All questions on this form are Supplemental (use depends on study type and design).

* 1. Record date of evaluation: *(ddMMMyyyy)*

*Record the highest grade of toxicity diagnosed since the previous evaluation. If this is the first evaluation, record the highest toxicity diagnosed since Day 0. The toxicity grades are based on the NCI CTCAE Version 5.0. Grading should be completed based on the entire definition, as some definitions in this form may be truncated.*

**General Disorders**

* 1. Fever:

|  |  |
| --- | --- |
| 0-Grades 0-2   1. Grade 3 - >40.0 degrees C (>104.0 degrees F) for <=24 hrs 2. Grade 4 - >40.0 degrees C (>104.0 degrees F) for > 24 hrs 5-Grade 5 - Death |  |
|  |
|  |
| 0-Grades 0-2  3-Grade 3 - Fatigue not relieved by rest; limiting self care ADL | |

* 1. Fatigue:

**Immune System Disorders:**

* 1. Allergic reaction

|  |  |  |  |
| --- | --- | --- | --- |
| 0-Grades 0-2  3-Grade 3 - Bronchospasm; hospitalization indicated; intravenous intervention indicated 4-Grade 4 - Life-threatening consequences; urgent intervention indicated  5-Grade 5 - Death |  |  | |
|  |
|  |
| 0-Grades 0-2  3-Grade 3 - Symptomatic bronchospasm; parenteral intervention indicated; edema/angioedema; hypotension 4-Grade 4 - Life-threatening consequences; urgent intervention indicated  5-Grade 5 - Death | | |  |
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* 1. Anaphylaxis:

**GI Disorders**

* 1. Mucositis:

0-Grades 0-2

3-Grade 3 - Severe symptoms; limiting self care ADL or interfering with oral intake; hospitalization 4-Grade 4 - Life-threatening consequences; urgent intervention indicated

5-Grade 5 - Death

* + 1. Which location(s) did the mucositis occur? Oral:.0-No 1-Yes Esophagus:0-No 1-Yes Intestinal:0-No 1-Yes Anal:0-No 1-Yes



Other:0-No 1-Yes



Specify other organ location:

* 1. Nausea:



0-Grades 0-2

3-Grade 3 - Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated

* 1. Vomiting:

|  |  |  |  |
| --- | --- | --- | --- |
| 0-Grades 0-2  3-Grade 3 - Tube feeding, TPN, or hospitalization indicated 4-Grade 4 - Life-threatening consequences  5-Grade 5 - Death |  |  | |
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|  |
| 0-Grades 0-2  3-Grade 3 - Increase of >=7 stools per day over baseline; hospital indicated; severe ostomy output 4-Grade 4 - Life-threatening consequences; urgent intervention indicated  5-Grade 5 - Death | | |  |
|  |
|  |
| 0-Grades 0-2  3-Grade 3 - Severe pain; vomiting; medical intervention indicated (e.g., analgesia, nutritional supp) 4-Grade 4 - Life-threatening consequences; urgent intervention indicated  5-Grade 5 - Death | | |  |
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* 1. Diarrhea:
  2. Pancreatitis:

**Renal Disorders**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 0-Grades 0-2  3-Grade 3 - Gross hematuria; transfusion, IV medications, or hospitalization indicated 4-Grade 4 - Life-threatening consequences; urgent invasive intervention indicated  5-Grade 5 - Death | | | |  | |
|  | |
|  | |
| 0-Grades 0-2   1. Grade 3 - Hospitalization indicated 2. Grade 4 - Life-threatening consequences; dialysis indicated 5-Grade 5 - Death |  |  | | | |
|  |
|  |
| 0-Grades 0-2   1. Grade 3 - eGFR or CrCl 29 - 15 ml/min/1.73 m2 2. Grade 4 - eGFR or CrCl <15 ml/min/1.73 m2; dialysis or renal transplant indicated 5-Grade 5 - Death | | |  | |  |
|  | |  |
|  | |  |

* 1. Cystitis noninfective:
  2. Acute kidney injury:
  3. Chronic kidney disease:
  4. Did the patient receive dialysis?
     1. If yes, were laboratory values corrected?

**Hemorrhagic Disorders**

* 1. Hemorrhage:
     1. Which organ system was the hemorrhage associated with?

Specify other organ system:

**Cardiac Disorders**

* 1. Hypotension:

0-Grades 0-2

1. Grade 3 - Medical intervention indicated; hospitalization indicated
2. Grade 4 - Life-threatening consequences; urgent intervention indicated 5-Grade 5 - Death

0-No 1-Yes

0-No 1-Yes



|  |  |  |  |
| --- | --- | --- | --- |
| 0-Grades 0-2  3-Grade 3 - Transfusion indicated; invasive intervention indicated; hospitalization 4-Grade 4 - Life-threatening consequences; urgent intervention indicated  5-Grade 5 - Death | | |  |
|  |
|  |
| 1. CNS 2. Gastrointestinal 3-Genitourinary 3. Pulmonary, Upper Respiratory 4. Other |  |  | |
|  |
|  |

* 1. Hypertension:

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| --- | --- | --- | --- |
| 0-Grades 0-2  3-Grade 3 - Systolic BP >=160 mm Hg or diastolic BP >=100 mm Hg; medical intervention indicated 4-Grade 4 - Life-threatening consequences; urgent intervention indicated  5-Grade 5 - Death | | |  |
|  |
|  |
| 0-Grades 0-2  3-Grade 3 - Urgent intervention indicated; device (e.g. pacemaker); ablation 4-Grade 4 - Life-threatening consequences; hemodynamic compromise  5-Grade 5 - Death |  |  | |
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* 1. Cardiac arrhythmia:

Specify arrhythmia:

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0-Grades 0-2  3-Grade 3 - Severe symptoms; ECG changes consistent with infarction 4-Grade 4 - Life-threatening consequences; hemodynamically unstable 5-Grade 5 - Death |  | |  | | | | | | |
|  | |
|  | |
| 0-Grades 0-2   1. Grade 3 - Symptomatic due to drop in ejection fraction responsive to intervention 2. Grade 4 - Refractory or poorly controlled heart failure; intervention or heart transplant indicated 5-Grade 5 - Death | | | | | | | | |  |
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|  |
| 0-Grades 0-2   1. Grade 3 - Effusion with physiologic consequences 2. Grade 4 - Life-threatening consequences; urgent intervention indicated 5-Grade 5 - Death | |  | |  | | | | | |
|  | |
|  | |
| 0-Grades 0-2  3-Grade 3 - Symptomatic heart failure or other cardiac symptoms, responsive to intervention 4-Grade 4 - Refractory heart failure or other poorly controlled cardiac symptoms  5-Grade 5 - Death | | | | | | |  |  | |
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|  |
| 0-Grades 0-2  3-Grade 3 - Pericarditis with physiologic consequences (e.g., pericardial constriction) 4-Grade 4 - Life-threatening consequences; urgent intervention indicated  5-Grade 5 - Death | | | | |  |  | | | |
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* 1. Myocardial infarction:
  2. Left ventricular systolic dysfunction:
  3. Pericardial effusion:
  4. Restrictive cardiomyopathy:
  5. Pericarditis:

**Nervous System Disorders**

* 1. Somnolence:

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| --- | --- | --- | --- | --- | --- |
| 0-Grades 0-2   1. Grade 3 - Obtundation or stupor 2. Grade 4 - Life-threatening consequences; urgent intervention indicated 5-Grade 5 - Death | | |  |  | |
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|  |
| 0-Grades 0-2  3-Grade 3 - New onset seizures partial or generalized; multiple seizures despite medical intervention 4-Grade 4 - Life-threatening consequences; prolonged repetitive seizures  5-Grade 5 - Death | | | | |  |
|  |
|  |
| 0-Grades 0-2   1. Grade 3 - Severe symptoms; limiting self care ADL 2. Grade 4 - Life-threatening consequences; urgent intervention indicated 5-Grade 5 - Death | | |  |  | |
|  |
|  |
| 1. Motor 2. Sensory 3. Both motor and sensory |  |  | | | |
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|  |

* 1. Seizure:
  2. Neuropathy:

Specify neuropathy type:

* 1. Reversible posterior leukoencephalopathy syndrome (RPLS/PRES):

0-Grades 0-2

3-Grade 3 - Severe symptoms; limiting self care ADL; hospitalization 4-Grade 4 - Life-threatening consequences

5-Grade 5 - Death

**Blood and Lymphatic Disorders**

* 1. Thrombotic thrombocytopenic purpura / Thrombotic microangiopathy:

0-Grades 0-2

1. Grade 3 - Laboratory findings with clinical consequences (e.g., renal insufficiency, petechiae)
2. Grade 4 - Life-threatening consequences, (e.g. CNS hemorrhage or thrombosis/embolism; renal failure) 5-Grade 5 - Death
   1. SplenomegalyGrades (as defined by CTCAE)

**Vascular Disorders**

* 1. Capillary leak syndrome:

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| --- | --- | --- | --- |
| 0-Grades 0-2   1. Grade 3 - Severe symptoms; intervention indicated 2. Grade 4 - Life-threatening consequences; urgent intervention indicated 5-Grade 5 - Death |  |  | |
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|  |
| 0-Grades 0-2   1. Grade 3 - Urgent medical intervention indicated (e.g., pulmonary embolism) 2. Grade 4 - Life-threatening consequences; hemodynamic or neurologic instability 5-Grade 5 - Death | | |  |
|  |
|  |

* 1. Thromboembolic event:

**Musculoskeletal and Connective Tissue Disorders**

* 1. Avascular necrosis:*( AVASN)*

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| --- | --- | --- | --- |
| 0-Grades 0-2  3-Grade 3 - Severe symptoms; limiting self care ADL; elective operative intervention indicated 4-Grade 4 - Life-threatening consequences; urgent intervention indicated  5-Grade 5 - Death | | |  |
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|  |
| 0-Grades 0-2  3-Grade 3 - Loss of height >=2 cm; hospitalization indicated; limiting self care ADL | |  | |
| 0-Grades 0-2  3-Grade 3 - Severe pain; limiting self care ADL |  | | |
| 0-Grades 0-2  3-Grade 3 - Severe pain; limiting self care ADL |

* 1. Osteoporosis:*( OSTEO)*

|  |  |  |  |
| --- | --- | --- | --- |
| 0-Grades 0-2  3-Grade 3 - Decreased oxygen saturation at rest (e.g., pulse oximeter <88% or PaO2 <=55 mm Hg) 4-Grade 4 - Life-threatening airway compromise; urgent intervention indicated  5-Grade 5 - Death | | |  |
|  |
|  |
| 0-Grades 0-2   1. Grade 3 - Shortness of breath at rest; limiting self care ADL 2. Grade 4 - Life-threatening consequences; urgent intervention indicated 5-Grade 5 - Death |  |  | |
|  |
|  |
| 0-Grades 0-2  3-Grade 3 - Symptomatic with respiratory distress and hypoxia; operative indication incl. chest tube 4-Grade 4 - Life-threatening respiratory or hemodynamic compromise; urgent intervention indicated 5-Grade 5 - Death | | |  |
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|  |

**Respiratory, Thoracic and Mediastinal Disorders**

* 1. Hypoxia:*( HYPOX)*
  2. Dyspnea:*( DYSPN)*
  3. Pleural Effusion:*( PLEFF)*

**Metabolism and Nutrition Disorders**

* 1. Hyperglycemia:*( HYPGL)*

0-Grades 0-2

1. Grade 3 - Insulin therapy initiated; hospitalization indicated
2. Grade 4 - Life-threatening consequences; urgent intervention indicated 5-Grade 5 - Death

**Hepatic Disorders**

* 1. Hepatitis:*( HEPAT)* 0-No 1-Yes



* 1. Liver failure:*( LIVFL)* 0-No 1-Yes



* 1. ALT:*( ALT)*

|  |  |
| --- | --- |
| 0-Grades 0-2  3-Grade 3 - >5.0 - 20.0 x ULN  4-Grade 4 - >20.0 x ULN |  |
|  |
|  |
| 0-Grades 0-2  3-Grade 3 - >5.0 - 20.0 x ULN  4-Grade 4 - >20.0 x ULN |  |
|  |
|  |
| 0-Grades 0-2  3-Grade 3 - >3.0 - 10.0 x ULN  4-Grade 4 - >10.0 x ULN |  |
|  |
|  |
| 0-Grades 0-2  3-Grade 3 - >5.0 - 20.0 x ULN  4-Grade 4 - >20.0 x ULN |  |
|  |
|  |

* 1. AST:*( AST)*
  2. Bilirubin:*( BILIR)*
  3. Alkaline Phosphatase: *( ALKPH)*

**Indicate all clinical signs/symptoms of abnormal liver functioning:**

* 1. Jaundice:*( JAUND)* 0-No 1-Yes



* 1. Hepatomegaly:*( HEMLY)* 0-No 1-Yes



* 1. Right upper quadrant pain: *( RUQUA)*
  2. Weight gain (>5%) from baseline:*( WGTGN)*

0-No 1-Yes

0-No 1-Yes



**Indicate the etiology of the abnormal liver function:**

|  |  |  |  |
| --- | --- | --- | --- |
|  | Etiology | Biopsy Results | Doppler Ultrasound Results |
| 49. VOD: | 0-No *( VODET)* 1-Yes | 1-Positive 2-Negative  3-Equivocal *( VODBY)* 4-Not done | 1. Confirmed 2. Not confirmed *( VODDP)* 3-Not done |
| 50. GVHD: | 0-No *( GVHET)* 1-Yes | 1-Positive 2-Negative  3-Equivocal *( GVHBY)* 4-Not done | 1. Confirmed 2. Not confirmed *( GVHDP)* 3-Not done |
| 51. Infection: | 0-No *( INFET)* 1-Yes | 1-Positive 2-Negative  3-Equivocal *( INFBY)* 4-Not done | 1. Confirmed 2. Not confirmed *( INFDP)* 3-Not done |
| 52. Other: | 0-No *( OTHET)* 1-Yes | 1-Positive 2-Negative  3-Equivocal *( OTHBY)* 4-Not done | 1. Confirmed 2. Not confirmed *( OTHDP)* 3-Not done |
| 53. Unknown: | 0-No *( UNKET)* 1-Yes | 1-Positive 2-Negative  3-Equivocal *( UNKBY)* 4-Not done | 1. Confirmed 2. Not confirmed *( UNKDP)* 3-Not done |

Specify other etiology: *( OTHSP)*



62. Did any of the toxicities reported for this assessment period meet the criteria of an SAE? Y/N

63. If yes, specify any event(s) that met the criteria of an SAE: [Free text]

**Transfusion Reaction**

Did the patient receive a transfusion during the reporting period Yes No

Infusion related reaction

0 – Grades 0-2

3 – Prolonged;recurrence of symptoms following initial improvement;hospitalization indicated

4 – Life threatening consequences; urgent intervention indicated

5 – Death

Fever

1. Grade 0-2
2. >40.0 degrees C (>140.0 degrees F) for <= 24 hours
3. >40 degrees C (>104.0 degrees F) for > 24 hours
4. Death

Maculo-papular rash

1. Grade 0-2
2. Macules/papules covering >30% BSA with or without associated symptoms;limiting self-care ADL

Urticaria

1. Grade 0-2
2. Urticaria lesions covering >30% BSA; IV intervention indicated

Allergy reaction

1. Grade 0-2
2. Prolonged;recurrence of symptoms following initial improvement; hospitalization indicated
3. Life-threatening consequences; urgent intervention indicated
4. Death

Broncospasm

1. Grade 0-2
2. Limiting self-care ADL; oxygen saturation decreased
3. Life-threatening respiratory or hemodynamic compromise; intubation or urgent intervention indicated
4. Death

Hypoxia

1. Grade 0-2
2. Decreased oxygen saturation at rest (e.g., pulse oximeter <88% or PaO2 <= 55mm Hg)
3. Life-threatening airway compromise;urgent intervention indicated
4. Death

Anaphylaxis

1. No event
2. Symptomatic bronchospasm; parenteral intervention indicated; allergy-related edema/angioedema
3. Life-threatening consequences ;urgent intervention indicated
4. Death

Hematuria

1. Grade 0-2
2. Gross hematuria; transfusion, IV med, hosp, endoscopic, radiologic/operative intervention indicated
3. Life-threatening; urgent radiologic or operative intervention indicated
4. Death

Hemolysis

1. Grade 0-2
2. Transfusion or medical intervention indicated (e.g., steroids)
3. Life-threatening; urgent radiologic or operative intervention indicated
4. Death

Infection

1. Grade 0-2
2. IV antiobiotic, antifungal, or antiviral indicated; radiologic, operative intervention indicated
3. Life-threatening consequences; urgent intervention indicated
4. Death

Iron overload

1. Grade 0-2
2. Severe symptoms; intervention indicated
3. Life-threatening; urgent radiologic or operative intervention indicated
4. Death

Did the patient develop allo-antibodies? Yes No

**Hydroxyurea Reaction**

Did the patient receive Hydroxyurea during this reporting period? Yes No

Anemia

1. Grade 0-2
2. Hgb <8.0-6.5 g/dL; <4.9-4.0 mmol/L; <80-65g/L; transfusion indicated
3. Life-threatening consequences; urgent intervention indicated
4. Death

Neutropenia

1. Grade 0-2
2. <1000 – 500 mm^3; <1.0-0.5 x 10^9 L
3. <500/mm^3; <0.5 x 10^9 L

Nausea

1. Grade 0-2
2. Inadequate oral caloric or fluid intake; tube feeding, TPN, or hospitalization indicated

Diarrhea

1. Grade 0-2
2. Increase of >= 7 stools per day; incontinence; severe increase in ostomy; limiting self care ADL
3. Life-threatening consequences; urgent intervention indicated
4. Death

Constipation

1. Grade 0-2
2. Obstipation with manual evacuation indicated; limiting self care ADL
3. Life-threatening consequences; urgent intervention indicated
4. Death

Does the patient have hyperpigmentation of the skin under the nails?

Yes No

Does the patient have thinning hair?

Yes No

Oligospemia (reduced sperm)

1. Grade 0-2
2. Sperm concentration <13 million/mL or motility <32%

**Serious Adverse Event Reporting (See SAE Form)**

Did any of the events above lead to an advanced care intervention or intensive care unit admission/transfer as outline in the AE reporting?

Yes No

Specify Event: