# Patient Case Report Form

**Pharmacogenetic analysis in pediatric/adolescent**

**Hematologic-oncologic disease**

**Principal Investigator:**

|  |
| --- |
| **1. BASIC DATA** |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Organization** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | |
| **Subject No.** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | |
| **Sex** | \_\_\_\_\_\_\_\_\_\_\_\_M / F\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | | |
| **Date of Birth :** |  |  |  |  |  |  |  |  |  |  |
|  | **YEAR** | | | |  | **MONTH** | |  | **DAY** | |

|  |
| --- |
| **2. DIAGNOSIS** |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Diagnosis** | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(see #1) | | | | | | | | | |
| **Date of Initial Diagnosis :** |  |  |  |  |  |  |  |  |  |  |
|  | **YEAR** | | | |  | **MONTH** | |  | **DAY** | |

|  |
| --- |
| **3. TREATMENT** |

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Treatment start :** |  |  |  |  |  |  |  |  |  |  |
|  | **YEAR** | | | |  | **MONTH** | |  | **DAY** | |

**Chemotherapy History**

(ex. “0601 consolidation” “maintenance #1, #2”, not “HR 0601”)

|  |  |  |
| --- | --- | --- |
| **Protocol** | **Start date** | **End date** |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

**Hematopoietic stem cell transplantation**

**□ No**

**□ Yes**

**□ Allogeneic □ Autologous**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of HSCT** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **YEAR** | | | |  | **MONTH** | |  | **DAY** | |  |  |  |  |  |  |  |
|  |  | | | | | | | | | |  |  |
| **Conditioning regimen** | **START DATE** | | | | | | | | | |  |  | **END DATE** | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **YEAR** | | | |  | **MONTH** | |  | **DAY** | |  |  | **YEAR** |  | **MONTH** |  | **DAY** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **GVHD prophylaxis** | **□ No □ Yes**  **□ ATG (after d0)**  **□ Corticosteroids**  **□ Cyclosporine (CSA)**  **□ FK506**  **□ MTX**  **□ MMF**  **□ Cyclophosphamide (CPM)**  **□ Other drug, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | | | | |

**Was there further HSCT?**

**□ No**

**□ Yes**

**□ Allogeneic □ Autologous**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of HSCT** |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  | **YEAR** | | | |  | **MONTH** | |  | **DAY** | |  |  |  |  |  |  |  |
|  |  | | | | | | | | | |  |  |
| **Conditioning regimen** | **START DATE** | | | | | | | | | |  |  | **END DATE** | | | | |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **YEAR** | | | |  | **MONTH** | |  | **DAY** | |  |  | **YEAR** |  | **MONTH** |  | **DAY** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **GVHD prophylaxis** | **□ No □ Yes**  **□ ATG (after d0)**  **□ Corticosteroids**  **□ Cyclosporine (CSA)**  **□ FK506**  **□ MTX**  **□ MMF**  **□ Cyclophosphamide (CPM)**  **□ Other drug, specify:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_** | | | | | | | | | | | | | | | | |

**Was there further HSCT?**

**□ No**

**□ Yes**

**----- CRF 1 끝 (한번 입력받고 끝) ------**

입력되는 값이 1회성인 것 (basic data, diagnosis, treatment)과

EMR에서 주기적으로 업데이트 되는 것 (medication, lab history, 신체계측, adverse events)

이렇게 2가지로 분류되어 CRF 2 페이지로 제작되면 좋을 것 같아 구분하였습니다.

|  |
| --- |
| **1. Medication History** |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **약품명** | **투여용량** | **단위** | **투여경로** | **처방시작일** | **처방종료일** |
|  |  |  | 정맥(IV)  경구(PO)  척수강내(IT)  기타: \_\_\_\_\_\_ |  |  |
|  |  |  | 정맥(IV)  경구(PO)  척수강내(IT)  기타: \_\_\_\_\_\_ |  |  |
|  |  |  | 정맥(IV)  경구(PO)  척수강내(IT)  기타: \_\_\_\_\_\_ |  |  |

|  |
| --- |
| **2. Laboratory History** |

**Use following Lab:**

Amylase, ANC, aPTT, BUN, **Calcium**, Cholesterol, Cr, Direct Bilirubin, **Glucose**, GOT (AST), GPT (ALT), Hb, K, Lipase, Magnesium, Na, Phosphorus, PLT, PT, Total Bilirubin, Triglyceride, WBC, **Cardiac troponin I, NT-proBNP, CK-MB**

|  |  |  |  |
| --- | --- | --- | --- |
| **검사일** | **검사명** | **검사결과** | **검사단위** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |
| --- |
| **3. 신체계측** |

|  |  |  |  |
| --- | --- | --- | --- |
| **측정일** | **Body weight** | **Height** | **BSA** |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

|  |
| --- |
| **4. Adverse Events (CTCAE 4.0)** |

**Lab test related Adverse Event**

**\*Use following lab:**

**Complete Blood Counts**: Anemia (Hb), Leukopenia (WBC), Neutropenia (ANC), Thrombocytopenia (PLT)

**Chemistry & Coagulation & Urine:** aPTT 연장, PT INR 증가, ALT or GPT 증가, AST or GOT 증가, Bilirubin 상승, Cholesterol증가, Creatinine 상승, Amylase 증가, Lipase 증가, Ca 증가, Ca 감소, Glucose 증가, Glucose 감소, K 증가, K 감소, Mg 증가, Mg 감소, Na 증가, Na 감소, TG 증가, Uric acid 증가, Albumin 감소, P 감소, **Cardiac troponin I 증가, NT-proBNP, CK-MB**

|  |  |  |  |
| --- | --- | --- | --- |
| **발생일** | **검사분류\*** | **검사관련 이상반응\*** | **Adverse Event Grade** |
|  | **Complete Blood Counts**  **Chemistry & Coagulation & Urine** |  | **Gr3**  **Gr4** |
|  | **Complete Blood Counts**  **Chemistry & Coagulation & Urine** |  | **Gr3**  **Gr4** |
|  | **Complete Blood Counts**  **Chemistry & Coagulation & Urine** |  | **Gr3**  **Gr4** |
|  | **Complete Blood Counts**  **Chemistry & Coagulation & Urine** |  | **Gr3**  **Gr4** |

**Symptom related Adverse Event**

**\*Use following symptoms/diseases:**

**Allergy & Rash**: Allergic reaction, Anaphylaxis, Injection site reaction, Rash maculo-papular, Urticaria, Stevens-Johnson syndrome

**Fever & Infection:** Febrile neutropenia, Fever without neutropenia, Sepsis

**Cardiovascular:** Ejection fraction 감소, Heart failure, Hypertension, Hypotension, Myocarditis, Pericardial effusion, Pericarditis, Thromboembolic event

**Gastrointestinal:** Constipation, Diarrhea, Hepatic failure, Ileus, Mucositis oral, Pancreatitis, Gastrointestinal hemorrhage

**Neurologic:** Encephalopathy, Leukoencephalopathy, Peripheral motor neuropathy, Peripheral sensory neuropathy, Seizure

**Other:** Pneumonitis, Avascular necrosis, Cytokine releasing syndrome, Osteonecrosis of jaw, Osteoporosis, Cataract, Hearing impaired, Blurred vision, Other disorders - specify

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **발생일** | **분류** | **질병관련 이상반응** | **발생여부** | **If 이상반응 발생시,**  **CTCAE grade** |
|  | 🗹 **Allergy & Rash**  **Fever & Infection**  **Cardiovascular**  **Gastrointestinal**  **Neurologic**  **Other** | Allergic reaction | **Yes**  **NO** | **Grade 1**  **Grade 2**  **Grade 3**  **Grade 4**  **Grade 5**  **Unknown** |
|  | **Allergy & Rash**  **Fever & Infection**  **Cardiovascular**  **Gastrointestinal**  **Neurologic**  **Other** |  | **Yes**  **NO** | **Grade 1**  **Grade 2**  **Grade 3**  **Grade 4**  **Grade 5**  **Unknown** |
|  | **Allergy & Rash**  **Fever & Infection**  **Cardiovascular**  **Gastrointestinal**  **Neurologic**  **Other** |  | **Yes**  **NO** | **Grade 1**  **Grade 2**  **Grade 3**  **Grade 4**  **Grade 5**  **Unknown** |

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | **질병관련이상반응** | **발생여부** | **이상반응**  **발생시작일** | **Grade** | | | | | | | |
| **1** | | **2** | | **3** | | **4** | **Unknown** |
| **Allergy & Rash** | | | | | | | | | | | |
| **No**  **Yes** | Allergic reaction |  |  |  | |  | |  | |  |  |
| Anaphylaxis |  |  |  | |  | |  | |  |  |
| Injection site reaction |  |  |  | |  | |  | |  |  |
| Rash maculo-papular |  |  |  | |  | |  | |  |  |
| Urticaria |  |  |  | |  | |  | |  |  |
| Stevens-Johnson syndrome |  |  |  | |  | |  | |  |  |
| **Fever & Infection** | | | | | | | | | | | |
| **No**  **Yes** | Febrile neutropenia |  |  |  | |  | |  | |  |  |
| Fever without neutropenia |  |  |  | |  | |  | |  |  |
| Sepsis |  |  |  | |  | |  | |  |  |
| **Cardiovascular** | | | | | | | | | | | |
| **No**  **Yes** | Ejection fraction 감소 |  |  |  | |  | |  | |  |  |
| Heart failure |  |  |  | |  | |  | |  |  |
| Hypertension |  |  |  | |  | |  | |  |  |
| Hypotension |  |  |  | |  | |  | |  |  |
| Thromboembolic event |  |  |  | |  | |  | |  |  |
| **Gastrointestinal** | | | | | | | | | | | |
| **No**  **Yes** | Diarrhea |  |  |  | |  | |  | |  |  |
| Hepatic failure |  |  |  | |  | |  | |  |  |
| Ileus |  |  |  | |  | |  | |  |  |
| Mucositis oral |  |  |  | |  | |  | |  |  |
| Pancreatitis |  |  |  | |  | |  | |  |  |
| Lower Gastrointestinal hemorrhage |  |  |  | |  | |  | |  |  |
| Upper Gastrointestinal hemorrhage |  |  |  | |  | |  | |  |  |
| **Respiratory** | | | | | | | | | | | |
| **No**  **Yes** | Pneumonitis |  |  |  | |  | |  | |  |  |
| Retinoic acid syndrome |  |  |  | |  | |  | |  |  |
| Pulmonary fibrosis |  |  |  | |  | |  | |  |  |
| Bronchopulmonary hemorrhage |  |  |  | |  | |  | |  |  |
| Bronchospasm |  |  |  | |  | |  | |  |  |
| **Neurologic** | | | | | | | | | | | |
| **No**  **Yes** | Encephalopathy |  |  |  | |  | |  | |  |  |
| Leukoencephalopathy |  |  |  | |  | |  | |  |  |
| Peripheral motor neuropathy |  |  |  | |  | |  | |  |  |
| Peripheral sensory neuropathy |  |  |  | |  | |  | |  |  |
| Seizure |  |  |  | |  | |  | |  |  |
| **Renal, urinary** | | | | | | | | | | | |
| **No**  **Yes** | Acute kidney injury |  |  |  |  | |  | |  | | |
| Thrombotic thrombocytopenia purpura |  |  |  |  | |  | |  | | |
| Hemolytic uremic syndrome |  |  |  |  | |  | |  | | |
| Cystitis noninfective |  |  |  |  | |  | |  | | |
| **Others** | | | | | | | | | | | |
| **No**  **Yes** | Avascular necrosis |  |  |  |  | |  | | | | |
| Osteonecrosis of jaw |  |  |  |  | |  | | | | |
| Osteoporosis |  |  |  |  | |  | | | | |
| Cataract |  |  |  |  | |  | | | | |
| Hearing impaired |  |  |  |  | |  | | | | |
| Blurred vision |  |  |  |  | |  | | | | |
| Psychosis |  |  |  |  | |  | | | | |
| **Other disorders - specify** | |  |  |  |  | |  | | | | |

|  |
| --- |
| **Adverse Events Reference (CTCAE 4.03)** |

|  |  |  |
| --- | --- | --- |
| **Complete Blood Counts** | **Grade 3** | **Grade 4** |
| Anemia (Hb) | Hgb <8.0 g/dL or <4.9 mmol/L or <80 g/L |  |
| Leukopenia (WBC) | 1000 - 2000/mm3 or 1.0 - 2.0 x 109 /L | <1000/mm3 or <1.0 x 109 /L |
| Neutropenia (ANC) | 500 - 1000/mm3 or 0.5 – 1.0 x 109 /L | <500/mm3 or <0.5 x 109 /L |
| Thrombocytopenia (PLT) | 25,000 - 50,000/mm3 or 25.0 - 50.0 x 109 /L | <25,000/mm3; <25.0 x 109 /L |
| **Chemistry & Coagulation**  **& Urine** | **Grade 3** | **Grade 4** |
| aPTT 연장 | >2.5 x ULN; hemorrhage | - |
| PT INR 증가 | >2.5 x ULN | - |
| ALT or GPT 증가 | 5.0 - 20.0 x ULN | 20.0 x ULN |
| AST or GOT 증가 | 5.0 - 20.0 x ULN | 20.0 x ULN |
| Bilirubin 상승 | 3.0 - 10.0 x ULN | 10.0 x ULN |
| Cholesterol증가 | 400 - 500 mg/dL or 10.34 - 12.92 mmol/L | >500 mg/dL or >12.92 mmol/L |
| Creatinine 상승 | 3.0 - 6.0 x ULN | >6.0 x ULN |
| Amylase 증가 | 2.0 - 5.0 x ULN | >5.0 x ULN |
| Lipase 증가 | 2.0 - 5.0 x ULN | >5.0 x ULN |
| Ca 증가 | Corrected serum calcium of 12.5 - 13.5 mg/dL or 3.1 - 3.4 mmol/L  or Ionized calcium 1.6 - 1.8 mmol/L | Corrected serum calcium of >13.5 mg/dL or >3.4 mmol/L  or Ionized calcium >1.8 mmol/L |
| Ca 감소 | Corrected serum calcium of 6.0 - 7.0 mg/dL or 1.5-1.75 mmol/L  or Ionized calcium 0.8 - 0.9 mmol/L | Corrected serum calcium of <6.0 mg/dL or <1.5 mmol/L  or Ionized calcium <0.8 mmol/L |
| Glucose 증가 | 250 - 500 mg/dL or 13.9 - 27.8 mmol/L | >500 mg/dL or >27.8 mmol/L |
| Glucose 감소 | 30 - 40 mg/dL or 1.7-2.2 mmol/L | <30 mg/dL or <1.7 mmol/L |
| K 증가 | 6.0 - 7.0 mmol/L | >7.0 mmol/L |
| K 감소 | 2.5 - 3.0 mmol/L | <2.5 mmol/L |
| Mg 증가 | 3.0 - 8.0 mg/dL or 1.23 - 3.30 mmol/L | >8.0 mg/dL or >3.30 mmol/L |
| Mg 감소 | 0.7 - 0.9 mg/dL or 0.3 - 0.4 mmol/L | <0.7 mg/dL or <0.3 mmol/L |
| Na 증가 | 155 - 160 mmol/L | >160 mmol/L |
| Na 감소 | 120 - 130 mmol/L | <120 mmol/L |
| TG 증가 | 500 - 1000 mg/dL or 5.7 - 11.4 mmol/L | >1000 mg/dL or >11.4 mmol/L |
| Uric acid 증가 | ULN - 10 mg/dL (0.59 mmol/L) | >10 mg/dL or >0.59 mmol/L |
| Albumin 감소 | <2 g/dL, <20 g/L |  |
| P 감소 | 1.0 – 2.0 mg/dL or 0.3 – 0.6 mmol/L | <1.0 mg/dL or <0.3 mmol/L |
| **cardiac troponin I** 증가 | Levels above UNL |  |
| **NT-proBNP** | Levels above UNL |  |
| **CK-MB** | Levels above UNL |  |

|  |
| --- |
| **8. LAST FU** |

**Treatment status**

**□ On treatment**

**□ Completed**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Therapy completed:** |  |  |  |  |  |  |  |  |  |  |
| **(최종 치료 종료일)** | **YEAR** | | | |  | **MONTH** | |  | **DAY** | |

**Event**

**□ No**

**□ Relapse**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Relapse** |  |  |  |  |  |  |  |  |  |  |
|  | **YEAR** | | | |  | **MONTH** | |  | **DAY** | |

**□ Death**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Death** |  |  |  |  |  |  |  |  |  |  |
|  | **YEAR** | | | |  | **MONTH** | |  | **DAY** | |

**□ 2ndary malignancy or MDS, diagnosis \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**(see #1)

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of Diagnosis** |  |  |  |  |  |  |  |  |  |  |
|  | **YEAR** | | | |  | **MONTH** | |  | **DAY** | |

**Survival**

**□ Alive**

**□ Dead, cause of death \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**□ Related with drug adverse event, the drug was\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

**□ Not related**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Date of last FU** |  |  |  |  |  |  |  |  |  |  |
|  | **YEAR** | | | |  | **MONTH** | |  | **DAY** | |

**#1. Diagnosis**

**1 **

****

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| |  |  |  | | --- | --- | --- | | **Creatinine** | | | | Age | ? | ? | | 2–3 years | 0.2–0.7 (17.7–61.9) | 0.3–0.6 (26.5–53.0) | | 4–7 years |  |  | |  |  |  | |  |  |  |  |  |  |
|  | **Creatinine** |  |  |  |  |  |
|  | 2–3 years 0.2–0.7 (17.7–61.9) 0.3–0.6 (26.5–53.0) | | | | |  |
|  | 4–7 years 0.2–0.8 (17.7–70.7) 0.2–0.7 (17.7–61.9) | | | | |  |
|  | 8–10 years 0.3–0.9 (26.5–79.6) 0.3–0.8 (26.5–70.7) | | | | |  |
|  | 11–12 years 0.3–1.0 (26.5–88.4) 0.3–0.9 (26.5–79.6) | | | | |  |
|  | 13–17 years 0.3–1.2 (26.5–106.1) 0.3–1.1 (26.5–97.2) | | | | |  |
|  | 18–20 years 0.5–1.3 (44.2–115.0) 0.3–1.1 (26.5–97.2) | | | | |  |
|  |  |  |  |  |  |  |
|  | **Alkaline phosphatase** | | |  |  |  |
|  | 2–5 years 115–391 115–391 | | |  |  |  |
|  | 6–7 years 115–460 115–460 | | |  |  |  |
|  | 8–9 years 115–345 115–345 | | |  |  |  |
|  | 10–11 years 115–336 115–437 | | |  |  |  |
|  | 12–13 years 127–403 92–336 | | |  |  |  |
|  | 14–15 years 79–446 78–212 | | |  |  |  |
|  | 16–18 years 58–331 35–124 | | |  |  |  |
|  |  |  |  |  |  |  |
|  | **Phosphorus** | |  |  |  |  |
|  | 1 year: 3.8–6.2 mg/dL (1.23–2.0 mmol/L) | | | |  |  |
|  | 10 years: 3.6–5.6 mg/dL (1.16–1.81 mmol/L) | | | |  |  |
|  | Adults: 3.1–5.1 mg/dL (1.0–1.65 mmol/L) | | | |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |