



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

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Visit Date Form

Visit Date

 / /

dd MMM yyyy

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

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 \geq 30 years (25 if American-Indian, Alaska Native, Native Hawaiian or Other Pacific Islander) Yes No

Body Mass Index \geq 24.0 (22.5 kg/m² for Asians) and \leq 42.0 kg/m² Yes No

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

Exclusion Criteria

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

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. Meeting glycemic criteria for diabetes

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

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 adrenal insufficiency treated with physiologic doses of glucocorticoids who are otherwise stable are not excluded. Yes No

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

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

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

For male participants, all "Women Only" questions must be answered "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.

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

 / ▼ /

Protocol version participant enrolled under

...	▼
1.4	
1.5	
1.6	
1.7	

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

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:

Database-related outreach

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

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

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	
Web based – D2d	
Web based – Craigslist	
Web based – Google	
Web based – Facebook	
Web based – Twitter	
<< < Back 2/2 Next> >>	
Web based – Advertisement on internet	
Web based – 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

... ▼
Hispanic or Latino
Not Hispanic or Latino

Select ethnicity by participant self-identification.

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

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

Select race by participant self-identification.

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

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

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

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

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

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

international units

Record current total daily dose of
non-dietary calcium supplementation

mg

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.

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

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

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

Smoking History

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

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

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

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

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

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

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

Was the Food Frequency Questionnaire completed?

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

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

Social History

What is your current marital status?

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

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

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

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."

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?

...	▼
No	
Yes	
Prefer not to answer	

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

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

...	▼
Don't know	
Prefer not to answer	

Support and Education Program Meeting Attendance

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

...	▼
None	
1	
2	

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

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

international units

Record current total daily dose of non-dietary calcium supplementation

mg

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

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
 dd MMM yyyy
 Unscheduled -Confirmatory visit?

<input type="text"/>	/	<input type="text"/>	▼	/	<input type="text"/>
----------------------	---	----------------------	---	---	----------------------

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

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

Were the safety laboratory tests collected? Yes No

Were blood or urine specimens sent 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

Record current total daily dose of non-dietary calcium supplementation

international units

mg

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

Vital Signs Form

Height

cm

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

Weight

kg

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

Body Mass Index (BMI) (calculated)

kg/m²

System will calculate

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

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

Systolic Blood pressure average (calculated)

mmHg

Diastolic Blood pressure average (calculated)

mmHg

System will calculate

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. 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

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."

Medical History Log Form

Body System

...	▼
Skin HEENT Respiratory Cardiovascular Musculoskeletal Gastrointestinal Gynecologic Urogenital/Renal Endocrine/Metabolic Neurological Hematopoietic/Lymphatic Psychiatric or Mental Health Allergies	

Medical Condition

Start Date

or Event

<input type="text"/>	/	<input type="text"/>	▼	/	<input type="text"/>

Ongoing

dd

Resolved Date

<input type="text"/>	/	<input type="text"/>	▼	/	<input type="text"/>
MMM		yyyy			

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

uu vvvvvv

yy

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	<input type="text" value="..."/> <input type="text"/> ▼ 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 blank.

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.

Name of medication

Indication

...	▼
Diabetes Hypertension Osteoporosis Weight loss Hypercholesterolemia Other	

Other, specify

Dose

Dose Unit

...	▼
application cap g Gtt IU L Mcg Mcg/kg/min Mcg/min mEq mg mL Mmol ng/kg/min pack puff spray tab units Other	

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

If participant is on a combination medication, it must be entered as its' components. e.g. Caduet is entered as amlodipine and atorvastatin.

“Other” is only to be used at direction of CC (e.g. a new drug is approved that the needs to be tracked).

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 laboratory specimens collection

 / /

dd MMM yyyy

Was the participant fasting for at least 8 hours?

Yes No

Was a pregnancy test done?

Yes No Not Applicable

If yes, please record results

Positive Negative

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

White blood cell count

Hemoglobin

Hematocrit

Platelet count

AST

ALT

Serum calcium

Serum creatinine

Estimated creatinine clearance (GFR) (calculated)

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.

Hemoglobin A1c

Fasting Plasma Glucose

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

Safety Local Laboratory

Were the local (safety) laboratory tests collected

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

Date of laboratory specimens collection

	/		▼	/	
--	---	--	---	---	--

dd MMM yyyy

System will calculate

Estimated creatinine clearance (GFR) (calculated)

Was a pregnancy test done?

Yes No Not Applicable

If yes, please record results

Positive Negative

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

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

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.

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.

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

/ /
dd MMM yyyy

Note: date of specimen collection must be the same as the visit date.

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:

Date frozen specimens shipped to the Central Lab.

/ /
dd MMM yyyy

Frozen specimen tracking number

Name of the person who shipped the frozen specimens

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

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

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.

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 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

Collection Date										15/DEC/2009	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
#	Bar Code	Assay Code	Assay Name	Received Date	Assay Date	Result	Units	Quality Code	Assay Result Code	<input type="checkbox"/>				
1			HbA1c	Hemoglobin A1c		5.9	%		Normal result	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2			GLU0	Fasting plasma glucose		0	mg/dL		Normal result	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3			GLU120	120 minute/2 hour plasma glucose			IL		Normal result	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
4			UCACR	Urine calcium-creatinine ratio			mg/g		Normal result	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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

Collection Date										15/DEC/2009	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
#	Bar Code	Assay Code	Assay Name	Received Date	Assay Date	Result	Units	Quality Code	Assay Result Code	<input type="checkbox"/>				
1			UCACR			0.275	mg/g		Normal result	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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	

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.

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

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

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.

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	

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.

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

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 PHYSICAL 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

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.

Minutes per day

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

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

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

Minutes per day

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.

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

Enter the primary reason the participant discontinued the study pills

...	▼
Participant decision	
Adverse event	
Completed the study per protocol	
Lost to follow-up	
Other	

If Other, Specify

--

Date of study pills discontinued

<input type="text"/>	/	<input type="text"/>	▼	/	<input type="text"/>
dd		MMM			yyyy

Completed for permanent discontinuation of study pills.

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

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.

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

At End of Study Phone Call, only these questions appear.

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

<input type="text"/>	/	<input type="text"/>	▼	/	<input type="text"/>
dd		MMM			yyyy

Contact Date

Contact Mode

...	▼
Left voice mail	
Left message with person	
Sent certified letter	
Sent email	

If C **nment**

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

... ▼
Participant withdrew consent
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

Relatedness

Unrelated Unlikely Possible
 Probable Definite

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

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.**

Date Documents received by CC

Description of event or problem

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.

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

<input type="text"/>	/	<input type="text"/>	▼	/	<input type="text"/>
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)

<input type="text"/>	/	<input type="text"/>	▼	/	<input type="text"/>
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)

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."

Result

Lab name or site of testing

=====
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 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

If **Yes**, diagnosis made by:

...	▼
Central laboratory criteria COC concluded participant experienced new-onset diabetes	

Date of diagnosis:

<input type="text"/>	/	<input type="text"/>	▼	/	<input type="text"/>
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

Name of diabetes-specific medication:

Start date of diabetes-specific medication

<input type="text"/>	/	<input type="text"/>	▼	/	<input type="text"/>
dd		MMM			yyyy

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

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.

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

Reason for starting diabetes-specific medication:

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

If Non-diabetes indication, please specify:

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