Duration (Calculated) hours

System will calculate

Was OGTT done? ❍ Yes ❍ No

If No, reason ____

If AE, complete AE form . . .

- Participant diagnosed with diabetes or taking diabetes medication
- Adverse event
- Other

Other, specify ____

If OGTT was done, complete the following 3 questions:

Time participant finished drinking Trutol (24 hour clock 00:00-23:59) ____:____
hh mm

Time of 30 minute sample collection (24 hour clock 00:00-23:59) ____:____
hh mm

Time of 120 minute (2 hour) sample collection (24 hour clock 00:00-23:59) [ ] : [ ] hh mm

Method of blood sample collection [. . . ▼]
- Phlebotomy
- Saline or heparin lock
- Butterfly needle

If Keep Vein Open (KVO) IV is used, select "Saline or heparin lock."

Was urine aliquoted for the Biorepository? ❍ Yes ❍ No

Was blood collected for the Biorepository? ❍ Yes ❍ No

Was blood collected for DNA? ❍ Yes ❍ No

Laboratory specimens 6 digit Kit ID barcode number (found on specimen collection kit labels) [ ]

Please print this form and place barcode label on the printout.

Print completed eCRF, affix kit ID barcode label, and include as a packing slip when shipping refrigerated and frozen specimens.

Were there any issues with the collection or processing of the laboratory specimens? ❍ Yes ❍ No

If Yes, explain: [ ]

Date refrigerated specimens shipped to the Central Lab [ ] / [▼] / [ ] dd MMM yyyy

Must enter date shipped *prior* to the end of the day of shipment

Refrigerated specimen shipping tracking number [ ]

Name of the person who shipped the refrigerated specimens [ ]

In case there are questions about the shipment.

Date frozen specimens shipped to the Central Lab. [ ] / [▼] / [ ] dd MMM yyyy

Must enter date shipped *prior* to the end of the day of shipment

Frozen specimen tracking number [ ]

Name of the person who shipped the frozen specimens [ ]

In case there are questions about the shipment.

M03 Central Laboratory

Was urine specimen collected? ❍ Yes ❍ No

If Yes, volume of urine collected ____ mL

If No, explain: ____

Date of specimen collection
Note: date of specimen collection must be the same as the visit date.
__ / ▼ / ____
dd MMM yyyy

Laboratory specimens 6 digit Kit ID barcode number (found on specimen collection kit labels) ____

Please print this form and place barcode label on the printout.

Print completed eCRF, affix kit ID barcode label, and include as a packing slip when shipping frozen specimens.

Were there any issues with the collection or processing of the laboratory specimens? ❍ Yes ❍ No

If Yes, explain: ____

Date frozen specimens shipped to the Central Lab.
__ / ▼ / ____
dd MMM yyyy

Must enter date shipped *prior* to the end of the day of shipment

Frozen specimen tracking number ____

Name of the person who shipped the frozen specimens ____

In case there are questions about the shipment.

Semi Annual Central Laboratory Form

Date and time of last food or drink other than plain water (24 hour clock 00:00-23:59) ☐ / ☐ ▼ / ☐ ☐ : ☐
dd MMM yyyy hh mm

Date and time of fasting sample collection (24 hour clock 00:00-23:59) ☐ / ☐ ▼ / ☐ ☐ : ☐
dd MMM yyyy hh mm

Note: Date of fasting sample collection must be the same as the visit date.

Fasting Duration (Calculated) hours

System will calculate

Was blood collected for the Biorepository? ❍ Yes ❍ No

Laboratory specimens 6 digit Kit ID barcode number (found on specimen collection kit labels) ☐

Please print this form and place barcode label on the printout.

Were there any issues with the collection or processing of the laboratory specimens? ❍ Yes ❍ No

If Yes, explain: ☐

Print completed eCRF, affix kit ID barcode label, and include as a packing slip when shipping frozen specimens.

Date refrigerated specimens shipped to the Central Lab ☐ / ☐ ▼ / ☐
dd MMM yyyy

Refrigerated specimen shipping tracking number ☐

Name of the person who shipped the refrigerated specimens ☐

Must enter date shipped *prior* to the end of the day of shipment

In case there are questions about the shipment.

Date frozen specimens shipped to the Central Lab. ☐ / ☐ ▼ / ☐
dd MMM yyyy

Frozen specimen tracking number ☐

Name of the person who shipped the frozen specimens ☐

Must enter date shipped *prior* to the end of the day of shipment

In case there are questions about the shipment.

Central Laboratory Confirmatory Tests

Was urine specimen collected for calcium creatinine ratio? ❍ Yes ❍ No

If Yes, volume of urine collected ☐ mL

Was blood drawn for Hemoglobin A1c? ❍ Yes ❍ No

Was blood drawn for fasting plasma glucose? ❍ Yes ❍ No

If the question "Was blood drawn for the fasting plasma glucose?" is Yes, then the following 2 questions must be answered.

Date and time of last food or drink other than plain water (24 hour clock 00:00-23:59) ☐ / ☐ ▼ / ☐ ☐ : ☐
dd MMM yyyy hh mm

Date and time of fasting sample collection (24 hour clock 00:00-23:59) ☐ / ☐ ▼ / ☐ ☐ : ☐
dd MMM yyyy hh mm

Note: Date of fasting sample collection must be the same as the visit date.

Fasting Duration (Calculated) hours

System will calculate

Was a confirmatory 2 hour OGTT done? ❍ Yes ❍ No

If the question "Was a confirmatory 2 hour OGTT done?" is Yes, then the following 2 questions must be answered

Time participant finished drinking Trutol (24 hour clock 00:00-23:59) ☐ : ☐
hh mm

Time of 120 minute (2 hour) sample collection (24 hour clock 00:00-23:59) ☐ : ☐
hh mm

Method of blood sample collection ▼

. . .
Phlebotomy
Saline or heparin lock
Butterfly needle

If Keep Vein Open (KVO) IV is used, select "Saline or heparin lock."

Laboratory specimens 6 digit Kit ID barcode number (found on specimen collection kit labels) ☐

Please print this form and place barcode label on the printout.

Print completed eCRF, affix kit ID barcode label, and include as a packing slip when shipping frozen specimens.

Were there any issues with the collection or processing of the laboratory specimens? ❍ Yes ❍ No

If Yes, explain:

Date refrigerated specimens shipped to the Central Lab / / dd MMM yyyy

Must enter date shipped *prior* to the end of the day of shipment

Refrigerated specimen shipping tracking number

Name of the person who shipped the refrigerated specimens

In case there are questions about the shipment.

Date frozen specimens shipped to the Central Lab. / / dd MMM yyyy

Must enter date shipped *prior* to the end of the day of shipment

Frozen specimen tracking number

Name of the person who shipped the frozen specimens

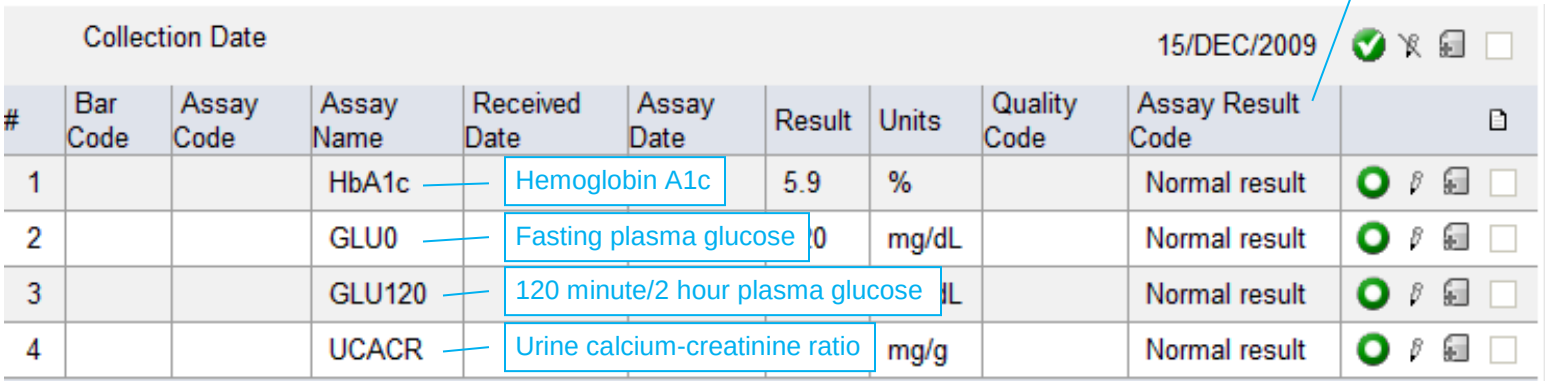
In case there are questions about the shipment.

Central Laboratory Upload

The data in this form is uploaded from the Central Laboratory. Site staff will be able to view, but not edit the data.

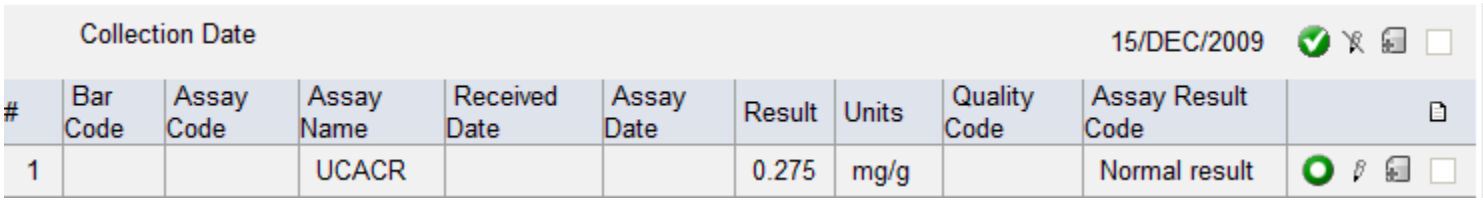
Note: example A is of a baseline form where all results are visible. Example B is of the form at a 12 month follow-up visit where the glycemia measures are not visible to the site (participant has not met the diabetes outcome); only the urine calcium-creatinine ratio is visible.

Example A – Baseline visit, all results visible



Assay Result Code is entered by the lab and will say Normal result unless there was a problem with the sample (e.g. hemolyzed) or the Central Lab's ability to perform the analysis. It is not an interpretation of the value reported.

Example B – M12 visit, participant has not met diabetes outcome, only safety measure is visible



Physical Activity Questionnaire Form

Data entered is transcribed from the paper IPAQ the participant completed.

PART 1: JOB-RELATED PHYSICAL ACTIVITY

1. Do you currently have a job or do any unpaid work outside your home? If No, Skip to PART 2: TRANSPORTATION ❍ Yes ❍ No

2. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, digging, heavy construction, or climbing up stairs as part of your work? Think about only those physical activities that you did for at least 10 minutes at a time.

Days per week . . .

- No vigorous job related physical activity (skip to question 4)
- 1
- 2
- 3
- 4
- 5
- 6
- 7

3. How much time did you usually spend on one of those days doing vigorous physical activities as part of your work?

Hours per day ☐

Minutes per day ☐

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do moderate physical activities like carrying light loads as part of your work? Please do not include walking.

Days per week . . .

- No vigorous job related physical activity (skip to question 6)
- 1
- 2
- 3
- 4
- 5
- 6
- 7

5. How much time did you usually spend on one of those days doing moderate physical activities as part of your work?

Hours per day ☐

Minutes per day ☐

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

6. During the last 7 days, on how many days did you walk for at least 10 minutes at a time as part of your work? Please do not count any walking you did to travel to or from work.

Days per week . . . ▼

No vigorous job related physical activity (skip to PART 2)
1
2
3
4
5
6
7

7. How much time did you usually spend on one of those days walking as part of your work?

Hours per day ☐

Minutes per day ☐

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

8. During the last 7 days, on how many days did you travel in a motor vehicle like a train, bus, car, or tram?

Days per week . . . ▼

No vigorous job related physical activity (skip to question 10)
1
2
3
4
5
6
7

9. How much time did you usually spend on one of those days traveling in a train, bus, car, tram, or other kind of motor vehicle?

Hours per day ☐

Minutes per day ☐

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

10. During the last 7 days, on how many days did you bicycle for at least 10 minutes at a time to go from place to place?

Days per week

. . . ▼
No vigorous job related physical activity (skip to question 12)
1
2
3
4
5
6
7

11. How much time did you usually spend on one of those days to bicycle from place to place?

Hours per day ☐

Minutes per day ☐

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

12. During the last 7 days, on how many days did you walk for at least 10 minutes at a time to go from place to place?

Days per week

. . . ▼
No vigorous job related physical activity (skip to PART 3)
1
2
3
4
5
6
7

13. How much time did you usually spend on one of those days walking from place to place?

Hours per day ☐

Minutes per day ☐

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, chopping wood, shoveling snow, or digging in the garden or yard?

Days per week . . . ▼

No vigorous job related physical activity (skip to question 16)
1
2
3
4
5
6
7

15. How much time did you usually spend on one of those days doing vigorous physical activities in the garden or yard?

Hours per day ☐

Minutes per day ☐

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do moderate activities like carrying light loads, sweeping, washing windows, and raking in the garden or yard?

Days per week . . . ▼

No vigorous job related physical activity (skip to question 18)
1
2
3
4
5
6
7

17. How much time did you usually spend on one of those days doing moderate physical activities in the garden or yard?

Hours per day ☐

Minutes per day ☐

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do moderate activities like carrying light loads, washing windows, scrubbing floors and sweeping inside your home?

Days per week

. . .

No vigorous job related physical activity (skip to PART 4)
1
2
3
4
5
6
7

19. How much time did you usually spend on one of those days doing moderate physical activities inside your home?

Hours per day ____

Minutes per day ____

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSCIAL ACTIVITY

20. Not counting any walking you have already mentioned, during the last 7 days, on how many days did you walk for at least 10 minutes at a time in your leisure time?

Days per week

. . .

No vigorous job related physical activity (skip to question 22)
1
2
3
4
5
6
7

21. How much time did you usually spend on one of those days walking in your leisure time?

Hours per day ____

Minutes per day ____

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

22. Think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do vigorous physical activities like aerobics, running, fast bicycling, or fast swimming in your leisure time?

Days per week . . .

- No vigorous job related physical activity (skip to question 24)
- 1
- 2
- 3
- 4
- 5
- 6
- 7

23. How much time did you usually spend on one of those days doing vigorous physical activities in your leisure time?

Hours per day ____

Minutes per day ____

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do moderate physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis in your leisure time?

Days per week . . .

- No vigorous job related physical activity (skip to PART 5)
- 1
- 2
- 3
- 4
- 5
- 6
- 7

25. How much time did you usually spend on one of those days doing moderate physical activities in your leisure time?

Hours per day ____

Minutes per day ____

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

PART 5: TIME SPENT SITTING

26. During the last 7 days, how much time did you usually spend sitting on a weekday?

Hours per day ☐

Minutes per day ☐

27. During the last 7 days, how much time did you usually spend sitting on a weekend day?

Hours per day ☐

Minutes per day ☐

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

All times must be entered as hours and minutes in whole numbers e.g. if participant records 90 minutes, RC must enter 1 hour and 30 minutes OR if participant records 45 minutes, RC must enter 0 hours and 45 minutes.

Quality of Life

Was the Quality of Life questionnaire completed? ❍ Yes ❍ No – participant opted out ❍ No – other reason

Please provide reason questionnaire was not completed

Complete if "No – other reason" selected above.

PROMIS-29

Data entered is transcribed from the paper QoL questionnaire the participant completed.

Global Health

In general, would you say your health is: ❍ Excellent ❍ Very Good ❍ Good ❍ Fair ❍ Poor

Physical Function

Are you able to do chores such as vacuuming or yard work?
❍ Without any difficulty ❍ With a little difficulty ❍ With some difficulty ❍ With much difficulty ❍ Unable to do

Are you able to go up and down stairs at a normal pace?
❍ Without any difficulty ❍ With a little difficulty ❍ With some difficulty ❍ With much difficulty ❍ Unable to do

Are you able to go for a walk of at least 15 minutes?
❍ Without any difficulty ❍ With a little difficulty ❍ With some difficulty ❍ With much difficulty ❍ Unable to do

Are you able to run errands and shop?
❍ Without any difficulty ❍ With a little difficulty ❍ With some difficulty ❍ With much difficulty ❍ Unable to do

Anxiety

In the past 7 days…

I felt fearful ❍ Never ❍ Rarely ❍ Sometimes ❍ Often ❍ Always

I found it hard to focus on anything other than my anxiety
❍ Never ❍ Rarely ❍ Sometimes ❍ Often ❍ Always

My worries overwhelmed me ❍ Never ❍ Rarely ❍ Sometimes ❍ Often ❍ Always

I felt uneasy ❍ Never ❍ Rarely ❍ Sometimes ❍ Often ❍ Always

Depression

In the past 7 days…

I felt worthless ❍ Never ❍ Rarely ❍ Sometimes ❍ Often ❍ Always

I felt helpless ❍ Never ❍ Rarely ❍ Sometimes ❍ Often ❍ Always

I felt depressed ❍ Never ❍ Rarely ❍ Sometimes ❍ Often ❍ Always

I felt hopeless ❍ Never ❍ Rarely ❍ Sometimes ❍ Often ❍ Always

Fatigue

During the past 7 days...

I feel fatigued ❍ Not at all ❍ A little bit ❍ Somewhat ❍ Quite a bit ❍ Very Much

I have trouble starting things because I am tired

❍ Not at all ❍ A little bit ❍ Somewhat ❍ Quite a bit ❍ Very Much

How run-down did you feel on average?

❍ Not at all ❍ A little bit ❍ Somewhat ❍ Quite a bit ❍ Very Much

How fatigued were you on average?

❍ Not at all ❍ A little bit ❍ Somewhat ❍ Quite a bit ❍ Very Much

Sleep Disturbance

In the past 7 days...

My sleep quality was ❍ Very Poor ❍ Poor ❍ Fair ❍ Good ❍ Very Good

My sleep was refreshing ❍ Not at all ❍ A little bit ❍ Somewhat ❍ Quite a bit ❍ Very Much

I had a problem with my sleep ❍ Not at all ❍ A little bit ❍ Somewhat ❍ Quite a bit ❍ Very Much

I had difficulty falling asleep ❍ Not at all ❍ A little bit ❍ Somewhat ❍ Quite a bit ❍ Very Much

Ability to Participate in Social Roles and Activities

I have trouble doing all of my regular leisure activities with others

❍ Never ❍ Rarely ❍ Sometimes ❍ Usually ❍ Always

I have trouble doing all of the family activities that I want to do

❍ Never ❍ Rarely ❍ Sometimes ❍ Usually ❍ Always

I have trouble doing all of my usual work (include work at home)

❍ Never ❍ Rarely ❍ Sometimes ❍ Usually ❍ Always

I have trouble doing all of the activities with friends that I want to do

❍ Never ❍ Rarely ❍ Sometimes ❍ Usually ❍ Always

Pain Interference

In the past 7 days…

How much did pain interfere with your day to day activities?

❍ Not at all ❍ A little bit ❍ Somewhat ❍ Quite a bit ❍ Very Much

How much did pain interfere with work around the home?

❍ Not at all ❍ A little bit ❍ Somewhat ❍ Quite a bit ❍ Very Much

How much did pain interfere with your ability to participate in social activities?

❍ Not at all ❍ A little bit ❍ Somewhat ❍ Quite a bit ❍ Very Much

How much did pain interfere with your household chores?

❍ Not at all ❍ A little bit ❍ Somewhat ❍ Quite a bit ❍ Very Much

Pain Intensity

In the past 7 days…

How would you rate your pain on average?

❍ 0 - No Pain ❍ 1 ❍ 2 ❍ 3 ❍ 4 ❍ 5
❍ 6 ❍ 7 ❍ 8 ❍ 9 ❍ 10 - Worst imaginable pain

Study Pill Distribution

Did the participant report taking the study pills as prescribed?

. . .
Yes
No
Not applicable – study pill discontinued

If No, explain:

Were any pills returned at this visit? ❍ Yes ❍ No

If yes, enter the number of pills returned

Was a bottle of study pills assigned at this visit? ❍ Yes ❍ No

If Yes: Bottle Number assigned at this visit

Confirm that bottle assigned as dispensed ❍ Yes ❍ No

If No, explain:

Rate of Adherence (calculated)

Enter from SPIRS certificate / bottle.

At Randomization, only these questions appear.

System will calculate at follow-up visits.

Discontinuation of Study Pills

Completed for permanent discontinuation of study pills.

Enter the primary reason the participant discontinued the study pills

. . .

- Participant decision
- Adverse event
- Completed the study per protocol
- Lost to follow-up
- Other
- Safety labs – high serum calcium (per DSMP)
- Safety labs – low GFR (per DSMP)
- Safety labs – high urine calcium creatinine ratio (per DSMP)

"Lost to follow-up" is not to be selected until the study is completed and attempts to contact the participant have been unsuccessful.

If Other, specify

Date of study pills discontinued

dd / MMM / yyyy

Non-Visit Contact

This form is only completed for those participants who will not be coming in for the scheduled study visit and once contact has been made. All contact attempts should be recorded in the Contact Log *or* source documents.

Reason participant is unable to complete an in-person visit

Type of Contact

. . .
Phone
Email
Other

Did the participant report any adverse events? If yes, please record adverse event to Adverse Event folder. ❍ Yes ❍ No

Have there been any changes to the participant's diabetes, antihypertensive, osteoporosis, weight-loss, or lipid lowering medication(s)? If yes, record new medications or changes to existing medications on the concomitant medication form. ❍ Yes ❍ No

Record current total daily dose of non-dietary vitamin D supplementation ____ international units

Record current total daily dose of non-dietary calcium supplementation ____ mg

Record the sum of vitamin D and calcium from all supplements taken. If none, enter "0."

Did the participant report taking the study pills as prescribed?

. . .
Yes
No
Not applicable – study pill discontinued

If No, explain:

Since last contact with D2d, did participant have a visit with a healthcare provider? ❍ Yes ❍ No

If Yes, explain the reason for the visit. *(e.g. Was it a routine visit? Was it for a specific complaint? Were they told they have diabetes or have they started on a diabetes medication?)*

Describe plan to conduct next encounter

This form is only completed once contact has been made. All contact attempts should be recorded in the Contact Log *or* source documents.

Scheduled Contact

Date of Contact

dd / MMM / yyyy

Type of Contact

. . .
- Phone
- Email
- Other

Did the participant report any adverse events? If yes, please record adverse event to Adverse Event folder. ❍ Yes ❍ No

Have there been any changes to the participant's diabetes, antihypertensive, osteoporosis, weight-loss, or lipid lowering medication(s)? If yes, record new medications or changes to existing medications on the concomitant medication form. ❍ Yes ❍ No

Did the participant report taking the study pills as prescribed?

. . .
- Yes
- No
- Not applicable – study pill discontinued

If No, explain:

Since last contact with D2d, did participant have a visit with a healthcare provider? ❍ Yes ❍ No

If Yes, explain the reason for the visit. *(e.g. Was it a routine visit? Was it for a specific complaint? Were they told they have diabetes or have they started on a diabetes medication?)*

End of Study Telephone Contact

Completed two weeks after End of Study Visit.

Date of Contact

[ ] / [ ] / [ ]
dd MMM yyyy

Type of Contact

[. . .]
- Phone
- Email
- Other

Did the participant report any adverse events? If yes, please record adverse event to Adverse Event folder.

❍ Yes ❍ No

Call Log

Contact Follow-up Log Form

Contact Date

dd / MMM / yyyy

Contact Mode

. . .

- Left voice mail
- Left message with person
- Sent certified letter
- Sent email

If Other, please comment

Use of this form is optional to record contact attempts with a participant. If this form is not utilized, this information must be recorded in the source documents.

Study Completion

Date of study completion or early withdrawal ____ / ____ / ____
dd MMM yyyy

Did participant complete the study per protocol? ❍ Yes ❍ No

If no, select the primary reason for withdrawal

. . .
Withdrew consent prior to baseline
Withdrew consent prior to randomization
Withdrew consent after randomization
Adverse event
Lost to follow-up
Other

If Other, Specify

Completed at the very end of the study (after End of Study Phone Call) or when consent is withdrawn.

Attempts to contact participants should continue until the CC announces the study is complete or participant withdraws consent.

"Lost to follow-up" is not to be selected until the study is completed and attempts to contact the participant have been unsuccessful.

Adverse Events

Adverse Event

. . .

- Upper respiratory infection
- Pneumonia
- Headache
- Skin rash
- Skin infection
- Urinary tract infection
- Phlebitis
- Nephrolithiasis
- Lung cancer
- Colon cancer
- Breast cancer
- Prostate cancer
- Leukemia
- Lymphoma
- Myocardial infarction
- Stroke
- Coronary procedure (e.g. PTCA, cardiac surgery)
- Hypercalcemia
- Hyperphosphatemia
- Hypercaciuria
- Anemia
- Thrombocytopenia
- Fracture
- Other

Select Adverse Event from dropdown list or, if not on dropdown list, select "Other."

Other, specify:

If adverse event is a fracture, specify the bone (enter all affected bones, separated by comma):

Record a diagnosis. If no diagnosis available, enter the symptoms reported.

Is this a Worsening Status of a Previously Reported Adverse Event? ❍ Yes ❍ No

AE Start Date ___ / ___ / ___
dd MMM yyyy

Ongoing? ☐

AE End Date ___ / ___ / ___
dd MMM yyyy

Is the adverse event serious? ❍ Yes ❍ No

If AE is Serious, check reason(s)

Check all that apply.

Death ☐

Life Threatening Condition ☐

New hospitalization or prolongation of existing hospitalization ☐

Persistent or Significant Disability or Incapacity ☐

Congenital Anomaly or Birth Defect ☐

Any Other Significant Hazard ☐

Expectedness ❍ Expected ❍ Unexpected

Refer to Data and Safety Monitoring Plan (DSMP) in MOP section 14 for list of expected events.

Relatedness ❍ Unrelated ❍ Unlikely ❍ Possible ❍ Probable ❍ Definite

If possible, probable, or definite select one of the following: . . .

- Related to study pills
- Related to other study procedure

Severity ❍ Mild ❍ Moderate ❍ Severe

Frequency ❍ Single event ❍ Re-occurring event

Outcome ❍ Resolved ❍ Condition still present ❍ Death

Action Taken (check all that apply)

No action, participant continues in the study ☐

Study pills temporarily held, participant continues in the study ☐

Study pills permanently discontinued, participant continues in the study ☐

Participation in study permanently discontinued and participant has gone "off study" ☐

Intervention, new medication ☐

Intervention, other ☐

If other intervention specify

Does this adverse event meet the definition of an Unanticipated Problem (UAP)? ❍ Yes ❍ No

Did this adverse event result in a request to unmask study drug assignment? ❍ Yes ❍ No

If Yes, did unmasking occur? ❍ Yes ❍ No

If Yes, provide brief explanation of unmasking.

If yes, who was unmasked (check all that apply)?

Investigator ☐

Participant ☐

Date unmasking occurred ____ / ____ / ____
dd MMM yyyy

Provide any additional comments

If serious adverse event or unanticipated problem, were supporting documents sent to the CC for SOS review? ❍ Yes ❍ No

If 'no' selected above, explain

Date supporting documents sent to CC ____ / ____ / ____
dd MMM yyyy

Prior to submitting any source documents for Safety and Outcomes review, the PI must sign off on adverse event.

==========

This section is to be completed by the Safety and Outcomes Committee.

System Organ Class

AE Safety Term

Refer to Data and Safety Monitoring Plan (DSMP) in MOP section 14 for definition of UAP.

Refer MOP section 14 for instruction on sending supporting documents to the CC.

Site staff cannot enter or edit this section, but once data is entered by SOC, data will be available for viewing.

Date Documents received by CC

Description of event or problem

Relevant Tests/Laboratory Data, Including dates

Additional information related to the: Description of event or problem, Relevant Tests/Laboratory Data and Other Relevant history, including pre-existing medical conditions

Therapy Start Date

Therapy End Date

Therapy Ongoing

Concomitant Medical products and therapy dates

Safety outcome determination

Date Safety Report sent to all participating Investigators

Please make any additional comments or provide clarification to any information collected on this form as related to the adverse event.

Diabetes Adjudication

Date participant reported the diagnosis of diabetes or the prescribing or start of diabetes-specific medication to site

[ ] / [▼] / [ ]
dd MMM yyyy

Type of initial contact with site

. . .
- Telephone call
- E-mail
- Study visit
- Other

Setting of diabetes diagnosis or prescribing of diabetes-specific medication

. . .
- Outpatient primary care office
- Outpatient specialist office
- Hospital – emergency room
- Hospital – inpatient
- Hospital – day surgery
- Health screening – community health fair
- Health screening – employee health
- Other

Professional making the diagnosis of diabetes or prescribing of diabetes-specific medication

. . .
- Physician
- Nurse Practitioner, Physician Assistant, Surgical Assistant
- Nurse
- Community health worker
- Pharmacist
- Other

Date of diabetes diagnosis (or start of diabetes specific medication)

[ ] / [▼] / [ ]
dd MMM yyyy

Reason for testing or reason for prescribing a diabetes specific medication

. . .
- Routine (well visit, pre-op, health screening, other)
- Symptoms of diabetes (provide details in field below)
- Other illness or hospitalization (provide details in field below)
- Other (provide details in field below)

Provide additional information and details regarding the reason for testing

Site fills out top of the form (until red line) using information recorded from Non-D2d Diabetes Diagnosis Worksheet.

Documents are then sent to the CC for forwarding to the COC. COC adjudication result is entered at bottom of page. The RC and PI will receive an email notifying them to review this form and complete the Diabetes Outcome form.

Date participant started diabetes medication ☐/☐▼/☐
dd MMM yyyy

What diabetes medications were prescribed? (enter generic name) ☐

Enter generic name only. Use MedLine database (http://www.nlm.nih.gov/medlineplus/druginformation.html) to find generic name.

(Adjudication committee will see all concomitant medications, just record diabetes medications started after diagnosis)

Has the participant made any lifestyle changes since the diagnosis of diabetes or start diabetes-specific medication? ❍ Yes ❍ No

If yes, describe the changes ☐

Medical Records requested ❍ Yes ❍ No

If no, provide reason ☐

Date medical records received ☐/☐▼/☐
dd MMM yyyy

Provide a narrative summary of the medical records relevant to the diagnosis of diabetes or prescribing or start of diabetes-specific medication. ☐

Enter outside of study glycemia measures

Date of test ☐/☐▼/☐
dd MMM yyyy

Test . . . ▼
- Hemoglobin A1c (%)
- Fasting plasma glucose (mg/dl)
- 2 hour plasma glucose after 75g glucose load (mg/dl)
- Random plasma glucose (mg/dl)
- Glucometer reading (mg/dl)

Result ☐

Lab name or site of testing ☐

This section of the form is a log. To add additional log lines (i.e. additional test results), save form and click "Add Log Line."

==========

This section is to be completed by the Clinical Outcomes Committee.

Site staff cannot enter or edit this section, but once entered by COC, data will be available for viewing. Information entered in this section is needed to complete the Diabetes Outcome form.

Participant experienced new-onset diabetes

Indicate date of onset

Participant did not experience new-onset diabetes

If applicable, indicate start date of diabetes-specific pharmacotherapy

Reason for starting medication

If reason for starting medication is a non-diabetes indication, please specify

Insufficient information for adjudication

If applicable, indicate start date of diabetes-specific pharmacotherapy

Reason for starting medication

If reason for starting medication is a non-diabetes indication, please specify

Diabetes Outcome

This form is completed if the participant is diagnosed with diabetes by central lab criteria or if participant starts a diabetes-specific medication.

This form is completed if diabetes is diagnosed or if the participant needs to be censored for the outcome of diabetes because she was started on a diabetes-specific medication.

Was participant diagnosed with diabetes by meeting the D2d study Central Laboratory criteria or was the diabetes outcome adjudicated by the Clinical Outcomes Committee (COC) adjudication? ❍ Yes ❍ No

When participant meets diabetes outcome criteria based on central lab results, RC will click yes. If through adjudication, CC will alert site when a determination is made.

If **Yes**, diagnosis made by:

. . .

Central laboratory criteria
COC concluded participant experienced new-onset diabetes

Date of diagnosis: ___ / ___ / ____
dd MMM yyyy

Note: If diagnosis is made by central laboratory criteria, enter date of first diagnostic value from the central laboratory. If diagnosis is made by adjudication, enter date from the Diabetes Adjudication form.

If **No**, complete the remainder of this form.

Choose one of the following:

. . .

Started diabetes medication, despite central laboratory resting not meeting study criteria for diabetes.
Started diabetes medication. Did not have central laboratory testing. COC concluded participant did not experience new onset diabetes.
Started diabetes medication. Did not have central laboratory testing. COC has insufficient information for adjudication of diabetes.

Enter data from the Non-d2d Diabetes Diagnosis Worksheet and Diabetes Adjudication

Enter generic name only. Use MedLine database (http://www.nlm.nih.gov/medlineplus/druginformation.html) to find generic name.

Name of diabetes-specific medication:

Start date of diabetes-specific medication ___ / ___ / ____
dd MMM yyyy

Reason for starting diabetes-specific medication: . . .

- Non-diabetes indication
- Clinician made diabetes diagnosis, non-confirmed

If Non-diabetes indication, please specify: