

Data Collection Worksheet

Please Note: The Data Collection Worksheet (DCW) is a tool to aid investigators to integrate the collection of PhenX measures in your study. The PhenX measures that you selected and added to your Cart are presented in the DCW in alphabetical order. The DCW includes worksheets for data collection. Variables derived from the collected data are shown in the Data Dictionary (DD) with variable names and unique PhenX variable identifiers. The collection of DCWs produced by the Toolkit is not designed as a data collection instrument. Each investigator will decide how to integrate PhenX measures into data collection for their study.

Bleeding Log

1. Date of bleed event
2. Location of bleed event
3. Which of the following symptoms did you have? (All that apply)
 - Unusual feeling in the joint
 - Warmth over the skin
 - Pain
 - Swelling
 - Stiffness
 - Loss of range of motion
 - None of the above
4. Did you treat your bleed with RICE?
 - Yes
 - No
 - Unknown
5. Did you treat your bleed with factor?
 - Yes
 - No

5a. If yes, did you take more factor than your normal prescribed dose?

Yes

No

Unknown

6. How would you describe your response* to factor treatment?

Excellent

Good

Moderate

None

RICE stands for: Rest, Ice, Compression, Elevation.

* International Society on Thrombosis and Hemostasis definition for response to treatment:

- Excellent - Complete pain relief within 8 hours and/or complete resolution of signs of bleeding after the initial injection and not requiring any further replacement therapy for relief of persistent symptoms and signs in the same joint within 72 hours.
- Good - Significant pain relief and/or improvement in signs of bleeding within approximately 8 hours after a single injection but requiring more than one dose of replacement therapy within 72 hours for complete resolution.
- Moderate - Modest pain relief and/or improvement in signs of bleeding within approximately 8 hours after the initial injection and requiring more than one injection within 72 hours but without complete resolution.
- None - No or minimal improvement, or condition worsens, within approximately 8 hours after the initial injection.

International Society on Thrombosis and Hemostasis Definitions

New Bleed:

- After an initial moderate to excellent response to treatment, a new bleed is defined as a bleed occurring > 72 hours after stopping treatment for the original bleed for which treatment was initiated.

Joint Bleed:

- An unusual sensation "aura" in the joint, in combination with any of the following:
 - increasing swelling or warmth of the skin over the joint;
 - increasing pain; or
 - progressive loss of range of motion or difficulty in using the limb as compared with baseline.
- In infants and young children, reluctance to use the limb alone may be indicative of a joint/muscle bleed.

Target Joint:

- Three or more spontaneous bleeds into a single joint within a consecutive 6-month period.
- Where there have been < 2 bleeds into the joint within a consecutive 12-month period, the joint is no longer considered a target joint.

Annualized Bleeding Rate (ABR)

The Hemophilia Inhibitors Working Group recommends that the calculation of annualized bleeding rate (ABR) be based on the number of bleeds instead of number of infusions or amount of prescribed therapeutics. Additionally, when reporting annualized bleeding rate, investigators should specify the methodological details including the measures used (e.g., bleed logs, infusion logs, dispensing logs); monitoring methods (e.g., patient recall, electronic recording, administrative databases); and the time frame of data collection.

Protocol source: <https://www.phenxtoolkit.org/protocols/view/910101>