CHAI Interface

Research 2014

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: 1.5

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 Trash bin link in the menu to the far right.
- 2. Choose the items to restore or delete in mass.

FRONTEND

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. Fill the form as fully as possible

REGIMENS:

Edit something:

1. Fill the form as fully as possible

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. Fill the form as fully as possible

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. Fill the form as fully as possible

REFERENCES:

Edit something:

1. Fill the form as fully as possible

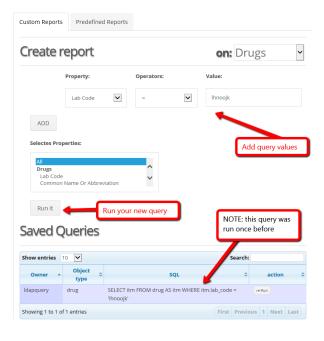
TRASH BIN:

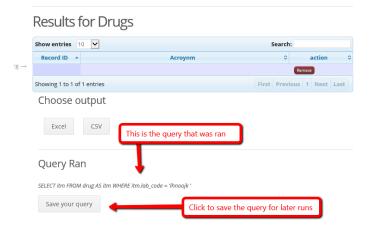
Note: you may only do a soft deletion of from the system of the record. What this means is that if you don't have admin rights on the system you will not be able to clear items from the trash bin.

REPORTS:

Save a report:

- 1. Run a report. Select your values and click run.
- 2. Once you have run a report, just click save at the bottom and you'll be able to run it again.





APPENDIX A - (AE) LIST

ADVERSE EVENTS

Abnormal Dreams -- Unusual or atypical Dreams

Acute Renal Insufficency -- 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 elecrolyte imbalance, Increase in serum creatinine level

Alopecia -- Loss of Hair

Anemia -- Decrease of hemoglobin in blood

Anthraigias -- Joint Pain

Anxiety -- An abnormal and overwhelming sence of apprehension of fear often marked by phsiological 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 -- Inflamation of bile duct or entire biliary tree

Cholencystitis -- Inflammation of gal bladder

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

Chronic Renal Insufficency -- 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 feeliing sad, marked by inactivity, difficulty with thinking, increase or decrease of appetite, feelings of dejection, hopelessness, attempt ot commit suicide

Diabetes Mellirtus -- Deficency 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 cholerserol, 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 o fgas in stomache and intestines

G.I. Intolerance -- Upset Stomach

Headache -- Pain in the head

Hepatic Flares -- Sudden increase in liver enzymes

Hepatomegaly -- Liver enlargement

Hyperbilirubenimia -- Excess bilirubin in the blood

Hypercholesterolemia -- Excess cholseterol in the blood

Hyperpigmentation -- excess pigment in bodily part or tissue

Hypertension -- High blood pressure

Hypertriglyceridemia -- excess amount of triglyceriedes in the blood

Hyperuricemia -- Excess uric acid in the blood

Hypohosphatemia -- Deficency of phosphates in the blood

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

Ingrown Nails -- When the edge of the anil grows down and into the skin o fthe toes- may present as pai, 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

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

Loss of appetite -- Loss fo 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 presnece of usually 3+ group of factors: High blood pressure, abdomina obesity, high triglyceride leevels, 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 invoulentary urge to vomit

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

Nightmares -- Distrurbing dreams

Osteopenia -- Reduced bone mineral density

Pain (Back, Leg, Neck) -- State of physical, emotional, or mental lack of well-being or pysical, emotiona, 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 -- Distroted sence 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

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

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

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 bloodstreem

Lipoatropy -- Loss of subcutaneous fat

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

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

Nephrolithiasis -- Kidney stones

Nephrotixicity -- 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 -- Generalize weakness that affects the muscles which controll respiration

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

Pancreatitis -- Inflimation of the pancreas

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

Prematurity --

QT Interval Prologation -- 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 ofspots or red, inflamed skin that is usually a symptom of an underlying condition or disorder

Rhabdomyolsis -- Severe muscle pain that is caused by breakdwon of muscle cells

Seizure -- Uncontrolled electrical activity in teh brain, which may producte a physical covulsion, monor physical signs, thought distrubances, or a combination of symptoms

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

Stevens-Johnsons 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 presnt as medical emergency and require hospitalization

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

Increased liver enzymes --