



PVDOMICS STUDY

Detailed Serious Adverse/Adverse Event Form #401

Instructions: See page 2 for detailed instructions on form completion.

Events Reporting Timelines

Event	Report on Form		Phone call and e-mail to DCC co-PIs ¹⁾	Report to Local IRB as required	Auto e-mail sent to :	
	400 (report immediately upon learning of the event)	401			400	401
Any SAE within 24 hours of study procedure (regardless of relatedness or expectedness) ²⁾	X	X (within 1 week of learning of the event)	X	X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC co-PIs DCC NHLBI OSMB Chair
A) Any death ²⁾ OR B) Life-threatening SAE that is: - possibly, probably or definitely related to a study procedure <u>AND</u> - unexpected or expected, but of greater severity than described in consent ²⁾	X	X (within 1 week of learning of the event)		X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC co-PIs DCC NHLBI OSMB Chair
Non-fatal, non-life-threatening SAE or unanticipated adverse event that is: - possibly, probably or definitely related to a study procedure <u>AND</u> - unexpected or expected, but of greater severity than described in consent	X	X (within 2 weeks of learning of the event)		X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC NHLBI OSMB Chair
Non-fatal event that happened more than 24 hours after study procedure and is: - not related or unlikely to be related to a study procedure OR - possibly, probably or definitely related to a study procedure but is expected and accurately described in the consent	X	X (within 4 weeks of learning of the event)		X	DCC co-PIs DCC Clinical site (PI and Coordinators)	DCC

¹⁾ For SAEs within 24 hours of study procedure:

The clinical center PI must notify the DCC **immediately** upon learning about the event as follows:

- Call one of the DCC co-PIs [Dr. Beck at (216) 444-9927 or Dr. Erzurum at (216) 312-3116] AND
- Send an e-mail to both Drs. Beck and Erzurum (beckg@ccf.org, erzurum@ccf.org). Be sure to use the option in your e-mail software that requests a delivery receipt.

²⁾ These classes of safety events are subject to expedited reporting to NHLBI and the OSMB. All other safety events are reported to NHLBI and the OSMB as part of routine reports.

Instructions: This form is completed as soon as the Clinical Center identifies that a participant event has occurred. An event can be an adverse event (AE) and/or serious adverse event (SAE) such as but not limited to: life threatening condition, hospitalization, death or other event. Refer to MOP for details on AEs and SAEs. Events that occur during the study period or within 2 weeks of study completion should be reported. The timeline and procedures for AE/SAE reporting follow the guidelines by PVDOMICS OSMB and NHLBI Adverse Event and Unanticipated Problem Reporting Policy. Enter this form with the available information within the timeline. Add further details and final outcome later if not available at the time. The form is considered incomplete until the final outcome information is provided.

It is up to the physician's clinical judgment to decide when an adverse event (SAE or AE) has occurred. Enter this adverse event form when the Clinical Center Study Team (Physician and Study Coordinator) feels that the participant has had an event (such as, a sign, symptom or disease) that the Study Team feels is important to document for the PVDOMICS Study. For SAE's, AE's, review and complete each main section question*.

This form should be entered following the deadlines in the table above with as much information as available at the time. You will be able to go back and **update the form as many times as needed until the final outcome is available**. Once you enter the final outcome (i.e., Q22a is not 6=Not available yet), the form will be considered final and any further changes will need to go through the inquiry system.



PVDOMICS STUDY

Detailed Serious Adverse/Adverse Event Form #401

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1. Identification Number

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2. Alphacode

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3. Date center first heard of event (mm/dd/yyyy)

4. Date of event onset (mm/dd/yyyy)..... ____/____/____

DEATH

5. Did the participant die? (0=No-skip to Q8, 1=Yes)

Detailed documentation regarding the participant's death (if hospitalized at time of death: expiration summary, autopsy report, lab reports, etc., or, if not hospitalized at time of death: physician summary, autopsy, office notes, etc.) should be submitted to the DCC when requested.

6. a. Date of death (mm/dd/yyyy)..... ____/____/____

b. Did this death occur within 24 hours of study procedure (0=No, 1=Yes)

c. In the Clinical Center Physician's judgment, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol?

(0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely).....

d. If the event was possibly, probably, or definitely caused by any procedure or device, that was done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent?

1=Unexpected – not mentioned in the consent

2=Expected, but of greater severity than mentioned in the consent

3=Expected and accurately described in the consent

e. Where did the death occur?

1=In a hospital, in the emergency room

2=In a hospital, not in the emergency room

9=Location unknown

3=In the participant's home

4=In a nursing home or other skilled care facility

(Contact the DCC if another code is needed)

f. Was an autopsy performed? (0=No, 1=Yes, 9=unknown)

If YES, be sure to include the autopsy report in the documentation.

The list of cause(s) of death needs to be completed by the Principal Investigator:

	Cause(s) of Death (Note: A procedure code cannot be a primary cause of death.)	MedDRA Auto-populated
7a. Primary Cause:		
7b. Secondary Cause:		
7c. Additional Cause:		
7d. Additional Cause:		
7e. Additional Cause:		

HOSPITALIZATION:

8. Was there an in-patient hospitalization? (0=No, skip to Q16, 1=Yes) _____
- Date of hospital admission (mm/dd/yyyy) _____ / _____ / _____
 - Did this hospitalization occur within 24 hours of study procedure (0=No, 1=Yes)..... _____
 - Was this a planned hospitalization (0=No, 1=Yes, 9=Unknown)..... _____
 - In the Clinical Center Physician's judgment, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol?
(0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely)..... _____
 - If the event was possibly, probably, or definitely caused by any procedure or device, that was done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent? _____
 1=Unexpected – not mentioned in the consent
 2=Expected, but of greater severity than mentioned in the consent
 3=Expected and accurately described in the consent

The list of causes needs to be completed by the Principal Investigator:

	Cause(s) of Hospital Admission – (Note: A procedure code cannot be a primary cause of hospitalization)	MedDRA Auto-populated
9a. Primary Cause:		
9b. Secondary Cause:		
9c. Additional Cause:		
9d. Additional Cause:		
9e. Additional Cause:		
9f. Additional Cause:		

10. Did the participant have a surgical procedure done during this hospitalization? (0=No, 1=Yes)

	Type of Procedure(s) Performed While in Hospital	MedDRA Auto-populated
10a.Procedure 1		
10b.Procedure 2		
10c.Procedure 3		
10d.Procedure 4		

11. a. Did the participant receive a functioning transplant during this hospitalization? (0=No, 1=Yes). _____
- b. If Q11a = 1, type of transplant received?..... _____
- | | |
|--------------------------|-------------------------|
| 1=Single-lung transplant | 4=Heart-lung transplant |
| 2=Double-lung transplant | 5=Other transplant |
| 3=Heart transplant | |

12. Was there prolongation of existing hospitalization? (0=No, 1=Yes) _____

a. Did this event occur within 24 hours of study procedure (0=No, 1=Yes) _____

b. In the Clinical Center Physician's judgment, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol?
(0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely) _____

c. If the event was possibly, probably, or definitely caused by any procedure or device, that was done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent? _____

1=Unexpected – not mentioned in the consent

2=Expected, but of greater severity than mentioned in the consent

3=Expected and accurately described in the consent

The list of causes needs to be completed by the Principal Investigator:

	Cause(s) of Prolongation of Hospitalization	MedDRA Auto-populated
13a. Primary Cause:		
13b. Secondary Cause:		
13c. Additional Cause:		
13d. Additional Cause:		
13e. Additional Cause:		

14. Did this hospitalization result in a persistent or significant incapacity? (0=No, 1=Yes) _____

15. a. Status of participant at the end of hospitalization _____

1=Discharged to home

2=Discharged to be admitted to rehab, a nursing home or other facility

3=Died

4=Still in hospital (*only use this option if several weeks have elapsed*)

b. If Q15a = 1 or 2, date of discharge (mm/dd/yyyy) _____ / _____ / _____

*Note: If the participant is still in the hospital (Q15a=4) at the time of the initial completion of the form, Q15a-b need to be updated when this information becomes available.***LIFE-THREATENING EVENT**

16. Did the participant experience a life threatening event? (0=No, 1=Yes) _____

a. Did this life-threatening event occur within 24 hours of study procedure (0=No, 1=Yes) _____

b. Did this life threatening event require treatment (0=No, 1=Yes) _____

c. In the Clinical Center Physician's judgment, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol?
(0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely) _____

d. If the event was possibly, probably, or definitely caused by any procedure or device, that was done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent? _____

1=Unexpected – not mentioned in the consent

2=Expected, but of greater severity than mentioned in the consent

3=Expected and accurately described in the consent

The list of life-threatening cause(s) needs to be completed by the Principal Investigator:

	Life-Threatening Cause(s)	MedDRA Auto-populated
17a. Cause 1:		
17b. Cause 2:		
17c. Cause 3:		
17d. Cause 4:		
17e. Cause 5:		

18. Did the life-threatening event result in a persistent or significant incapacity? (0=No, 1=Yes)

OTHER EMERGENCY DEPARTMENT VISIT AND SAE/AE

19. Did participant have an **Emergency Department** visit? (0=No, 1=Yes, complete below)

- a. Did this ED visit occur within 24 hours of study procedure (0=No, 1=Yes)
 - b. In the Clinical Center Physician's judgment, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol?
(0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely)
 - c. If the event was possibly, probably, or definitely caused by any procedure or device that was done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent?
- 1=Unexpected – not mentioned in the consent
2=Expected, but of greater severity than mentioned in the consent
3=Expected and accurately described in the consent

	Condition(s)-Enter signs/symptoms/condition description(s) that triggered the ER visit - (database will allow as many conditions as needed)	MedDRA Auto-populated
19c. Condition 1:		
19d. Condition 2:		
19e. Condition 3:		
19f. Condition 4:		
19g. Condition 5:		

Continued on next page

20. In the opinion of the physician, was/were there other diagnoses and/or signs and/or symptoms not previously documented that are important to document for the PVDOMICS Study (0=No, 1=Yes, complete below)

If SAE, for column labeled '**If SAE, Study Caused?**':

In the Clinical Center Physician's judgment, was this event caused by any procedure or device that was done as part of the PVDOMICS Study protocol?

(0=No, 1=Unlikely, 2=Possibly, 3=Probably, 4=Definitely)

For column labeled '**If SAE, Expected?**' Use the following response codes:

If the event was possibly, probably, or definitely caused by any procedure or device that was done as part of the PVDOMICS protocol, was it expected and accurately described in the study consent?

1=Unexpected – not mentioned in the consent,

2=Expected, but of greater severity than mentioned in the consent,

3=Expected and accurately described in the consent

	Condition(s)-Enter signs/symptoms/condition description(s) (database will allow as many conditions as needed)	MedDRA Auto-populated	AE/SAE? 1=AE only 2=SAE, ≤ 24 hrs of PVD test 3=SAE, >24 hrs of PVD test	If SAE, Study Caused?	If SAE, Expected?
20a. Condition 1:			—	—	—
20b. Condition 2:			—	—	—
20c. Condition 3:			—	—	—
20d. Condition 4:			—	—	—
20e. Condition 5:			—	—	—

21. Did participant have an outpatient surgical procedure done? (0=No, 1=Yes, complete below)

	Cause(s) for which Procedure(s) Performed as an Outpatient	MedDRA Auto-populated
21a.Cause 1		
21b.Cause 2		

	Type of Procedure(s) Performed as an Outpatient	MedDRA Auto-populated
21c.Procedure 1		
21d.Procedure 2		

22. a. Final outcome of event

0=Recovered without treatment

1=Recovered with treatment

2=Event continuing without treatment (if continues, use same date as Q200-date form completed)

3=Event continuing and controlled with treatment (if continues, use same date as Q200-date form completed)

4=Event continuing and not controlled with treatment (if continues, use same date as Q200-date form completed)

5=Participant died

6=Not yet available

22. b. Date of final outcome (mm/dd/yyyy) ____/____/____

If Q22a=6 at time of the initial form completion, Q22a and Q22b need to be updated when the final outcome information is available. Once you enter the final outcome (i.e., Q22a is not 6=Not available yet), the form will be considered final and any further changes will need to go through the inquiry system.

23. Please write a summary of what happened, what action was taken and final outcome.

200. Date form completed (mm/dd/yyyy) ____/____/____

201. Username of PVDOMICS Study staff member completing this form..... _____

202. Username of physician reviewing accuracy and completeness
of this form..... _____

(Username is the first 6 letters of physician's last name and first initial.)

Clinical Center Use Only

Date form entered (mm/dd/yyyy) ____/____/____

Username of person entering this form _____

The Data Coordinating Center (DCC) will notify clinical center staff to complete and enter Form 402 when an event (hospitalization, ER visit, other SAE and/or death) shows that a packet needs to be scanned and uploaded to DCC secure portal. See the MOP for detailed instructions on processing the packet.