



PVDOMICS STUDY

Two-Week Event Assessment - Form #185

Coordinator Instructions: This form is to be completed two weeks after a participant has completed the PVDOMICS study*. The participant is to be contacted and asked the following questions. If a participant has been to the emergency room, hospital or had an unscheduled medical appointment, please obtain the information needed to complete the appropriate adverse or serious adverse event research form.

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1. Identification Number

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2. Alphacode

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3. Date of contact: (mm/dd/yyyy)

Health-related Participant Questions:

4. Have you (the participant) been hospitalized? (0=No, 1=Yes).....

5. Have you (the participant) been to the Emergency Room or Department (0=No, 1=Yes)

6. Have you (the participant) had an unscheduled doctor visit? (0=No, 1=Yes, explain in comments)

7. Brief Comments (enter into database. Recall that Forms 400 & 401 must be completed if unanticipated AE or if SAE.)

Other Participant Question:

8. May we contact you again for future studies?
(0=No, 1=Yes, 8=N/A-did not speak directly with participant)

Coordinator Use only

100. Who did coordinator contact in order to obtain AE/SAE information?
1=Participant (recommended), 2=Family member/Significant other, 8=Other

a. Was Spanish translator used to 'speak' with participant? (0=No, 1=Yes)

101 If, after contacting someone other than participant, did participant die
within the previous two weeks since last PVDOMICS visit? (0= No, 1= Yes).....
(if yes, Forms 400 and 401 should be completed as soon as possible)

b. Date of death (mm/dd/yyyy) / /

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

201. Username of person reviewing completeness of this form

Clinical Center Use Only

Date Form Entered (mm/dd/yyyy) / /

Username of person entering this form

* Effective July 1, 2017, use this form for participants currently enrolled in PVDOMICS.