

CHAI Research Interface

2013

The Goal of this document is to provide you a guide, with which you may add and edit items in the CHAI HIV research data interface.

Revision: 1

HELP DOC.

GENERAL NOTES:

- Save/apply buttons will save the data and return you to your current location
- Submit buttons save the data and send you to the list of the items you were editing.

ADMIN

You can log in to the admin from two directions. From the upper right hand gear icons or type the url address after the root of '/admin'.

Add/Edit user:

1. Under the menu item "Users" click on Users list
2. Click "New User" at the top
3. Fill in the form
4. Click save

Note: the User Network ID for CHAI is your email. IE: username@clintonhealthaccess.org

Add/Edit Privileges:

1. Under the menu item "Groups" click on Users list
2. Choose the "Privileges" tab
3. Click "New Privileges" at the top
4. Fill in the form
5. Click save

Apply Privileges:

1. Under the menu item "Groups" click on Users list
2. Choose the group to edit under the "Groups" tab
3. Move to the "Privileges" tab and check which privileges apply
4. Click save

Add/Edit Groups:

1. Under the menu item "Groups" click on Users list
2. Choose the group to edit under the "Groups" tab
3. Fill in the form
4. Click save

Add/Edit Taxonomy:

1. Under the menu item "Sites" click on Taxonomies
2. Choose the Taxonomy type from the left navigation bar

3. Click the + New Button
4. Fill in the form
5. Click save

Note: Url and Content are optional and used in templates only. Skip this.

Restore a Deleted record/permanently remove:

1. Click the Trashbin link in the menu to the far right.
2. Choose the items to restore or delete in mass.

FRONTEND

Finish after finalizing UI

CLINICAL TRIALS:

This module of the CHAI database is designed to capture information related to clinical trials being performed on ARVs. Information needed in this module will come from many sources including regulatory documents, innovator publications, www.clinicaltrials.gov, and other associated publications or presentations at conferences. For drug products under development and therefore with clinical trials in the early stages (Phase 1, 2, and potentially 3), information may be more difficult to find as it might not yet be publicly available with the exception of the information publicly available on www.clinicaltrials.gov

Edit something:

1. Click save
- 2.

REGIMENS:

Edit something:

1. Click save
- 2.

DRUG PRODUCTS:

This module of the CHAI database is designed to capture information on drug products used as part of ARV therapy. Information needed in this module will largely come from regulatory documents associated with the approval of the drug product for marketing and particularly from the drug product approved package insert. For drug products under development and therefore in the IND stage, information may be more difficult to find as it might not yet be publicly available.

Edit something:

1. Click save
- 2.

DRUG SUBSTANCES:

This module of the CHAI database is designed to capture chemistry-related information on the active pharmaceutical ingredient (API) in drug products. Information needed in this module will largely come from regulatory documents associated with the approval of the drug product for marketing and particularly from the chemistry review section of the dossier. For drug substances under development and therefore in the IND stage, information may be more difficult to find as it might not yet be publicly available. Information may also come from publications on the API in chemistry and related journals and presentations.

Edit something:

1. Click save
- 2.

REFERENCES:

Edit something:

1. Click save
- 2.

TRASH BIN:

Note: you may only do a soft deletion of from the system of the record.

APPENDIX A – (AE) LIST

ADVERSE EVENTS

Abnormal Dreams -- Unusual or atypical Dreams

Acute Renal Insufficiency -- Aka Acute Renal Failure (ARF) or Acute Renal Injury (ARI)- Means a rapidly progress loss of renal function, characterized by decrease urine production, fluid and electrolyte imbalance, Increase in serum creatinine level

Alopecia -- Loss of Hair

Anemia -- Decrease of hemoglobin in blood

Arthralgias -- Joint Pain

Anxiety -- An abnormal and overwhelming sense of apprehension of fear often marked by physiological signs (as sweating, tension, increase pulse), by doubt concerning reality and nature of the threat, and by self-doubt about one's capacity to cope with it.

Asthenia -- Weakness, due to lack or loss of strength

Blood Clotting -- Process which involves shedding of blood and interaction of thrombin to form insoluble fibrin network

Cholangitis -- Inflammation of bile duct or entire biliary tree

Cholecystitis -- Inflammation of gall bladder

Cholelithiasis -- Presence of a stone in the common bile duct

Chronic Renal Insufficiency -- Aka Chronic Renal Failure, or Chronic Renal Disease, which is a progressive loss of renal function over period of months or years. Often present with high levels of creatinine which indicate low glomerular filtration rate.

Coughing -- To expel air from the lungs suddenly

Depression -- State of feeling sad, marked by inactivity, difficulty with thinking, increase or decrease of appetite, feelings of dejection, hopelessness, attempt to commit suicide

Diabetes Mellitus -- Deficiency of insulin and characterized by chronic increase in blood glucose and other long term complications

Diarrhea -- Abnormally frequent intestinal evacuations with more or less fluid stools

Dizziness -- Sensation of unsteadiness accompanied by feeling of movement within the head

Dyslipidemia -- Elevation of total cholesterol, LDL and triglyceride levels

Emesis -- Vomiting

Erythema -- Redness

Fatigue -- Weariness or exhaustion

Fever -- Rise of body temperature above the normal

Flank Pain -- Pain in one side of the abdominal area

Flatulence -- Presence of excessive amount of gas in stomach and intestines

G.I. Intolerance -- Upset Stomach

Headache -- Pain in the head

Hepatic Flares -- Sudden increase in liver enzymes

Hepatomegaly -- Liver enlargement

Hyperbilirubinemia -- Excess bilirubin in the blood

Hypercholesterolemia -- Excess cholesterol in the blood

Hyperpigmentation -- excess pigment in bodily part or tissue

Hypertension -- High blood pressure

Hypertriglyceridemia -- excess amount of triglycerides in the blood

Hyperuricemia -- Excess uric acid in the blood

Hypophosphatemia -- Deficiency of phosphates in the blood

Impaired Concentration -- Difficulty in maintaining a fixed, close, undivided attention

Ingrown Nails -- When the edge of the nail grows down and into the skin of the toes- may present as pain, redness, swelling around the nail

Insomnia -- Trouble sleeping

Insulin resistance -- Reduced sensitivity to insulin by body's insulin-dependence processes that result in lowered activity or increase in insulin production, often occurs in absence of diabetes

Jaundice -- Yellowish pigment of the skin, tissues and certain body fluids caused by deposition of bile pigments

Lethargy -- Drowsiness, state of being lazy, sluggish or indifferent

Lipodystrophy -- Loss of fat from or deposition of fat from tissue

Lipohypertrophy -- Lump under skin caused by accumulation of extra fat

Loss of appetite -- Loss of desire to eat food

Malaise -- Feeling of debility or lack of health

Male Gynecomastia -- Excessive development of breast in male

Metabolic Syndrome -- Syndrome marked by presence of usually 3+ group of factors: High blood pressure, abdominal obesity, high triglyceride levels, low HDL levels, high fasting blood sugar, which are linked to an increased risk of cardiovascular disease and type 2 diabetes, and Alzheimer's disease

Myalgia -- Pain in one or more muscle

Myopathy -- Disorder of muscle tissue or muscles

Nausea -- A sensation of unease and discomfort in the upper stomach with an involuntary urge to vomit

Neurological Toxicities -- Damage to the nervous system presenting symptoms from limb weakness, numbness, loss of memory/vision

Nightmares -- Disturbing dreams

Osteopenia -- Reduced bone mineral density

Pain (Back, Leg, Neck) -- State of physical, emotional, or mental lack of well-being or physical, emotional, or mental uneasiness that ranges from mild discomfort or dull distress to acute often unbearable agony, may be generalized or localized

Pneumonia -- Inflammation and consolidation of lung tissue followed by resolution, accompanied by fever, chills, cough, and difficulty in breathing

Prolong PR Interval -- Increased PR interval in heart rhythm, may increase risk of atrial fibrillation

Pruritus -- Localized or generalized itching

Sneezing -- A sudden violent spasmodic audible expiration of breath through the nose and mouth especially as a reflex act following irritation of the nasal mucous membrane

Somnolence -- Quality or state of being drowsy

Suicidal ideation -- Increase inclination to cause suicide

Taste Perversion -- Distorted sense of taste

Torsades de pointes -- Heart arrhythmia which is characterized by fluctuation of QRS complexes

Vomiting -- Act of disgorging contents of stomach through mouth

Weight change --

SEVERE ADVERSE EVENTS

Birth Defects --

Death --

Fanconi syndrome -- Disorder of proximal renal tubules in which certain substances (Amino acids, glucose, uric acid, phosphates) normally absorbed into the blood stream by kidneys are released in the urine instead

Hematuria -- Presence of blood or red blood cells in urine

Hepatic toxicity -- Drug-induced liver damage which manifest as abnormal liver enzyme testes

Hypersensitivity syndrome -- Severe, idiosyncratic multi-system reaction defined by fever, rash and internal organ involvement which may occur 1-8 weeks after exposure to drugs

Immune reconstitution syndrome -- Collection of inflammatory disorders associated with paradoxical worsening of preexisting infectious processes following HAART initiation

Intracranial Hemorrhage -- Bleeding within cranial vault, includes cerebral hemorrhage and subarachnoid hemorrhage

Lactic Acidosis -- Type of metabolic acidosis caused by accumulation of lactic acid in bloodstream

Lipoatrophy -- Loss of subcutaneous fat

Liver failure -- Condition in which the liver fails to fulfill its function or is unable to meet the demands made on it. Anorexia, fatigue, and weakness are common symptoms of liver cell failure, whereas jaundice indicates a biliary obstruction and fever may accompany viral or alcoholic liver diseases.

Mitochondrial Infraction -- Heart attack, often due to blood clots that block flow of blood through coronary artery

Nephrolithiasis -- Kidney stones

Nephrotoxicity -- Drug toxicity in kidney

Neural Tube Defects -- Major birth defect present as abnormal of the neural tube which gives rise to the central nervous system

Neurologic toxicities -- Drug induced toxicities in the nervous system

Neuromuscular Weakness -- Generalized weakness that affects the muscles which control respiration

Neutropenia -- Abnormally low count of neutrophils, which is a type of white blood cells

Pancreatitis -- Inflammation of the pancreas

Peripheral Neuropathy -- Numbness and pain in hands and feet, can also be described as a tingling or burning sensation

Prematurity --

QT Interval Prolongation -- Heart rhythm disorder in which QT interval is longer than normal, which can cause fast and chaotic heart beats, may trigger sudden fainting spell or seizure

Rash -- Group of spots or red, inflamed skin that is usually a symptom of an underlying condition or disorder

Rhabdomyolysis -- Severe muscle pain that is caused by breakdown of muscle cells

Seizure -- Uncontrolled electrical activity in the brain, which may produce a physical convulsion, motor physical signs, thought disturbances, or a combination of symptoms

Steatosis -- Fatty liver, collection of excessive amounts of triglycerides and other fats inside liver cells

Stevens-Johnson's Syndrome -- Rare and serious disorder in which skin and mucous membranes react severely, begins with flu-like symptoms, followed by painful red or purplish rash that spreads and blisters, eventually causing top layer of skin to die and shed, often presents as medical emergency and require hospitalization

Stroke -- Aka cerebral vascular accident (CVA), rapid loss of brain function due to a disturbance in blood supply to the brain may do to lack of blood flow caused by blockage

Increased liver enzymes --