



PVDOMICS STUDY

Adjudication Committee Reviewer Form #700

Instructions: Each Reviewer should complete a Form 700 for the case below based on all information available at time of review. This form should be entered into the PVDOMICS Study database by the clinical center staff.

Initial Packet includes: *PVD Assessment (F102), Comorbidity (F103), RHC (F280), CPET (F290/291+A), PFTs (F270/271), Meds (F110), Ht/Wt (F132), V/Q (F254), CT Results (F262), Sleep Study Results (F153/156)* **if available** in the database.

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1. Patient Identification Number

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2. Alphacode

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3. Date of Review (mm/dd/yyyy)

4. Identify PVD status of this participant based on all information available at time of review.....
 1=Control, go to Q200 2=Comparator, go to Q5. 3=PH, go to Q6.

5. If **Q4 is 2=Comparator**, based on the information currently available does reviewer agree with the Center PI's WHO group Comparator classification (*F102, Q9 and Q10*).....
 0=No, Reviewer disagrees with Center PI
 1=Yes, Reviewer agrees with Center PI's WHO Group Assignment
 9=Unable to determine at this time – additional information is needed (skip to Q9)

If **Q5 is 0=No**, based on the information currently provided to the reviewer, what WHO Group(s) Comparator classification does this participant falls into?

- a. What is the Primary WHO Group Comparator classification?.....
 1=WHO Group 1 3=WHO Group 3 5=WHO Group 5
 2=WHO Group 2 4=WHO Group 4
- b. What is the Secondary WHO Group Comparator classification?
 1=WHO Group 1 3=WHO Group 3 5=WHO Group 5
 2=WHO Group 2 4=WHO Group 4 8=Not applicable

If Q5a-b were answered, skip to Q10 and provide rationale for final classification and Adjudication Committee review.

6. If **Q4 is 3=PH**, does reviewer agree with the Center PI's WHO group assignment (*F102, Q17*) based on information from review packet?
 0=No, Reviewer disagrees with Center PI
 1=Yes, Reviewer agrees with Center PI's WHO Group Assignment
 9=Unable to determine at this time – additional information is needed (skip to Q9)

7. If **Q6 is 0=No**, based on the information currently provided to the reviewer, what WHO group(s) does the participant fall in?
 Please identify WHO Groups using the codes below:
 1=WHO Group 1 3=WHO Group 3 5=WHO Group 5
 2=WHO Group 2 4=WHO Group 4 6=Mixed

If response to **Q7 is 6=Mixed**, please identify WHO Groups 1-5 (8=Not applicable):

- a. What is the Primary WHO Group classification?.....
 b. What is the Secondary WHO Group classification?.....
 c. What is the Tertiary WHO Group classification?.....

If Q7a and b = WHO Groups 1 and/or 2 and/or 3, complete Q8.

Note: Participant can only be classified once in Q8a-e:

8. a. Is this participant's PH considered Mixed WHO Groups 2 & 3 as defined below (0=No, skip to 8c, 1=Yes, 9=Unable to determine at this time, *must complete Q9*).....

Definition:

- PCW > 18, LAH, LAE, atrial fib **AND**
- COPD, IPF, SSc-ILD, OHS, OSA, non-parenchymal restrictive lung diagnosis or CPFE

- b. What is mixed WHO Group for 2 and 3?

1=WHO 2, 3: acute worsening in PCW with fluid challenge, exercise, pulmonary vasodilator

2=WHO 3, 2: acute worsening of oxygenation or only mild elevation of PCW

9=Unable to determine at this time-additional information needed (*must complete Q9*)

- c. Is this participant's PH considered WHO 1 & 3 as described below (0=No, 1=Yes).....

Features of WHO 1: i.e.

- autoimmune serology, positive family history **AND**
- mild (COPD, IPF, SSc-ILD, OHS, OSA, non-parenchymal restrictive lung diagnosis, CPFE); i.e. evidence of progressive PH in response to activity and/or over time with stability of hypoxemia or mild parenchymal lung disease

- d. Is this participant's PH considered WHO 1, 2 as described below (0=No, 1=Yes)

- WHO 1, 2: PAH (WHO 1, autoimmune serology) with provocation elevation in PCW

- e. Is this participant's mixed PH described as 'other'? (0=No, 1=Yes).....

9. Are there any other data not included in the packet that would enable the reviewer to make a better decision? (0=No, 1=Yes, 8=Not applicable).....

- a. If yes, what data does reviewer need to make a decision (0=No, 1=Yes)?

ECG Cardiac MRI ECHO

Clinical Labs Other _____, specify: _____

10. Please explain your rationale for final classification:

200. Date the form completed...../_____/_____

201. Username of Adjudication Committee Reviewer

(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 _____