

Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid integration of a PhenX protocol into a study. The PhenX DCW is not designed to be a data collection instrument. Investigators will need to decide the best way to collect data for the PhenX protocol in their study. Variables captured in the DCW, along with variable names and unique PhenX variable identifiers, are included in the PhenX Data Dictionary (DD) files.

1. Has a doctor ever told you that you had pulmonary embolus or blood clots in your lungs?

- 1 [] Yes
- 0 [] No
- 9 [] Dont Know

Complete the following for all hospitalized pulmonary embolism (PE)/deep vein thrombosis (DVT).

Complete the following if Outpatient (OP) records confirm deep vein thrombosis (DVT) or an autopsy report confirms pulmonary embolism.

- 2. Pulmonary embolism (PE) requiring hospitalization:
- 3. Date of Diagnosis: (M/D/Y) __ / __ / ____
- 4. Diagnosis: (Mark the one category that applies best).

1 [] Pulmonary embolism **not resulting from a procedure** within 60 days

2 [] Pulmonary embolism **during or following a procedure** within 60 days

5. Diagnosis of pulmonary embolism is based on:

(Mark all that apply.)

1 [] Hospital discharge summary with a diagnosis of pulmonary embolism

2 [] High probability on ventilation-perfusion lung scan (exclude moderate, intermediate, or low probability on ventilation-perfusion lung scan)

3 [] Positive findings on pulmonary angiogram or spiral CAT scan (CT).

4 [] Diagnosis of deep vein thrombosis (DVT) based on ≥1 deep vein thrombosis (DVT)

criteria in question 1.3 (link to Form 126 in Source section below) plus signs and symptoms suggestive of pulmonary embolism (PE) (e.g., acute chest pain, dyspnea, tachypnea, hypoxemia, tachycardia, or chest x-ray findings suggestive of pulmonary embolism)

8 [] Other, including autopsy

Diagnostic Criteria:

Pulmonary embolism (PE) is defined as present if the following are present:

- Pulmonary embolism reported as a diagnosis in the discharge summary AND
- Report of a positive findings on appropriate diagnostic studies, including:
 - Pulmonary ventilation/perfusion (V/Q) report describing either "high" or "moderate" probability of deficit ("low" probability V/Q studies will not be considered evidence for presence of pulmonary embolism).
 - Pulmonary angiography report describing either "cut off" of a vessel or "filling defect."
- Diagnosis of deep vein thrombosis (DVT) based on ≥1 DVT criteria (see Manual 8, Section 8.1.1 - Deep Vein Thrombosis) plus signs and symptoms of pulmonary embolism (i.e., acute chest pain, dyspnea, tachypnea, hypoxemia, tachycardia, or chest X-ray findings characteristic of pulmonary embolism).

Protocol source: <u>https://www.phenxtoolkit.org/protocols/view/41301</u>