

# CHAI Research Interface

# 2014

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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](http://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](http://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.

The screenshot shows the 'Create report' interface. At the top, there are tabs for 'Custom Reports' and 'Predefined Reports'. Below them is a dropdown menu set to 'on: Drugs'. The main form has three sections: 'Property:', 'Operators:', and 'Value:'. The 'Property:' section has a dropdown for 'Lab Code'. The 'Operators:' section has a dropdown for '='. The 'Value:' section has a text input field containing 'lhnoojk'. Below these sections is an 'ADD' button. To the left of the 'ADD' button is a 'Select Properties' section with a list box containing 'All', 'Drugs', 'Lab Code', and 'Common Name Or Abbreviation'. Below the list box is a 'Run it' button. A red arrow points from the 'Run it' button to a red box containing the text 'Run your new query'. Another red arrow points from the 'Value:' text input field to a red box containing the text 'Add query values'. Below the 'Run it' button is a 'Saved Queries' section. It has a table with columns 'Owner', 'Object type', 'SQL', and 'action'. The table contains one entry: 'Idapquery', 'drug', 'SELECT itm FROM drug AS itm WHERE itm.lab\_code = 'lhnoojk'', and 're-Run'. A red arrow points from the 'SQL' cell to a red box containing the text 'NOTE: this query was run once before'. At the bottom of the 'Saved Queries' section is a 'Showing 1 to 1 of 1 entries' label and navigation buttons: 'First', 'Previous', '1', 'Next', 'Last'.

The screenshot shows the 'Results for Drugs' interface. At the top, there is a 'Show entries' dropdown set to '10' and a 'Search:' text input field. Below these is a table with columns 'Record ID', 'Acronym', and 'action'. The table contains one entry: '1', 'lhnoojk', and 'Remove'. Below the table is a 'Showing 1 to 1 of 1 entries' label and navigation buttons: 'First', 'Previous', '1', 'Next', 'Last'. Below the table is a 'Choose output' section with two buttons: 'Excel' and 'CSV'. A red arrow points from the 'CSV' button to a red box containing the text 'This is the query that was ran'. Below the 'Choose output' section is a 'Query Ran' section. It contains the SQL query: 'SELECT itm FROM drug AS itm WHERE itm.lab\_code = 'lhnoojk''. Below the query is a 'Save your query' button. A red arrow points from the 'Save your query' button to a red box containing the text 'Click to save the query for later runs'.

# 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** --