Assessments are to be completed using the same follow-up form

* PRE INFUSION (include data up to start of preparative regimen)
* POST\_INFUSION\_YEAR\_2
* POST\_INFUSION\_YEAR\_5
* POST\_INFUSION\_YEAR\_10
* POST\_INFUSION\_YEAR\_15
1. **Laboratory Studies at Diagnosis**

Date CBC tested: (testing done within 6 weeks of diagnosis)
WBC: [ ]  Not tested

Lymphocytes: % [ ]  Not tested

Polymorphonuclear leukocytes (PMN): % [ ]  Not tested

Hemoglobin: [ ]  Not tested [ ]  Transfused RBC < 30 days from date of test

Immunoglobulin Analysis
Specify the following quantitative immunoglobulins measured prior to any disease treatment:
IgG: [ ]  Not tested

IgM: [ ]  [x]  Not tested

IgA: [ ]  Not tested

Did the recipient receive supplemental intravenous immunoglobulins (IVIG)?

[ ]  Yes

[ ]  No

[ ]  Unknown

1. **Lymphocyte Analysis**

Were lymphocyte analyses performed? [ ]  Yes [ ]  No

|  |
| --- |
| Date of most recent testing performed: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)Absolute lymphocyte count: cells / µL (cells / mm3)CD3 (T cells): valueCD4 (T helper cells): valueCD8 (cytotoxicT cells): valueCD20 (B lymphocyte cells): valueCD56 (natural killer (NK) cells): valueCD4+ / CD45RA+(naive T cells): valueCD4+ / CD45RO+(memory T cells): valueSpecify units [ ]  x 109/L(x 1 03/mm3)[ ]  x 106/L[ ]  Not tested |

1. **Antibody Response**

Date antibody responses were assessed: *(date closest to diagnosis, before any IVIG)*

\_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

Absent Low Normal Not tested

 [ ] [ ]  [ ]  [ ]  Bacteriophage phi X-174 or other neoantigen

  [ ] [ ]  [ ] [ ]  Diptheria

 [ ] [ ]  [ ]  [ ]  uIsohemagglutinin anti-A

 [ ]  [ ]  [ ]  [ ]  Isohemagglutinin anti-B

 [ ] [ ]  [ ]  [ ]  Protein conjugated HIB or pneumococcal vaccine

 Tetanus

Unconjugated pneumococcal polysaccharide: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_/ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Number of serotypes producing a protective level / Total serotypes tested from vaccine

1. **Lymphocyte Function**

Date lymphocyte function was assessed: \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ - \_\_\_ \_\_\_ \_\_\_ \_\_\_ (DD-MMM-YYYY)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Absent (< 10% of control) | Low (10-30% of control) | Normal (> 30% of control) | Not Tested |
| Anti-CD3 |  |  |  |  |
| Candida antigen |  |  |  |  |
| Concavalin A (ConA) |  |  |  |  |
| Phytohemagglutinin (PHA) |  |  |  |  |
| Pokeweed mitogen (PWM) |  |  |  |  |
| Tetanus antigen |  |  |  |  |

1. Clinical Features Assessed between Diagnosis and the Start of the Preparative Regimen

Infections (See Infection CRF) Identified between Diagnosis and the Start of the Preparative Regimen.

Specify the presence of all clinically significant infections identified between diagnosis and the start of the preparative regimen. If any given infection was identified, use the Codes for Commonly Reported Organisms on the following page to report the organism present.

Only report an organism once, even if it was identified at the same site in subsequent infections.

Hepatitis [ ] Yes [ ]  No

If yes, indicate:

First organism

Second organism

Third organism

Specify other organism

If hepatitis was present, was it a prominent feature of ID?

[ ]  Yes

[ ]  No

Meningitis / encephalitis [ ] Yes [ ]  No

If yes, indicate:

First organism

Second organism

Third organism

Specify other organism

If meningitis / encephalitis was present, was it a prominent feature of ID?

[ ]  Yes

[ ]  No

Pneumonia [ ] Yes [ ]  No

If yes, indicate:

First organism

Second organism

Third organism

Specify other organism

If pneumonia was present, was it a prominent feature of ID?

[ ]  Yes

[ ]  No

Severe or protracted diarrhea: [ ]  Yes [ ]  No

If yes, indicate:

First organism

Second organism

Third organism

Specify other organism

If diarrhea was present, was it a prominent feature of ID?

[ ]  Yes

[ ]  No

Systemic infection [ ]  Yes [ ]  No

If yes, indicate:

First organism

Second organism

Third organism

Specify other organism

If systemic infection was present, was it a prominent feature of ID?

[ ]  Yes

[ ]  No

Other infection [ ]  Yes [ ]  No

If yes, indicate:

First organism

Second organism

Third organism

Specify other organism

Specify other infection site:

If other infe ction was present, was it a prominent feature of ID?

[ ]  Yes

[ ]  No

## General Instructions

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* POST\_INFUSION\_YEAR\_15

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

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