



Manual of Procedures

Section 21. Non-diabetes Outcome Assessment

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21.1 OVERVIEW OF NON-DIABETES OUTCOMES

As the largest modern trial enrolling participants with prediabetes, the D2d study can achieve the following additional aims: (1) evaluate the effect of vitamin D supplementation on incident cancer and cardiovascular disease (CVD); (2) define the cancer and CVD risk in people with prediabetes.

- ✓ Existing D2d study procedures and processes will be harnessed to obtain the data needed to adjudicate cancer (CA) and cardiovascular disease (CVD) outcomes in the most efficient manner.
- ✓ There is no additional burden to participants and no safety concerns. Minimal additional burden for sites is expected.

21.2 CANCER OUTCOME ASSESSMENT

Cancer outcomes will be assessed at scheduled study encounters (4 times/year), by asking a few specific questions related to cancer screening and any diagnoses of cancer (see Appendix).

The following are cancer / pre-cancer related outcomes that the D2d study is interested in:

- Cancer diagnosis of any type
- Colonoscopy (preventive or symptom related)
- Breast biopsy
- Prostate biopsy
- Skin cancer

21.2.1 Implementation

Appendix 1a will be used first to collect data since randomization. At subsequent visits, Appendix 1b will be used to collect data since the last encounter (phone or visit).

- Each time a participant responds positively to a question or reports a diagnosis of cancer, site staff will collect supporting medical record documentation related to the event (e.g., physician notes, pathology reports, laboratory results). The **Cancer Record Submission Checklist/Coversheet (Appendix 2)** will be utilized to ensure essential records are collected.
- Site staff will de-identify the records, and send to the CC with Appendix 2 as a cover page.

Upon receipt of the records, the CC will organize into an event file, communicate with the site regarding incomplete files and, once complete, will forward the file to the Cancer Clinical Events Committee (CA-CEC) for adjudication. The CA-CEC will review the information and the event adjudication will be entered into the EDC by the CC.

21.2.2 Cancer Outcome Assessment e-CRF completion

- When a participant responds positively to a cancer question or reports a diagnosis of cancer, the site will initiate the D2d EDC Non-Diabetes Outcome Cancer e-CRF.

This e-CRF is added utilizing the “Add event” drop down on the participant’s EDC homepage. After the form is added, it will appear in the listing of forms on the left side of the screen. The log

form is similar to the adverse event form in EDC. Multiple cancer events will be captured in the same log form by adding a row (as in the AE log form). Please see examples below

Page: Non-Diabetes Outcome: Cancer - Non-Diabetes Outcome: Cancer (1)

Currently viewing line 1 of 1.
Click here to return to "Complete View".

Select Event:

Specify cancer diagnosis type:

Date of event (diagnosis, procedure, or biopsy):

Date document sent to CC:

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

Choose one of the following:

Cancer Outcome:

Cancer outcome, specify:

Specify:

Date of cancer event:

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Save

Form Saved

Subject: 010204
Page: Non-Diabetes Outcome: Cancer - Non-Diabetes Outcome: Cancer (1)

Select Event:	Specify cancer diagnosis type:	Date of event (diagnosis, procedure, or biopsy):	Date document sent to CC	***** This section is to be completed by the Clinical Events Outcomes Committee. *****	Cancer Outcome	Cancer outcome, specify	Sp
Colonoscopy	Colon	20 Apr 2015	04 Jul 2017	Choose one of the following:	--	--	--
Cancer Diagnosis	Colon cancer	20 Jul 2016	07 Sep 2016	--	--	--	--

Add a new Log line Inactivate

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Save

- **NOTE:** When a participant reports the diagnosis of cancer, the event will also need to be reported as an adverse event, following established procedures.
- Diagnostic or screening procedures are not entered as adverse events, (e.g. having a mammogram or colonoscopy are not adverse events).

21.3 CARDIOVASCULAR OUTCOME ASSESSMENT

CVD outcomes include only events that require hospitalization, and are classified as Serious Adverse Events (SAE); therefore the general questions currently asked for the collection of SAEs will be utilized. These will be adjudicated by the CVD Clinical Events Committee (CVD-CEC).

21.3.1 Implementation

- Sites will continue to report CVD SAEs via the EDC system, collect supporting documentation related to the event (e.g., medical records, laboratory results), de-identify the data and submit to the CC, as routinely done with all SAE, for review by the Safety and Outcomes Subcommittee.
 - In addition, the site will utilize the **CVD Record Collection Checklist (Appendix 3)** to ensure that essential records are collected for adjudication by the CVD-CEC reviewer. The checklist is included in the SAE packet sent to the Coordinating Center.
- If the CC reviews an SAE and considers it appropriate for CVD-CEC adjudication and the checklist (Appendix 3) was not used to collect essential records, the CC will ask the site to utilize the checklist and submit any additional medical records.
- Upon receipt of the records, the CC will organize into an event file, communicate with the site regarding incomplete files and, once complete, will forward the file to the CVD-CEC for

adjudication. The CVD-CEC will review the information and the event adjudication will be entered into the EDC by the CVD-CEC.

21.3.2 CVD Outcome Assessment e-CRF completion

- No additional forms need to be completed EDC.

21.3 APPENDICES

Appendix 1a: D2d Cancer Source Data Collection Form – Initial

Appendix 1b: D2d Cancer Source Data Collection Form – Subsequent

Appendix 2: Cancer Record Submission Checklist/Coversheet

Appendix 3: CVD Record Submission Checklist/Coversheet