



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.

Graft versus Host Disease

1. Did acute GVHD develop since the date of last report?

Yes

No

Unknown

2. Date of acute GVHD diagnosis: _ _ _ _ | _ _ | _ _

YYYY MM DD

3. Did acute GVHD persist since the date of last report?

Yes • Go to question 4

No • Go to question 12

Unknown - Go to question 12

Specify the maximum overall grade and organ staging of acute GVHD since the date of last report>:

4. Maximum overall grade of acute GVHD

I - Rash on < 50% of skin, no liver or gut involvement

II - Rash on > 50% of skin, bilirubin 2-3 mg/dL, or diarrhea 500-1000 mL/day or persistent nausea or vomiting

III - Bilirubin 3-15 mg/dL, or gut stage 2-4 diarrhea > 1000 mL/day or severe abdominal pain with or without ileus

IV - Generalized erythroderma with bullous formation, or bilirubin > 15 mg/dL

Not applicable (acute GVHD present but cannot be graded)

5. Date maximum overall grade of acute GVHD:

_____/_____/_____
YYYY MM DD

6. Skin

Stage 0 - no rash, no rash attributable to acute GVHD

Stage 1 - maculopapular rash, < 25% of body surface

Stage 2 - maculopapular rash, 25-50% of body surface

Stage 3 - generalized erythroderma, > 50% of body surface

Stage 4 - generalized erythroderma with bullae formation and/or desquamation

7. Lower intestinal tract (use mL/day for adult recipients and mL/kg/day for pediatric recipients)

Stage 0 - no diarrhea, no diarrhea attributable to acute GVHD /diarrhea < 500 mL/day (adult), or <10 mL/kg/day (pediatric)

Stage 1 - diarrhea 500 - 1000 mL/day (adult), or 10 - 19.9 mL/kg/day (pediatric)

Stage 2 - diarrhea 1001 - 1500 mL/day (adult), or 20-30 mL/kg/day (pediatric)

Stage 3 - diarrhea > 1500 mL/day (adult), or >30 mL/kg/day (pediatric)

Stage 4 - severe abdominal pain, with or without ileus, and/or grossly bloody stool

8. Upper intestinal tract

Stage 0 - no persistent nausea or vomiting

Stage 1 - persistent nausea or vomiting

9. Liver

Stage 0 - No liver acute GVHD / bilirubin < 2.0 mg/dL (< 34 µmol/L)

Stage 1 - bilirubin 2.0- 3.0 mg/dL (34-52 µmol/L)

Stage 2 - bilirubin 3.1-6.0 mg/dL (53-103 µmol/L)

Stage 3 - bilirubin 6.1-15.0 mg/dL (104-256 µmol/L)

Stage 4 - bilirubin > 15.0 mg/dL (> 256 μmol/L)

10. Other site(s) involved with acute GVHD

Yes

No

11. Specify other site(s): _____

12. Did chronic GVHD develop since the date of last report?

Yes

No

Unknown

13. Date of chronic GVHD diagnosis: ___ ___ ___ / ___ / ___ Date estimated

YYYY MM DD

- Go to question 15

14. Did chronic GVHD persist since the date of last report?

Yes

No

Specify the maximum grade of chronic GVHD since the date of last report:

15. Maximum grade of chronic GVHD {according to best clinical judgment)

Mild Moderate Severe Unknown

16. Specify if chronic GVHD was limited or extensive

Limited - localized skin involvement and/or liver dysfunction

Extensive - one or more of the following:

generalized skin involvement; or,

liver histology showing chronic aggressive hepatitis, bridging necrosis or cirrhosis; or,

involvement of eye: Schirmer's test with < 5 mm wetting; or

involvement of minor salivary glands or oral mucosa demonstrated on labial biopsy; or

involvement of any other target organ

17. Date of maximum grade of chronic GVHD:

____ / __ / __

YYYY MM DD

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Protocol source: <https://www.phenxtoolkit.org/protocols/view/850801>