



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 deep venous thrombosis or blood clots in your legs?

1 Yes

0 No

9 Dont Know

2. Have you ever been treated by a doctor or a nurse **with shots at home or as an outpatient (usually followed by blood thinning medications such as Coumadin, Warfarin)** for blood clots in the legs called deep vein thrombosis or DVT?

1 Yes

0 No

3. Have you ever **had outpatient test(s) performed** for blood clots in the legs called deep vein thrombosis or DVT?

1 Yes

0 No

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.

4. Deep vein thrombosis (DVT)

1 Yes

2 No

4a. Date of Diagnosis: (M/D/Y) ___ / ___ / _____

4b. Diagnosis: (*Mark the one category that applies best.*)

1 Deep vein thrombosis of lower extremities **not resulting from a procedure** within 60 days

2 Deep vein thrombosis of lower extremities **during or following a procedure** within 60 days

4c. Diagnosis of deep vein thrombosis is based on: (*Mark all that apply.*)

1 Hospital discharge summary with a diagnosis of deep vein thrombosis

2 Positive findings on a venogram

3 Positive findings using impedance plethysmography

4 Positive findings on doppler duplex, ultrasound, sonogram, or other non-invasive test examination

5 Positive findings on isotope scan

4d. Diagnosis of deep vein thrombosis reporting source: (*Mark one. If more than one category applies, mark the first applicable category.*)

1 Hospital inpatient

2 Hospital outpatient facility or clinic

3 Radiology or imaging facility

4 Physicians office/private medical practitioner

5 Nursing/convalescent home/hospice

6 Autopsy only

7 Death Certificate only

8 Other

Diagnostic Criteria:

The presence of thrombus within a deep vein of a lower extremity only and the accompanying inflammatory response in vessel wall is termed deep vein thrombosis. The diagnosis can be made when the diagnosis is present in the discharge summary **and any** of the following are recorded:

- Positive findings on a venogram, defined as presence of a filling defect or absence of filling.
- Positive findings on impedance plethysmography, duplex scan, or ultrasound,

defined as a report of a flow defect.

- Positive findings on doppler examination, defined as a demonstration of flow velocity disturbance.
- Positive findings on isotope scan (e.g., I125 fibrinogen scan).

Protocol source: <https://www.phenxtoolkit.org/protocols/view/41201>