

Form 202 – Medical Events

Selenium and Vitamin E Cancer Prevention Trial (S0000)				
Form 202: Medical Events				
Participant ID	Ppt Initials (L, F, M)	Study Site #	Contact #	<input type="checkbox"/> Check here if this form amends data submitted previously
<hr/>				
Instructions: Complete this form at Six Month and Annual Visits.				
<hr/>				
Date of Contact: <input style="width: 100px;" type="text"/> <small>mm/dd/yyyy</small>		Contact type: <input type="radio"/> Visit <input type="radio"/> Telephone		
<hr/>				
PROSTATE HEALTH				
1. Since his last contact, has the participant had any new prostate problems?				
<input type="radio"/> No (Go to #2)				
<input type="radio"/> Yes (Mark all that apply)				
<input type="checkbox"/> Grade 2 or 3 Prostatic Intraepithelial Neoplasia (PIN)				
<input type="checkbox"/> Symptomatic Benign Prostatic Hyperplasia (BPH)				
<input type="checkbox"/> Prostatitis				
<input type="checkbox"/> Other, specify: <input style="width: 150px;" type="text"/>				
<hr/>				
2. Has the participant had any of the following prostate related procedures or treatments since his last contact?				
<input type="radio"/> No (Go to #3)				
<input type="radio"/> Yes (Mark all that apply)				
<input type="checkbox"/> Prostate biopsy				
<input type="checkbox"/> Transurethral Resection of the Prostate (TURP)				
<input type="checkbox"/> Transurethral Incision of the Prostate (TUIP)				
<input type="checkbox"/> Transurethral Needle Ablation of the Prostate (TUNA)				
<input type="checkbox"/> Radical prostatectomy				
<input type="checkbox"/> Other prostatectomy				
<input type="checkbox"/> Prostate laser therapy				
<input type="checkbox"/> Microwave therapy (Prostatron)				
<input type="checkbox"/> Other, specify: <input style="width: 150px;" type="text"/>				
<hr/>				
OCULAR HEALTH				
3. Since his last contact, has the participant reported having an eye exam with an ophthalmologist or optometrist?				
<input type="radio"/> No				
<input type="radio"/> Yes				
<hr/>				
4. Since his last contact, has the participant reported having any of the following?				
<input type="radio"/> No (Go to #5)				
<input type="radio"/> Yes (Mark all that apply)				
<input type="checkbox"/> Diagnosis of cataract in either eye				
<input type="checkbox"/> Cataract extraction in either eye				
<input type="checkbox"/> Diagnosis of age-related macular degeneration in either eye				
<input type="checkbox"/> Treatment or follow-up with an eye doctor of a previously diagnosed age-related macular degeneration				
<hr/>				
LUNG HEALTH				
5. Since his last contact, has the participant reported a diagnosis of any of the following?				
<input type="radio"/> No (Go to #6)				
<input type="radio"/> Yes (Mark all that apply)				
<input type="checkbox"/> Emphysema				
<input type="checkbox"/> Chronic bronchitis				
<input type="checkbox"/> Asthma				
<input type="checkbox"/> COPD (Chronic Obstructive Pulmonary Disease)				

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Form 202 – Medical Events

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ENDPOINT ASSESSMENT

6. Since his last contact, has the participant reported a new occurrence of any of the following?

- ☐ No (Go to #7)
- ☐ Yes (Mark all that apply)
- ☐ Prostate cancer¹
 - ☐ Basal cell skin cancer
 - ☐ Squamous cell skin cancer
 - ☐ Other primary cancer²
 - ☐ Grade 3 or 4 Cardiovascular event (exclude grade 3 hypertension)³
 - ☐ Cardiovascular surgery or procedure³

STUDY MULTIVITAMIN

7. How many bottles of Study Multivitamin were dispensed?

- ☐ 0
- ☐ 1
- ☐ 2 or more

GENERAL HEALTH

8. Does the participant report having diabetes (either his doctor told him he has diabetes or he is taking medication for diabetes)?

- ☐ No
- ☐ Yes

9. Since his last contact, has the participant reported that he had either a sigmoidoscopy or a colonoscopy?

- ☐ No
- ☐ Yes (Mark all that apply)
- ☐ Sigmoidoscopy
 - ☐ Colonoscopy
 - ☐ Unknown

10. Since his last contact, has the participant reported that he was in the hospital or other health care facility overnight for physical health problems?

- ☐ No
- ☐ Yes, reason(s) for hospitalization:

Notes:

- (1) Complete Form 402 - Report of Prostate Cancer
- (2) Complete Form 403 - Report of Other Primary Cancer
- (3) Complete Form 404 - Report of Cardiovascular Events

Comments:

Submit

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Form 202 – Medical Events

Submission:	Web
Completed by:	Study Site Staff
When to complete and submit:	At each Six Month and Annual Visit or Contact
Contact Number:	016, 020, 026, 030, 036, 040, 046, 050, 056, 060, 066, 070, 076, 080 (the following may be applicable depending on the time-point of the study when the participant was randomized) 086, 090, 096, 100, 106, 110, 116, 120, 126, and 130

Form Instructions:

PROSTATE HEALTH

1. Since his last contact, has the participant had any new prostate problems?

“New prostate problems” are either newly diagnosed since the participant’s last contact or a previously resolved problem that has reoccurred since the last contact.

Most prostate problems may be classified as **Grade 2 or 3 Prostatic Intraepithelial Neoplasia (PIN)**, **Symptomatic Benign Prostatic Hyperplasia (BPH)**, or **Prostatitis**. Do not report elevated PSA, abnormal DRE, biopsy, prostatectomy, prostate cancer diagnosis, or non-prostate-related problems (e.g., gastrointestinal or renal problems) in this question. These conditions are asked about on other forms or in other questions.

For further information, see **Table 1 – Classifying Prostate Problems** at the end of these instructions.

If response is **Yes**, select all prostate problems that apply.

If **Other, specify** is selected as a response, indicate any prostate problems in the text field provided.

2. Has the participant had any of the following prostate related procedures or treatments since his last contact?

If response is **Yes**, select all prostate related procedures or treatments that apply.

If **Other, specify** is selected as a response, indicate any prostate related procedures or treatments in the text field provided.

OCULAR HEALTH

3. Since his last contact, has the participant reported having an eye exam with an ophthalmologist or optometrist?

Select **Yes** if the participant has had an eye exam for any reason.

4. Since his last contact, has the participant reported having any of the following?

Select a response for all subquestions. A participant who responds Yes to any of the subquestions may be eligible for the SELECT Eye Ancillary (SEE) Study (S0000B).

LUNG HEALTH

5. **Since his last contact, has the participant reported a diagnosis of any of the following?**
Select **Yes** if the participant has had a physician diagnose any of these diseases since his last contact.

ENDPOINT ASSESSMENT

6. **Since his last contact, has the participant reported a new occurrence of any of the following?**

If response is **Yes**, select all diagnoses that apply and complete the following additional forms:

If **Prostate cancer** is selected as a response, complete *Form 402 – Report of Prostate Cancer*.

If **Other primary cancer (excluding basal and squamous cell skin cancers)** is selected as a response, complete *Form 403 – Report of Other Primary Cancer*.

If the participant reports basal or squamous cell skin cancer, do not mark this box.

If **Grade 3 or 4 cardiovascular event (exclude grade 3 hypertension)** is selected as a response, complete *Form 404 – Report of Cardiovascular Events*, Parts 1 and 2.

If the participant only reports grade 3 hypertension, do not mark this box.

If **Cardiovascular surgery or procedure** is selected as a response, complete *Form 404 – Report of Cardiovascular Events*, Parts 1 and 3. Mark this box if the participant reports that he had any of the procedures listed in **Table 2 - Cardiovascular Surgery and Procedure List**, located at the end of these instructions.

If the participant reports a cardiovascular surgery or procedure that is not on the above list or one that does not fall under one of the above categories, do not mark this box.

Do not report cardioversion or aneurysm repair.

The cardiovascular surgeries and procedures SELECT is collecting are interventions. If the participant reports a cardiovascular surgery or procedure that is diagnostic in nature, do not mark this box. Examples of diagnostic procedures that should not be reported are listed below.

- Angiography
- Diagnostic heart catheterizations (where no angioplasty or stenting is done)
- Echocardiograms
- Exercise stress tests
- Perfusion scans

GENERAL HEALTH

- 8. Does the participant report having diabetes (either his doctor told him he has diabetes or he is taking medication for diabetes)?**

If the participant says his doctor told him he has diabetes or the participant is taking medication for his diabetes, then mark **Yes**.

- 9. Since his last contact, has the participant reported that he had either a sigmoidoscopy or a colonoscopy?**

If the participant reported either or both of these procedures, mark the appropriate box(es). If the participant does not know which procedure he had, mark **Unknown**. If the participant was registered to ACP **prior to this contact** and reports having had **only** a virtual colonoscopy, Mark **Yes** and obtain a new [Form 340 – Medical Record Release](#) and submit it to the ACP Coordinating Center. Otherwise, mark **No**.

- 10. Since his last contact, has the participant reported that he was in the hospital or other health care facility overnight for physical health problems?**

If the participant had an overnight stay in a hospital or any other health care facility for physical health reasons, mark **Yes** and briefly describe the specific reason for the hospitalization.

Table 1: Classifying Prostate Problems

Items in bold are pre-existing checkboxes on *Form 202 – Medical Events* and *Form 201 – 3 and 9 Month Phone Contact*. Italicized text indicates instructions for the items below.

Grade 2 or 3 Prostatic Intraepithelial Neoplasia (PIN)

Always mark Grade 2 or 3 PIN for items on this list:

High-grade PIN

Symptomatic BPH

1. Symptomatic BPH should be marked for items on this list unless there is some other known cause (e.g., renal failure):

Conditions:

- Urinary symptoms/LUTS, including:
 - Nocturia (getting up in the night to urinate)
 - Polyuria (pollakiuria, urinary frequency)
 - Urinary incontinence (dribbling)
 - Urgency (reduced urine capacity)
 - Retention (hard starting to urinate, delay in urine, weak stream/slow stream, hesitancy, incomplete voiding)
 - Anuria
 - Dysuria
 - Bladder obstruction (bladder outlet obstruction, bladder neck obstruction)
 - Bladder dysfunction (spastic bladder)
- Prostatism (“BPH symptoms”)

Medications:

- Avodart (Dutasteride)
- Flomax

*2. Symptomatic BPH **may** apply for items on this list:*

Conditions:

- Swollen prostate (Note: may also be due to Prostatitis. Select only a single cause for this condition. If the cause is unknown, select Symptomatic BPH.)

Procedures:

- Transurethral resection of the prostate (TURP)
- Transurethral incision of the prostate (TUIP)
- Transurethral needle ablation of the prostate (TUNA)
- Prostate laser therapy (Laser surgery)
- Microwave therapy (Prostatron)

Medications:

- Finasteride (Proscar, Propecia)
- Hytrin

If there is another known cause for a procedure, symptom, or medication listed in category 1 or 2 above, it is not a prostate problem and should not be indicated in this question.

Prostatitis

1. *Prostatitis always should be marked instead of “Other” for items on this list:*

- Prostate infection
- Inflamed prostate
- Prostate irritation
- Prostate pain/soreness/ache/tenderness/discomfort
- Swollen prostate (Note: may also be due to Symptomatic BPH. Select only a single cause for this condition. If the cause is unknown, select Symptomatic BPH.)

2. *Prostatitis may apply for items on this list:*

Medications:

- Antibiotics (especially Cipro)

If a prostate infection is not the cause of a condition listed in category 1 above, mark “Other” and describe the condition.

If there is another known cause for an item listed in category 2 above, the medication is not prostate-related.

Other

The following are prostate conditions of interest which do not fall under one of the three categories above. If the participant has experienced one of these problems, mark Yes, indicate Other, specify, and describe the condition.

- Hematospermia (blood in semen/ejaculate)
- Hematuria (blood in urine)
- Asymptomatic BPH (enlarged prostate, hypertrophy, hyperplasia, increased prostate size)
- Erectile impotence
- Sexual dysfunction

THE FOLLOWING SHOULD NEVER BE RECORDED IN THIS QUESTION:

- DRE results (Abnormal, suspicious, hard prostate, firm prostate, lump in prostate, nodular prostate, asymmetry, spongy prostate, rough spot, irregularity)
- PSA results (Elevated, high, increased, rising, above normal)
- Ultrasound results (Echograph, hypoechoic, isoechoic, hyperechoic)
- Biopsy results (Atypical cells, glandular atypia)
- Prostate cancer diagnosis
- Prostatectomy
- Prostate lesion

Table 2: Cardiovascular Surgery and Procedure List

Items in bold are in the drop-list; italicized items are for reference.

Ablation therapy**Angioplasty**

Below is a list of different kinds of angioplasty:

Angioplasty

Atherectomy

Balloon angioplasty

Balloon dilation of coronary artery

Laser angioplasty

Plaque removal with a laser

Removal of artery plaque

Stent placement

Bypass surgery

Below are other names for bypass surgery:

CABG

Coronary artery bypass grafting surgery

Coronary artery bypass surgery

Non-coronary bypass (e.g., femoral-popliteal bypass)

Carotid endarterectomy**Correction of congenital heart defects****Heart transplant****Heart valve repair**

Below is a list of different types of heart valve repair:

Heart valve dilation

Valvuloplasty

Annuloplasty

Heart valve replacement**Internal cardioverter defibrillator placement (or replacement)****Pacemaker placement (or replacement)****Unknown**