

D2d SOURCE DOCUMENTS, VERSION 2013.09.20

The following document contains a list of revisions that have been made to D2d source document template forms. This revision list is provided to ensure that site-specific source documents are modified correctly and include all necessary data collection fields.

Form Overview

Listed below are all D2d Source Document forms and their current status.

Form	Status
Screening Visit	Revisions
Baseline Visit	Revisions
Randomization Visit	Revisions
Month 3 Visit	Revisions
Month 6 Visit	Revisions
Annual Visit	Revisions
Semi-Annual Visit	Revisions
End of Study Visit	Revisions
Interim Phone Call	Revisions
End of Study Phone Call	Revisions
Unscheduled Visit	Deleted
Confirmatory Visit	Deleted
Unscheduled/Confirmatory Visit	New
Concomitant Medications	No changes
Physical Exam	New

Revision List

Listed below are the revisions that have been made to each D2d Source Document form. These revisions fall into three categories:

- Revised – the indicated text/question has been revised. Revised text within a question appears in **bold**
- Added – the indicated text/question/section has been added to the form
- Deleted – the indicated text/question has been deleted from the form

All Forms – Revisions that have been made to all forms that have the specified section

Action	Section	Details
REVISED	Header	“Study ID” has been renamed “Enrollment ID”
REVISED	Header	Enrollment ID field revised to accommodate the <u>6</u> digit enrollment ID
ADDED	Follow-up questions	Added a field to collect total supplemental vitamin D intake
ADDED	Follow-up questions	Added a field to collect total supplemental calcium intake
REVISED	Physical measurements	Blood pressure cuff size dimensions removed as these may vary by machine
ADDED	Fasting laboratory collection	Added field: “Note any issues with specimen collection or processing”
REVISED	Oral Glucose Tolerance Test	Revised last column of table “COMMENTS/ISSUES WITH COLLECTION OR PROCESSING ”
REVISED	Study Pills	Revised study pill adherence question as follows: “Did participant report taking the study pills as prescribed ” and “If no , explain”
REVISED	Study Pills	Revised options for “Disposition of returned study pills”

Screening Visit

Action	Section	Details
REVISED	Demographics	For “Sex” question, order of male and female options revised to match EDC
REVISED	Demographics	Revised question as follows: “Highest level of education complete, including home schooling ”
REVISED	Demographics	Revised question as follows: “If yes, select all family members that have been diagnosed with diabetes”
REVISED	Demographics	Revised options for “How did the participant find out about the study?”
REVISED	Demographics	Revised options for “What was the mode of initial contact with the participant?”
ADDED	Medical history	Added four questions under the header “Women Only Questions” about pregnancy and breastfeeding
ADDED	Screening Inclusion/Exclusion Criteria	

Baseline Visit

Action	Section	Details
REVISED	Physical Exam	“Examination Result” options changed from “Not Done” to “Not Examined” to be consistent with EDC
ADDED	Fasting laboratory collection	Added yes/no question: “Urine collected”
REVISED	Social/Lifestyle History	Revised options for “Do you currently smoke”
REVISED	Social/Lifestyle History	Revised options for “If yes, age when started smoking regularly”
ADDED	Baseline Inclusion/Exclusion Criteria	

Randomization Visit

Action	Section	Details
REVISED	Randomization and Study Pills	Reminder note added to “Dispensed pill bottle number” question

Month 6 Visit

Action	Section	Details
REVISED	Study Pills	Reminder note added to “Dispensed pill bottle number” question

Annual Visit

Action	Section	Details
ADDED	Social/Lifestyle History	
ADDED	Fasting laboratory collection	Added yes/no question: “Urine collected”
REVISED	Study Pills	Reminder note added to “Dispensed pill bottle number” question

Semi-Annual Visit

Action	Section	Details
REVISED	Study Pills	Reminder note added to “Dispensed pill bottle number” question

End of Study Visit

Action	Section	Details
REVISED	Summary of visit activities	Medical history revised to reflect that a complete medical history is required at the end of study visit
REVISED	Summary of visit activities	Physical exam revised to reflect that a complete physical exam is required at the end of study visit
ADDED	Medical History	Form added to reflect that it is required at end of study visit
ADDED	Physical Exam	Form added to reflect that it is required at end of study visit
ADDED	Fasting laboratory collection	Added “10 mL SST tube – for serum calcium, creatinine to local lab” to blood tubes drawn
ADDED	Fasting laboratory collection	Added yes/no question: “Urine collected”

Interim Phone Call

Action	Section	Details
REVISED	Follow-up Questions	Revised study pill adherence question as follows: “Did participant report taking the study pills as prescribed ” and “If no , explain”