# Adverse Events of Special Interest

## AESI Supplement Trigger

[Revision: Initial revision of study]

(Visit ID = 150 (*) / Visit Display Name = Adverse Events of Special Interest / Visit Abbrev = AESI / PageID = 40 / Page Display Name = AESI Supplement Trigger / Description = AESI Supplemental Trigger)

Enter the adverse event serial number(s) associated with this AESI case.

| | |
|---|---|
| Adverse event serial number | |
| Adverse event serial number | |
| Adverse event serial number | |
| Adverse event serial number | |
| Adverse event serial number | |
| * AESI Supplemental form | ○ BMD decrease/Bone Fractures eCRF<br>○ Elevated Hepatic Transaminases eCRF<br>○ Mood and Depression Related Events eCRF |

# AESI: BMD decrease/Bone Fractures

[Revision: Initial revision of study]

(Visit ID = 150 (*) / Visit Display Name = Adverse Events of Special Interest / Visit Abbrev = AESI / PageID = 10 / Page Display Name = AESI: BMD decrease/Bone Fractures / Description = AESI: BMD decrease/Bone Fractures)

| | |
|---|---|
| * AE serial number | |
| AE serial number | |
| AE serial number | |
| AE serial number | |
| AE serial number | |
| * Description of event leading to the fracture | ○ Fall from standing position<br>○ Fall from estimate height &equiv 2 steps up<br>○ Fall from estimate height > 2 steps up<br>○ Motor vehicle accident<br>○ Other |
| * Other, specify | |
| * Do any family members have a history of hip fractures? | ○ No<br>○ Yes<br>○ Unknown |
| * Do any family members have a history of other fractures? | ○ No<br>○ Yes<br>○ Unknown |
| * Any history of glucocorticoid use? | ○ No<br>○ Yes |

| | | |
|---|---|---|
| * Previous treatment with antiepileptics? | ○ No<br>○ Yes | |
| * Has patient had a bone density scan prior to study entry? | ○ No<br>○ Yes | |
| * If Yes, date of scan | | (UNK-UNK-UNK) |
| * If Yes, results | | |

# AESI: Elevated Hepatic Transaminases

[Revision: Initial revision of study]

(Visit ID = 150 (*) / Visit Display Name = Adverse Events of Special Interest / Visit Abbrev = AESI / PageID = 20 / Page Display Name = AESI: Elevated Hepatic Transaminases / Description = AESI: Elevated Hepatic Transaminases)

| | |
|---|---|
| * AE serial number | |
| AE serial number | |
| AE serial number | |
| AE serial number | |
| AE serial number | |
| * Does the patient have clinical symptoms associated with the adverse event? | ○ No<br>○ Yes |
| **If Yes, please check all symptoms that apply:** | |
| Anorexia | ☐ |
| Fatigue | ☐ |
| Nausea | ☐ |
| Vomiting | ☐ |
| Dark urine | ☐ |
| Pruritis | ☐ |
| Jaundice | ☐ |
| Fever | ☐ |
| Abdominal pain | ☐ |
| Confusion | ☐ |
| Tremor | ☐ |
| Asterixis | ☐ |
| Other symptoms | ☐ |

| | |
|---|---|
| * Other, specify | |

**Any change to prior medical history or new risk factors preceding event?**

| | |
|---|---|
| * Alcohol use | ○ No<br>○ Yes |
| * Specify | |
| * Use of recreational drugs | ○ No<br>○ Yes |
| * Specify | |
| * Travel outside the country | ○ No<br>○ Yes |
| * Specify | |
| * Use of herbal supplements or teas? | ○ No<br>○ Yes |

If Yes, record on Concomitant Medications Details form.

| | |
|---|---|
| * Use of new prescription or over the counter medications? | ○ No<br>○ Yes |

If Yes, record on Concomitant Medications Details form.

**Other relevant history?**

| | |
|---|---|
| * Acupuncture or tattoo | ○ No<br>○ Yes |
| * Specify | |
| * Occupational toxin exposure | ○ No<br>○ Yes |

If Yes, record on Comorbidity Details form.

| | |
|---|---|
| * Family history of liver disease | ○ No<br>○ Yes |

| | | |
|---|---|---|
| * Relationship to patient | ○ | Aunt, biological |
| | ○ | Brother, full |
| | ○ | Brother, half |
| | ○ | Child, biological |
| | ○ | Cousin, biological |
| | ○ | Father, biological |
| | ○ | Grandchild, biological |
| | ○ | Grandfather, biological |
| | ○ | Grandmother, biological |
| | ○ | Mother, biological |
| | ○ | Relative, first degree |
| | ○ | Sister, full |
| | ○ | Sister, half |
| | ○ | Twin |
| | ○ | Twin, dizygotic |
| | ○ | Twin, Monozygotic |
| | ○ | Uncle, biological |
| | ○ | Other |
| * Other, specify | | |
| * Type of liver disease | | |
| * Other relevant history | ○ | No |
| | ○ | Yes |
| If Yes, record on Comorbidity Details form. | | |
| * Please indicate if any additional diagnostic tests have been ordered. Please enter relevant data on the corresponding SAE Supplemental form. | ○ | No |
| | ○ | Yes |
| Prothrombin time | ☐ | |
| Albumin | ☐ | |

| | |
|---|---|
| CPK | ☐ |
| Anti-Hepatitis A virus IgM | ☐ |
| Hepatitis B surface antigen | ☐ |
| Anti-Hepatitis B core antigen IgM | ☐ |
| Anti-Hepatitis B surface antigen | ☐ |
| Anti-Hepatitis C serologies | ☐ |
| Hepatitis E serologies | ☐ |
| Anti-nuclear antibodies (ANA) | ☐ |
| Anti-smooth muscle antibodies (ASMA) | ☐ |
| Abdominal ultrasound | ☐ |
| CMV IgM and IgG | ☐ |
| Anti-mitochondrial Ab Test | ☐ |
| EBV panel (VCA IgM, VCA IgG, EBNA) | ☐ |
| Computed Tomography (CT) scan | ☐ |
| Eosinophil count | ☐ |
| Endoscopic Retrograde Cholangiopancreatography (ERCP) | ☐ |
| Liver biopsy | ☐ |
| HIV Ab | ☐ |
| Other | ☐ |
| * Other, specify | |

# AESI: Mood and Depression Related Events

[Revision: Initial revision of study]

(Visit ID = 150 (*) / Visit Display Name = Adverse Events of Special Interest / Visit Abbrev = AESI / PageID = 30 / Page Display Name = AESI: Mood and Depression Related Events / Description = AESI: Mood and Depression Related Events)

| | | |
|---|---|---|
| * AE serial number | | |
| AE serial number | | |
| AE serial number | | |
| AE serial number | | |
| AE serial number | | |
| * Please specify the symptoms that the patient exhibited with the event (List symptoms other than those already on the adverse event form. If the reported symptom(s) include depression/depressed mood, record other related symptoms including suicidality if present. Please refer the patient to a mental health provider if suicidal ideation or behavior is reported or as needed on the investigator's judgement. | | |
| * Was this event treated? | ○ No<br>○ Yes | |
| * Does the investigator feel that there is an alternative etiology for this event? | ○ No<br>○ Yes | |
| * If Yes, specify | | |
| * Was the patient seen by a mental health provider for this event? | ○ No<br>○ Yes | |
| * If Yes, date | | (UNK-UNK-UNK) |

| | | |
|---|---|---|
| * If Yes, findings | | |
| * Has the patient previously experienced any neuropsychiatric symptoms? | ○ No<br>○ Yes | |
| * If Yes, previously experienced symptom | | |
| * If Yes, date of onset of prior symptom | | (UNK-UNK-UNK) |
| * If Yes, duration of prior symptom | | |
| * If Yes, treatment of prior symptom | | |
| * Does the patient have a relevant family history? | ○ No<br>○ Yes | |
| * If Yes, specify | | |