# 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** | |
| **Date of Treatment end :** |  |  |  |  |  |  |  |  |  |  |
|  | **YEAR** | | | |  | **MONTH** | |  | **DAY** | |

|  |
| --- |
| **4. LAST FU** |

**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 \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

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

|  |
| --- |
| **5. COMPLICATION during Chemotherapy** |

치료 중 Grade 3이상의 이상반응 발생 시에 항목에 따라 기록. 개별 이상반응 발생시마다 아래의 sheet를 기록

이상반응 발생일 (YYYY/MM/DD) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ 이상반응 호전일 (YYYY/MM/DD) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Complete Blood Counts** | **Grade 3** | | **Grade 3 Yes/No** | | **Grade 4** | | **Grade 4 Yes/No** |
| Anemia | Hgb <8.0 g/dL; <4.9 mmol/L; <80 g/L; transfusion indicated | |  | | Life-threatening consequences; urgent intervention indicated | |  |
| Leukopenia | <2000 - 1000/mm3; <2.0 - 1.0 x 10e9 /L | |  | | <1000/mm3; <1.0 x 10e9 /L | |  |
| Neutropenia | <1000 - 500/mm3; <1.0 - 0.5 x 10e9 /L | |  | | <500/mm3; <0.5 x 10e9 /L | |  |
| Thrombocytopenia | <50,000 - 25,000/mm3; <50.0 - 25.0 x 10e9 /L | |  | | <25,000/mm3; <25.0 x 10e9 /L | |  |
| **Chemistry & Coagulation & Urine** | **Grade 3** | | **Grade 3 Yes/No** | | **Grade 4** | | **Grade 4 Yes/No** |
| aPTT 연장 | >2.5 x ULN; hemorrhage | |  | | - | |  |
| PT INR 증가 | >2.5 x ULN; >2.5 times above baseline if on anticoagulation | |  | | - | |  |
| 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; >10.34 - 12.92 mmol/L | |  | | >500 mg/dL; >12.92 mmol/L | |  |
| Creatinine 상승 | >3.0 baseline; >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;>3.1 - 3.4 mmol/L; Ionized calcium >1.6 - 1.8 mmol/L; hospitalization indicated | |  | | Corrected serum calcium of >13.5 mg/dL; >3.4 mmol/L; Ionized calcium >1.8 mmol/L; life-threatening consequences | |  |
| Ca 감소 | Corrected serum calcium of <7.0 - 6.0 mg/dL; <1.75 - 1.5 mmol/L; Ionized calcium <0.9 - 0.8 mmol/L; hospitalization indicated | |  | | Corrected serum calcium of <6.0 mg/dL; <1.5 mmol/L; Ionized calcium <0.8 mmol/L; life-threatening consequences | |  |
| Glucose 증가 | >250 - 500 mg/dL; >13.9 - 27.8 mmol/L; hospitalization indicated | |  | | >500 mg/dL; >27.8 mmol/L; life-threatening consequences | |  |
| Glucose 감소 | <40 - 30 mg/dL; <2.2 - 1.7 mmol/L | |  | | <30 mg/dL; <1.7 mmol/L; life-threatening consequences; seizures | |  |
| K 증가 | >6.0 - 7.0 mmol/L; hospitalization indicated | |  | | >7.0 mmol/L; life-threatening consequences | |  |
| K 감소 | <3.0 - 2.5 mmol/L; hospitalization indicated | |  | | <2.5 mmol/L; life-threatening consequences | |  |
| Mg 증가 | >3.0 - 8.0 mg/dL; >1.23 - 3.30 mmol/L | |  | | >8.0 mg/dL; >3.30 mmol/L; life-threatening consequences | |  |
| Mg 감소 | <0.9 - 0.7 mg/dL; <0.4 - 0.3 mmol/L | |  | | <0.7 mg/dL; <0.3 mmol/L; life-threatening consequences | |  |
| Na 증가 | >155 - 160 mmol/L; hospitalization indicated | |  | | >160 mmol/L; life-threatening consequences | |  |
| Na 감소 | <130 - 120 mmol/L | |  | | <120 mmol/L; life-threatening consequences | |  |
| TG 증가 | >500 mg/dL - 1000 mg/dL; >5.7 mmol/L - 11.4 mmol/L | |  | | >1000 mg/dL; >11.4 mmol/L; life-threatening consequences | |  |
| Uric acid 증가 | >ULN - 10 mg/dL (0.59 mmol/L) with physiologic consequences | |  | | >10 mg/dL; >0.59 mmol/L; life-threatening consequences | |  |
| Albumin 감소 | <2 g/dL; <20 g/L | |  | | Life-threatening consequences; urgent intervention indicated | |  |
| P 감소 | <2.0 - 1.0 mg/dL; <0.6 - 0.3 mmol/L | |  | | <1.0 mg/dL; <0.3 mmol/L; life-threatening consequences | |  |
| Hematuria | Gross hematuria; transfusion, IV medications or hospitalization indicated; elective endoscopic, radiologic or operative intervention indicated; limiting self care ADL | |  | | Life-threatening consequences; urgent radiologic or operative intervention indicated | |  |
| Proteinuria | Pediatric: urine P/C >1.9 | |  | | - | |  |
| **Allergy & Rash** | | **Definition** | | **Grade 3** | | **Grade 3이상 Yes/No** | |
| Allergic reaction | | A disorder characterized by an adverse local or general response from exposure to an allergen. | | Prolonged (e.g., not rapidly responsive to symptomatic medication and/or brief interruption of infusion); recurrence of symptoms following initial improvement; hospitalization indicated for clinical sequelae (e.g., renal impairment, pulmonary infiltrates) | |  | |
| Anaphylaxis | | A disorder characterized by an acute inflammatory reaction resulting from the release of histamine and histamine-like substances from mast cells, causing a hypersensitivity immune response. Clinically, it presents with breathing difficulty, dizziness, hypotension, cyanosis and loss of consciousness and may lead to death. | | Symptomatic bronchospasm, with or without urticaria; parenteral intervention indicated; allergy-related edema/angioedema; hypotension | |  | |
| Erythema multiforme | | A disorder characterized by target lesions (a pink-red ring around a pale center). | | Target lesions covering >30% BSA and associated with oral or genital erosions | |  | |
| Injection site reaction | | A disorder characterized by an intense adverse reaction (usually immunologic) developing at the site of an injection. | | Ulceration or necrosis; severe tissue damage; operative intervention indicated | |  | |
| Papulopustular rash | | A disorder characterized by an eruption consisting of papules (a small, raised pimple) and pustules (a small pus filled blister), typically appearing in face, scalp, and upper chest and back Unlike acne, this rash does not present with whiteheads or blackheads, and can be symptomatic, with itchy or tender lesions. | | Papules and/or pustules covering >30% BSA, which may or may not be associated with symptoms of pruritus or tenderness; limiting self-care ADL; associated with local superinfection with oral antibiotics indicated | |  | |
| Pruritus | | A disorder characterized by an intense itching sensation. | | Intense or widespread; constant; limiting self care ADL or sleep; oral corticosteroid or immunosuppressive therapy indicated | |  | |
| Purpura | | A disorder characterized by hemorrhagic areas of the skin and mucous membrane. Newer lesions appear reddish in color. Older lesions are usually a darker purple color and eventually become a brownish-yellow color. | | Combined area of lesions covering >30% BSA; spontaneous bleeding | |  | |
| Rash pustular | | A disorder characterized by a circumscribed and elevated skin lesion filled with pus. | | IV antibiotic, antifungal, or antiviral intervention indicated; radiologic or operative intervention indicated | |  | |
| Urticaria | | A disorder characterized by an itchy skin eruption characterized by wheals with pale interiors and well-defined red margins. | | Urticarial lesions covering >30% BSA; IV intervention indicated | |  | |
| Stevens-Johnson syndrome | | A disorder characterized by less than 10% total body skin area separation of dermis. The syndrome is thought to be a hypersensitivity complex affecting the skin and the mucous membranes. | | Skin sloughing covering <10% BSA with associated signs (e.g., erythema, purpura, epidermal detachment and mucous membrane detachment) | |  | |
| **Fever & Infection** | | **Definition** | | **Grade 3** | | **Grade 3이상 Yes/No** | |
| Febrile neutropenia | | A disorder characterized by an ANC <1000/mm3 and a single temperature of >38.3 degrees C (101 degrees F) or a sustained temperature of >=38 degrees C (100.4 degrees F) for more than one hour | | ANC <1000/mm3 with a single temperature of >38.3 degrees C (101 degrees F) or a sustained temperature of >=38 degrees C (100.4 degrees F) for more than one hour | |  | |
| Fever without neutropenia | | A disorder characterized by elevation of the body's temperature above the upper limit of normal. | | >40.0 degrees C (>104.0 degrees F) for <=24 hrs | |  | |
| Sepsis | | A disorder characterized by the presence of pathogenic microorganisms in the blood stream that cause a rapidly progressing systemic reaction that may lead to shock. | | - | |  | |
| **Cardiovascular** | | **Definition** | | **Grade 3** | | **Grade 3이상 Yes/No** | |
| Ejection fraction 감소 | | The percentage computed when the amount of blood ejected during a ventricular contraction of the heart is compared to the amount that was present prior to the contraction. | | Resting ejection fraction (EF) 39 - 20%; >20% drop from baseline | |  | |
| Heart failure | | A disorder characterized by the inability of the heart to pump blood at an adequate volume to meet tissue metabolic requirements, or, the ability to do so only at an elevation in the filling pressure. | | Severe with symptoms at rest or with minimal activity or exertion; intervention indicated | |  | |
| Hypertension | | A disorder characterized by a pathological increase in blood pressure; a repeatedly elevation in the blood pressure exceeding 140 over 90 mm Hg. | | Stage 2 hypertension (systolic BP >=160 mm Hg or diastolic BP >=100 mm Hg); medical intervention indicated; more than one drug or more intensive therapy than previously used indicated  Pediatric: Same as adult | |  | |
| Hypotension | | A disorder characterized by a blood pressure that is below the normal expected for an individual in a given environment. | | Medical intervention or hospitalization indicated | |  | |
| Thromboembolic event | | A disorder characterized by occlusion of a vessel by a thrombus that has migrated from a distal site via the blood stream. | | Thrombosis (e.g., uncomplicated pulmonary embolism [venous], non-embolic cardiac mural [arterial] thrombus), medical intervention indicated | |  | |
| **Gastrointestinal** | | **Definition** | | **Grade 3** | | **Grade 3이상 Yes/No** | |
| Constipation | | A disorder characterized by irregular and infrequent or difficult evacuation of the bowels. | | Obstipation with manual evacuation indicated; limiting self care ADL | |  | |
| Diarrhea | | A disorder characterized by frequent and watery bowel movements. | | Increase of >=7 stools per day over baseline; incontinence; hospitalization indicated; severe increase in ostomy output compared to baseline; limiting self care ADL | |  | |
| Ileus | | A disorder characterized by failure of the ileum to transport intestinal contents. | | Severely altered GI function; TPN indicated | |  | |
| Mucositis oral | | A disorder characterized by inflammation of the oral mucosal. | | Severe pain; interfering with oral intake | |  | |
| Pancreatitis | | A disorder characterized by inflammation of the pancreas. | | Severe pain; vomiting; medical intervention indicated (e.g., analgesia, nutritional support) | |  | |
| Gastrointestinal hemorrhage | | A disorder characterized by bleeding from the upper gastrointestinal tract (oral cavity, pharynx, esophagus, and stomach). | | Transfusion, radiologic, endoscopic, or elective operative intervention indicated | |  | |
| **Neurologic** | | **Definition** | | **Grade 3** | | **Grade 3이상 Yes/No** | |
| Encephalopathy | | A disorder characterized by a pathologic process involving the brain. | | Severe symptoms; limiting self care ADL | |  | |
| Leukoencephalopathy | | A disorder characterized by diffuse reactive astrocytosis with multiple areas of necrotic foci without inflammation. | | Severe symptoms; extensive T2/FLAIR hyperintensities, involving periventricular white matter involving 2/3 or more of susceptible areas of cerebrum +/- moderate to severe increase in SAS and/or moderate to severe ventriculomegaly | |  | |
| Peripheral motor neuropathy | | A disorder characterized by inflammation or degeneration of the peripheral motor nerves. | | Severe symptoms; limiting self care ADL; assistive device indicated | |  | |
| Peripheral sensory neuropathy | | A disorder characterized by inflammation or degeneration of the peripheral sensory nerves. | | Severe symptoms; limiting self care ADL | |  | |
| Seizure | | A disorder characterized by a sudden, involuntary skeletal muscular contractions of cerebral or brain stem origin. | | Multiple seizures despite medical intervention | |  | |
| **Others** | | **Definition** | | **Grade 3** | | **Grade 3이상 Yes/No** | |
| Pneumonitis | | A disorder characterized by inflammation focally or diffusely affecting the lung parenchyma. | | Severe symptoms; limiting self care ADL; oxygen indicated | |  | |
| Avascular necrosis | |  | |  | |  | |
| Osteonecrosis of jaw | | A disorder characterized by a necrotic process occurring in the bone of the mandible. | | Severe symptoms; limiting self care ADL; elective operative intervention indicated | |  | |
| Osteoporosis | | A disorder characterized by reduced bone mass, with a decrease in cortical thickness and in the number and size of the trabeculae of cancellous bone (but normal chemical composition), resulting in increased fracture incidence. | | Loss of height >=2 cm; hospitalization indicated; limiting self care ADL | |  | |
| Hearing impaired | | A disorder characterized by partial or complete loss of the ability to detect or understand sounds resulting from damage to ear structures. | | Pediatric (on a 1, 2, 3, 4, 6 and 8kHz audiogram): hearing loss sufficient to indicate therapeutic intervention, including hearing aids): Threshold shift >20 dB at 3 kHz and above in at least one ear ; additional speech-language related services indicated. | |  | |
| Blurred vision | | A disorder characterized by visual perception of unclear or fuzzy images. | | Limiting self care ADL | |  | |
| Other disorders - specify | |  | | Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of existing hospitalization indicated; disabling; limiting self care ADL | |  | |

**상기 이상 반응 발생 1주일 전부터 투여한 약물 전체**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **약물명** | **프로토콜상**  **예정 투여량/day** | **실제 투여량/day** | **투여일 (YYYY/MM/DD)** | **이상반응이후**  **중단 혹은 변경 사항** |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

|  |
| --- |
| **6. ALL의 경우 추가 조사항목** |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Cycle** | **유지요법 시작일** | **Cycle 시작시 BSA** | **Cycle 시작시 6MP 투여량 (mg)** | **Cycle시작시 MTX 투여량 (mg)** |
| **1st** |  |  |  |  |
| **2nd** |  |  |  |  |
| **3rd** |  |  |  |  |
| **Last cycle ( )** |  |  |  |  |

**#1. Diagnosis**

**1 **

****