

Summarized variables in AELOG (excluding open-text)

NAME	LABEL
StudyEvent	StudyEvent
AERelation	AE Relatedness
AEAction	AE Action Taken
AEOutcome	AE Outcome
AEExpected	AE Expectedness
AEIntensity	AE Intensity
AE Serious	AE Serious
llt_code	MedDRA Lowest Level Term ID Number
AEENDDAY	AE End Day (relative to randomization)
AESTARTDAY	AE Start Day (relative to randomization)

Summarized open-text variables in AELOG

NAME	LABEL
AEName	Adverse Event (AE)
hlgt_name	MedDRA High Level Group Term
hlt_name	MedDRA High Level Term
llt_name	MedDRA Lowest Level Term
pt_name	MedDRA Preferred Term
soc_name	MedDRA System Organ Class

Variables in AELOG without summary

NAME	LABEL
PUDID	Subject ID
Occurrence	Occurrence
ItemGroupRepeatKey	ItemGroupRepeatKey

AELOG Summaries

	N	Percent
StudyEvent		
Safety Data	870	100%
Adverse Event (AE)		
headache	1	0%
Abdominal Cramping	1	0%
Abdominal Distention	1	0%
Abdominal Pain	4	0%
Abdominal pain	6	1%
Abdominal tenderness	1	0%
Abominal Pain	1	0%
Abscess at insulin pump insertion site on right buttock	1	0%
Acute Respiratory Distress Syndrome	1	0%
Acute pancreatitis	1	0%
Additional 10mL/kg fluid bolus for tachycardia	1	0%
Agitated	1	0%
Agitation	1	0%
Alkalosis	1	0%
Altered Mental Status	3	0%
Altered mental status	3	0%
Anxiety related to diabetes care	1	0%
Arm Pain	1	0%
Arm pain	1	0%
Aspiration Pneumonia	1	0%
Back Pain	1	0%
Back pain	1	0%
Bloodshot eyes	1	0%
Blurry vision	1	0%
Body pain	1	0%
Bradycardia	1	0%
Bradychardic	1	0%
Burning in the back of throat	1	0%
Burning with administration of KCl	1	0%
C. Dificile Enterocolitis	1	0%
Candida Vulvovaginitis	1	0%
Candida infection - skin	1	0%
Candida infection - urine	1	0%
Candidal Rash	1	0%

(Continued)

AELOG Summaries

	N	Percent
Adverse Event (AE)		
Candidiasis	1	0%
Candidiasis (oral & vaginal)	1	0%
Candidiasis of vulva and vagina	1	0%
Candidiasis of mouth	1	0%
Cardiac Arrest	1	0%
Cardiac Injury	1	0%
Cardiac Murmur	1	0%
Cellulitis Infection	1	0%
Cerebral Edema	7	1%
Cerebral Infarcts	1	0%
Cerebral edema	5	1%
Chest Pain	3	0%
Chest pain	3	0%
Chest tightness	1	0%
Chest/rib pain	1	0%
Chills	2	0%
Coagulopathy	1	0%
Cold extremities	1	0%
Constipation	11	1%
Continuing headache	1	0%
Cough	5	1%
Critical low level of potassium	1	0%
Decrease in blood glucose	1	0%
Decreased GCS to 13	1	0%
Decreased bowel sounds	1	0%
Decreased mental status	2	0%
Decreased mental status, GCS 8	1	0%
Decreased perfusion	1	0%
Decreasing Bicarbonate Levels	1	0%
Dehydration	1	0%
Difficulty swallowing	1	0%
Dizziness	2	0%
Drop in GCS from 13 to 12 after randomization but before study treatment was started	1	0%
Drop in Glucose	1	0%
Drop in Sodium Levels	2	0%

(Continued)

AELOG Summaries

	N	Percent
Adverse Event (AE)		
Drop in bicarbonate (9 mmol/L)	1	0%
Dyspepsia	1	0%
Ear Pain	1	0%
Ear pain	1	0%
Ear pain while chewing	1	0%
Elevated TSH	1	0%
Elevated TTG IgA	1	0%
Elevated blood pressure	1	0%
Elevated lipase	1	0%
Emesis	1	0%
Epigastric pain	2	0%
Epistaxis	1	0%
Erythematous Oropharynx	1	0%
Erythematous forearms	1	0%
Esophageal irritation	1	0%
Esophagitis	1	0%
Face Pain	1	0%
Falling Glucose	1	0%
Feeling hot/flushed face	1	0%
Fever	22	3%
Fever - low grade	1	0%
Fever due to Strep pharyngitis	1	0%
Fever to 100.4F	1	0%
Fever to 38.6 overnight	1	0%
Fever/UTI	1	0%
Flu A positive	1	0%
Frequent PVCs	1	0%
GCS Drop	2	0%
GCS decreased to 12	1	0%
Gastroesophageal Reflux	1	0%
Gastroesophageal Refluc	1	0%
Genital yeast infection	1	0%
Grade 4 hypoglycemia	1	0%
Hand Edema	1	0%
Hand pain	1	0%
Headache	48	6%

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AELOG Summaries

	N	Percent
Adverse Event (AE)		
Headache	1	0%
Heartburn	2	0%
Hematemesis	1	0%
Hematochezia	1	0%
Hematuria	1	0%
Hematuria/UIT	1	0%
Hepatomegaly	1	0%
Hyperchloremia	2	0%
Hyperchloremic	1	0%
Hyperchloremic Acidosis	6	1%
Hyperchloremic acedosis	3	0%
Hyperchloremic acidosis	6	1%
Hyperchloremic acidosis (Cl 123; Bicarb 15)	1	0%
Hyperchloremic metabolic acidosis	1	0%
Hyperchloremic Acidosis	1	0%
Hyperglycemia	3	0%
Hyperkalemia	7	1%
Hypernatremia	1	0%
Hypertension	2	0%
Hypertriglyceridemia	1	0%
Hypocalcemia	2	0%
Hypoglycemia	1	0%
Hypoglycemia	26	3%
Hypoglycemia due to either insulin pump malfunction or error	1	0%
Hypoglycemic (after insulin drip end)	1	0%
Hypoglycemic Episode	1	0%
Hypoglycemia	1	0%
Hypokalemia	20	2%
Hypokalemia (K 2.3)	1	0%
Hypokalemic	3	0%
Hypomagnesemia	1	0%
Hypomagnesium	1	0%
Hyponatremia	6	1%
Hypophosphatemia	5	1%
Hypotension 86/40	1	0%
Hypoxia	1	0%

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AELOG Summaries

	N	Percent
Adverse Event (AE)		
IV Irritation	1	0%
IV Site Pain	1	0%
IV arm pain	1	0%
IV infiltrate	2	0%
IV irritation	1	0%
IV site pain	2	0%
Inconsolable Crying	1	0%
Incontinence	1	0%
Increase in blood glucose	1	0%
Increased Abdominal Pain	1	0%
Increased abdominal pain	2	0%
Increased potassium	1	0%
Increasing Acidosis	1	0%
Intermittent bradycardia	1	0%
Irritability	4	0%
Irritation @ IV site	1	0%
Itching	1	0%
Itching on arm	1	0%
Junctional Cardiac Rhythm	1	0%
L arm pain (heme stick)	1	0%
Left Lower Lobe pneumonia	1	0%
Left hand PIV Tenderness	1	0%
Left hand pain	2	0%
Left hand puffiness	1	0%
Leg pain	1	0%
Low CPK	1	0%
Low Glucose	1	0%
Low Magnesium	2	0%
Low Potassium	3	0%
Low blood pressure	1	0%
Low drop in sodium levels	1	0%
Low grade fever	1	0%
Low phosphate level	1	0%
MRSA bacteremia	1	0%
Medication Error -double dose of insulin	1	0%
Metapneumovirus	1	0%

(Continued)

AELOG Summaries

	N	Percent
Adverse Event (AE)		
Middle Ear Effusion	1	0%
Mild Diffuse Cerebral Edema	1	0%
Mouth hurts	1	0%
Mouth pain	1	0%
Nasal congestion	1	0%
Nausea	4	0%
Neck Pain	1	0%
Nosebleeds	1	0%
Oral Candida	1	0%
Oral Thrush	1	0%
Otitis Media	2	0%
Otitis media	1	0%
PIV Infiltration	1	0%
PIV infiltrate	2	0%
PVCs	1	0%
Pain	1	0%
Pain @ IV Site	1	0%
Pain @ IV site	1	0%
Pain at IV site	6	1%
Pain in Right Hand	1	0%
Pancreatitis	1	0%
Peaked T-Waves	1	0%
Persistent Tachycardia	3	0%
Pharyngitis	2	0%
Phlebitis	1	0%
Pink rash on trunk	1	0%
Pneumothorax	1	0%
Possible Cerebral Edema	1	0%
Postoperative Tonsillectomy Hemorrhage	1	0%
Presence of lice in head	1	0%
Preseptal cellulitis	1	0%
Pressure Ulcers	1	0%
Prolonged QTc Interval	1	0%
Pruritis	1	0%
Pyurea	1	0%
Pyuria	1	0%

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AELOG Summaries

	N	Percent
Adverse Event (AE)		
Rapid Strep Test Positive	1	0%
Rapidly decreasing glucose (208) on D10	1	0%
Rapidly decreasing osmolality (330) on D10	1	0%
Rash	4	0%
Rash on scalp	1	0%
Rash spread to abdomen	1	0%
Rectal pain	1	0%
Red throat	1	0%
Renal Injury	1	0%
Repeat episode of DKA	1	0%
Rib pain	1	0%
Right Shoulder Pain	1	0%
Right middle finger swelling	1	0%
Right wrist pain	1	0%
Seizures	1	0%
Shivering	1	0%
Sinusitis	1	0%
Skin breakdown from pulse oximeter probe	1	0%
Slowly resolving acidosis	1	0%
Soar throat	1	0%
Sore Throat	5	1%
Sore throat	11	1%
Sore tongue	1	0%
Sternal Chest Pain	1	0%
Strep Group A + throat culture	1	0%
Strep pharyngitis	1	0%
Stridor	1	0%
Swollen face and arm	1	0%
Tachycardia	3	0%
Tachypnea	1	0%
Throat Pain	2	0%
Throat pain	7	1%
Tongue pain	1	0%
Transient chest tightening	1	0%
Transient mild hypertension	1	0%
URI with fever, rhinorrhea	1	0%

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AELOG Summaries

	N	Percent
Adverse Event (AE)		
Upper Back Pain	1	0%
Urethritis	1	0%
Uric acid crystalluria	1	0%
Urinary Tract Infection	2	0%
Urinary tract infection	2	0%
Urine - Hyaline and granular casts	1	0%
Urine inflammation/casts	1	0%
Urticaria	1	0%
Vaginal discharge	1	0%
Vaginal itch	1	0%
Vomiting	3	0%
Vomitting	1	0%
Vulvovaginitis	1	0%
Wheezing	2	0%
Wide-complex tachycardia	1	0%
Worsening Cerebral Edema	1	0%
Worsening Headache	1	0%
Worsening acidosis	1	0%
Worsening hypernatremia	1	0%
Yeast Infection	2	0%
abdomen pain	1	0%
abdominal cramps	1	0%
abdominal pain	4	0%
abdominal pain persistent	1	0%
abdominal paon	1	0%
acidosis	3	0%
altered mental status	9	1%
altered mental status: GCS declined to 8	1	0%
arm pain	2	0%
back pain	1	0%
blurred vision	1	0%
blurry vision	2	0%
body aches	1	0%
bradycardia	2	0%
candidal vaginitis	1	0%
candidal yeast infection	1	0%

(Continued)

AELOG Summaries

	N	Percent
Adverse Event (AE)		
central line occlusion	1	0%
cerebral edema	4	0%
chest pain	1	0%
chest pain - brief, non-cardiac burning chest pain, likely heartburn, resolved without intervention	1	0%
confusion	1	0%
congestion (nasal)	1	0%
constipation	9	1%
continued decreased PO intake	1	0%
cough	2	0%
decrease in bicarbonate	1	0%
decreased mental status	2	0%
decreased perfusion	1	0%
dental infection	1	0%
diarrhea	2	0%
difficulty getting breath	1	0%
dizziness	4	0%
drop in blood glucose	1	0%
drop in blood glucose to 55	1	0%
drop in blood sugar	1	0%
drop in blood sugar from 111 to 47	1	0%
dry skin	1	0%
elevated Cl level	1	0%
elevated Na level	1	0%
elevated WBC	1	0%
elevated amylase	1	0%
elevated lipase	1	0%
elevated liver function test	1	0%
emesis	1	0%
eye pain	2	0%
eyes bothering her	1	0%
fever	11	1%
frontal headache	1	0%
gastroesophageal reflux	1	0%
gum pain	1	0%
hand pain	1	0%

(Continued)

AELOG Summaries

	N	Percent
Adverse Event (AE)		
head lice	1	0%
headache	41	5%
headache/pain	1	0%
headaches	1	0%
heartburn	3	0%
hematemesis	1	0%
hyperchloremia	3	0%
hyperchloremic	1	0%
hyperchloremic acidosis	2	0%
hyperchloremic acidosis	17	2%
hyperchloremic acidosis (121 Cl, 12 bicarb)	1	0%
hyperchloremic metabolic acidosis	2	0%
hyperchloremic acidosis	1	0%
hyperchloremic acidosis	1	0%
hyperglycemia	1	0%
hyperkalemia	10	1%
hypernatremia	2	0%
hyperphosphatemia (while under therapy)	1	0%
hypertension	3	0%
hypoglycemia	17	2%
hypoglycemia(bs 52)	1	0%
hypoglycemic episode	1	0%
hypoglycemic episode	1	0%
hypokalemia	22	3%
hypokalemia (K 2.2)	1	0%
hypokalemia (K 2.4)	1	0%
hypomagnesemia	2	0%
hyponatremia	3	0%
hypophosphatemia	1	0%
hypophosphatemia	9	1%
hypotension	2	0%
hypothermia	1	0%
hypothyroidism	1	0%
hypovolemic shock	1	0%
increase in Beta Hydroxybutyrate	1	0%
increased nausea	1	0%

(Continued)

AELOG Summaries

	N	Percent
Adverse Event (AE)		
intermittent headache	1	0%
irritable	1	0%
itching	1	0%
itchy rash on legs	1	0%
knee/leg pain	1	0%
lack of correction of acidosis/hyperchloremic acidosis	1	0%
left arm pain at IV site	1	0%
left leg cellulitis	1	0%
low BUN level	1	0%
low K (potassium)	1	0%
low glucose	1	0%
low magnesium	1	0%
low phosphate	1	0%
low phosphate level	1	0%
low phosphate levels	1	0%
low potassium levels	1	0%
low urine output	1	0%
lymphadenopathy	1	0%
mild headache	2	0%
mild hyperchloremic acidosis	1	0%
mouth pain - not otherwise specified	1	0%
mouth sores	1	0%
muscle aches	1	0%
muscle spasms in jaw	1	0%
musculoskeletal and cutaneous infection	1	0%
nasal congestion	2	0%
nausea	10	1%
oral thrush	1	0%
oral ulceration	1	0%
pain at PIV site	1	0%
pain, IV site	1	0%
pain, unspecified	1	0%
perianal rash	1	0%
period of altered mental status possibly due to parasomnic event	1	0%
persistent RLQ abdominal pain	1	0%
pharyngitis	2	0%

(Continued)

AELOG Summaries

	N	Percent
Adverse Event (AE)		
postural hypotension	1	0%
pruritus	1	0%
pulmonary edema	1	0%
rash	3	0%
recurrent acidosis	1	0%
rhinorrhea	1	0%
right eye irritation (rubbing eye)	1	0%
slurred speech	1	0%
somnolence	1	0%
sore throat	10	1%
strep throat	1	0%
suicidal Ideation	1	0%
suicidal ideations	1	0%
suspected urinary tract infection	1	0%
syncope	1	0%
tachycardia	1	0%
throat pain	3	0%
tongue pain	1	0%
tooth pain	2	0%
unable to sleep (insomnia)	1	0%
urinary incontinence	1	0%
vaginal discharge	1	0%
vaginal yeast infection	1	0%
vaginitis	1	0%
vomiting	5	1%
vomiting 1 time	1	0%
warm skin	1	0%
worsening acidosis	2	0%
worsening cerebral edema	1	0%
worsening headache	1	0%
yeast in initial UA	1	0%
yeast rash	1	0%
AE Relatedness		
Not Related	651	75%
Possibly Related	204	23%
Probably Related	15	2%

(Continued)

AELOG Summaries

	N	Percent
AE Action Taken	22	3%
AE Action Taken		
Intervention: Surgery or Procedure		
Med Initiation, Change, or Discontinue		
Other		
None	243	28%
AE Outcome	807	93%
Recovered (returned to baseline)		
Recovered with sequelae		
Symptom(s) persist(s)		
Death		
AE Expectedness	505	58%
Expected		
Unexpected	365	42%
AE Intensity	725	83%
Mild		
Moderate		
Severe		
AE Serious	834	96%
No		
Yes	36	4%
MedDRA High Level Group Term	54	6%
Acid-base disorders		
Administration site reactions		
Anal and rectal conditions NEC		
Angioedema and urticaria		
Anxiety disorders and symptoms		
Appetite and general nutritional disorders		
Arteriosclerosis, stenosis, vascular insufficiency and necrosis		
Aural disorders NEC		
Bacterial infectious disorders		
Body temperature conditions		
Bone, calcium, magnesium and phosphorus metabolism disorders		
Bronchial disorders (excl neoplasms)		
Cardiac and vascular investigations (excl enzyme tests)		
Cardiac arrhythmias		
Central nervous system vascular disorders		

(Continued)

AELOG Summaries

	N	Percent
MedDRA High Level Group Term		
Coagulopathies and bleeding diatheses (excl thrombocytopenic)	1	0%
Complications associated with device	2	0%
Decreased and nonspecific blood pressure disorders and shock	6	1%
Deliria (incl confusion)	1	0%
Dental and gingival conditions	3	0%
Diabetic complications	1	0%
Ectoparasitic disorders	2	0%
Electrolyte and fluid balance conditions	86	10%
Endocrine investigations (incl sex hormones)	1	0%
Enzyme investigations NEC	1	0%
Epidermal and dermal conditions	22	3%
Exocrine pancreas conditions	2	0%
Eye disorders NEC	2	0%
Fungal infectious disorders	17	2%
Gastrointestinal haemorrhages NEC	3	0%
Gastrointestinal inflammatory conditions	1	0%
Gastrointestinal investigations	3	0%
Gastrointestinal motility and defaecation conditions	25	3%
Gastrointestinal signs and symptoms	64	7%
General system disorders NEC	23	3%
Glucose metabolism disorders (incl diabetes mellitus)	56	6%
Haematology investigations (incl blood groups)	1	0%
Headaches	100	11%
Hepatic and hepatobiliary disorders	1	0%
Hepatobiliary investigations	1	0%
Immunology and allergy investigations	1	0%
Increased intracranial pressure and hydrocephalus	20	2%
Infections - pathogen unspecified	27	3%
Injuries NEC	1	0%
Joint disorders	2	0%
Lipid metabolism disorders	1	0%
Lower respiratory tract disorders (excl obstruction and infection)	3	0%
Medication errors and other product use errors and issues	1	0%
Metabolic, nutritional and blood gas investigations	12	1%
Microbiology and serology investigations	3	0%
Middle ear disorders (excl congenital)	1	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA High Level Group Term		
Mood disorders and disturbances NEC	5	1%
Muscle disorders	2	0%
Musculoskeletal and connective tissue disorders NEC	19	2%
Neurological disorders NEC	9	1%
Neurological, special senses and psychiatric investigations	6	1%
Ocular infections, irritations and inflammations	2	0%
Oral soft tissue conditions	5	1%
Pleural disorders	1	0%
Procedural related injuries and complications NEC	1	0%
Psychiatric disorders NEC	21	2%
Renal and urinary tract investigations and urinalyses	6	1%
Renal disorders (excl nephropathies)	1	0%
Respiratory disorders NEC	10	1%
Respiratory tract signs and symptoms	41	5%
Seizures (incl subtypes)	1	0%
Sleep disorders and disturbances	1	0%
Spleen, lymphatic and reticuloendothelial system disorders	1	0%
Suicidal and self-injurious behaviours NEC	2	0%
Thyroid gland disorders	1	0%
Tongue conditions	3	0%
Upper respiratory tract disorders (excl infections)	9	1%
Urinary tract signs and symptoms	3	0%
Vascular disorders NEC	1	0%
Vascular hypertensive disorders	6	1%
Vascular inflammations	1	0%
Viral infectious disorders	1	0%
Vision disorders	5	1%
Vulvovaginal disorders (excl infections and inflammations)	3	0%
Water, electrolyte and mineral investigations	23	3%
MedDRA High Level Term		
Abdominal findings abnormal	1	0%
Acute and chronic pancreatitis	2	0%
Anal and rectal pains	1	0%
Angioedemas	1	0%
Anxiety symptoms	3	0%
Appetite disorders	1	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA High Level Term		
Bacteria identification and serology (excl mycobacteria)	2	0%
Bacterial infections NEC	3	0%
Bladder and urethral symptoms	2	0%
Body temperature altered	1	0%
Breathing abnormalities	2	0%
Bronchospasm and obstruction	2	0%
Calcium metabolism disorders	2	0%
Candida infections	13	1%
Carbohydrate tolerance analyses (incl diabetes)	11	1%
Cardiac auscultatory investigations	1	0%
Cardiovascular injuries	1	0%
Central nervous system haemorrhages and cerebrovascular accidents	1	0%
Chloride imbalance	7	1%
Circulatory collapse and shock	1	0%
Clostridia infections	1	0%
Coagulopathies	1	0%
Complications associated with device NEC	2	0%
Conditions associated with abnormal gas exchange	1	0%
Confusion and disorientation	1	0%
Coughing and associated symptoms	7	1%
Dental and oral soft tissue infections	1	0%
Dental pain and sensation disorders	2	0%
Dermal and epidermal conditions NEC	3	0%
Diabetic complications NEC	1	0%
Diarrhoea (excl infective)	2	0%
Digestive enzymes	3	0%
Disturbances in consciousness NEC	2	0%
Disturbances in initiating and maintaining sleep	1	0%
Dyspeptic signs and symptoms	6	1%
ECG investigations	2	0%
Ear disorders NEC	3	0%
Ear infections	3	0%
Ectoparasitic infestations	2	0%
Elevated triglycerides	1	0%
Emotional and mood disturbances NEC	5	1%
Febrile disorders	37	4%

(Continued)

AELOG Summaries

	N	Percent
MedDRA High Level Term		
Feelings and sensations NEC	3	0%
Female reproductive tract infections	3	0%
Flatulence, bloating and distension	1	0%
Fungal infections NEC	4	0%
Gastrointestinal and abdominal pains (excl oral and throat)	27	3%
Gastrointestinal atonic and hypomotility disorders NEC	23	3%
Gastrointestinal signs and symptoms NEC	2	0%
General signs and symptoms NEC	3	0%
Gingival pains	1	0%
Headaches NEC	100	11%
Hepatobiliary signs and symptoms	1	0%
Hyperglycaemic conditions NEC	4	0%
Hypoglycaemic conditions NEC	52	6%
Immunoglobulin analyses	1	0%
Implant and catheter site reactions	15	2%
Increased intracranial pressure disorders	20	2%
Infections NEC	4	0%
Infusion site reactions	7	1%
Injection site reactions	2	0%
Joint related signs and symptoms	2	0%
Laryngeal spasm, oedema and obstruction	1	0%
Liver function analyses	1	0%
Lower respiratory tract and lung infections	1	0%
Lower respiratory tract inflammatory and immunologic conditions	1	0%
Lymphatic system disorders NEC	1	0%
Magnesium metabolism disorders	4	0%
Medication errors, product use errors and issues NEC	1	0%
Mental disorders NEC	21	2%
Metabolic acidoses (excl diabetic acidoses)	44	5%
Metabolic alkaloses	1	0%
Metabolism tests NEC	1	0%
Middle ear disorders NEC	1	0%
Mineral and electrolyte analyses	22	3%
Mixed acid-base disorders	9	1%
Muscle pains	1	0%
Muscle tone abnormalities	1	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA High Level Term		
Musculoskeletal and connective tissue pain and discomfort	19	2%
Nasal congestion and inflammations	4	0%
Nasal disorders NEC	2	0%
Nausea and vomiting symptoms	27	3%
Neurologic diagnostic procedures	6	1%
Neurological signs and symptoms NEC	6	1%
Non-site specific gastrointestinal haemorrhages	3	0%
Non-site specific procedural complications	1	0%
Ocular disorders NEC	2	0%
Ocular infections, inflammations and associated manifestations	2	0%
Oedema NEC	1	0%
Oesophagitis (excl infective)	1	0%
Oral soft tissue pain and paraesthesia	3	0%
Pain and discomfort NEC	16	2%
Peripheral vascular disorders NEC	1	0%
Peripheral vasoconstriction, necrosis and vascular insufficiency	3	0%
Pharyngeal disorders (excl infections and neoplasms)	2	0%
Phlebitis NEC	1	0%
Phosphorus metabolism disorders	16	2%
Pituitary analyses anterior	1	0%
Pneumothorax and pleural effusions NEC	1	0%
Potassium imbalance	65	7%
Pruritus NEC	6	1%
Pulmonary oedemas	2	0%
Rashes, eruptions and exanthems NEC	12	1%
Rate and rhythm disorders NEC	15	2%
Renal failure and impairment	1	0%
Renal function analyses	1	0%
Seizures and seizure disorders NEC	1	0%
Sepsis, bacteraemia, viraemia and fungaemia NEC	1	0%
Skeletal and cardiac muscle analyses	1	0%
Skin injuries and mechanical dermatoses	1	0%
Sodium imbalance	13	1%
Speech and language abnormalities	1	0%
Stomatitis and ulceration	2	0%
Streptococcal infections	3	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA High Level Term		
Suicidal and self-injurious behaviour	2	0%
Thyroid hypofunction disorders	1	0%
Tongue signs and symptoms	3	0%
Total fluid volume decreased	1	0%
Upper respiratory tract infections	6	1%
Upper respiratory tract signs and symptoms	41	5%
Urinalysis NEC	4	0%
Urinary abnormalities	1	0%
Urinary tract function analyses NEC	1	0%
Urinary tract infections	8	1%
Urticarias	1	0%
Vascular hypertensive disorders NEC	6	1%
Vascular hypotensive disorders	5	1%
Vascular tests NEC (incl blood pressure)	1	0%
Ventricular arrhythmias and cardiac arrest	3	0%
Viral infections NEC	1	0%
Virus identification and serology	1	0%
Visual disorders NEC	5	1%
Vulvovaginal signs and symptoms	3	0%
Water and electrolyte analyses NEC	1	0%
White blood cell analyses	1	0%
MedDRA Lowest Level Term		
Abdominal cramps	2	0%
Abdominal distension	1	0%
Abdominal pain	21	2%
Abdominal tenderness	1	0%
Abscess	1	0%
Acidosis	5	1%
Acidosis aggravated	4	0%
Acute pancreatitis	1	0%
Acute respiratory distress syndrome	1	0%
Agitated	1	0%
Agitation	1	0%
Alkalosis	1	0%
Amylase increased	1	0%
Anxiety	1	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Lowest Level Term		
Aspiration pneumonia	1	0%
BUN decreased	1	0%
Back pain	3	0%
Bacteremia	1	0%
Beta-hydroxybutyric acid increased	1	0%
Blood bicarbonate decreased	3	0%
Blood chloride increased	1	0%
Blood glucose decreased	3	0%
Blood glucose increased	1	0%
Blood phosphate decreased	2	0%
Blood pressure increased	1	0%
Blood sodium decreased	2	0%
Blood sodium increased	1	0%
Bloodshot eye	1	0%
Blurred vision	1	0%
Blurry vision	4	0%
Bowel sounds decreased	1	0%
Bradycardia	5	1%
Breathlessness	1	0%
Burning in throat	1	0%
CPK decreased	1	0%
Candida rash	2	0%
Candidal infection NOS	1	0%
Candidiasis	2	0%
Candidiasis of mouth	1	0%
Candidiasis of vulva and vagina	1	0%
Cardiac arrest	1	0%
Cardiac murmur	1	0%
Catheter related complication	1	0%
Catheter site irritation	6	1%
Catheter site pain	9	1%
Cellulitis	1	0%
Cellulitis of leg	1	0%
Central line complication	1	0%
Cerebral edema	20	2%
Cerebral infarct	1	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Lowest Level Term		
Chest pain	9	1%
Chest tightness	2	0%
Chills	2	0%
Clostridium difficile colitis	1	0%
Coagulopathy	1	0%
Cold extremities	1	0%
Confusion	1	0%
Congestion nasal	1	0%
Constipation	20	2%
Cough	7	1%
Decreased blood sugar	2	0%
Decubitus ulcer	1	0%
Dehydration	1	0%
Diabetic ketoacidosis	1	0%
Diarrhea	2	0%
Dizziness	6	1%
Dry skin	1	0%
Dyspepsia	1	0%
Ear pain	3	0%
Edema hands	1	0%
Electrocardiogram QTc interval prolonged	1	0%
Electrocardiogram T wave peaked	1	0%
Emesis	2	0%
Epigastric pain	2	0%
Epistaxis	1	0%
Erythematous rash	1	0%
Esophageal discomfort	1	0%
Esophagitis	1	0%
Eye irritation	1	0%
Eye pain	2	0%
Facial pain	1	0%
Fever	37	4%
Flushed face	1	0%
Frontal headache	1	0%
Gastroesophageal reflux	3	0%
General body pain	2	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Lowest Level Term		
Glasgow coma scale abnormal	6	1%
Glucose decreased	3	0%
Glucose low	2	0%
Group A beta hemolytic Streptococcus positive	1	0%
Gum pain	1	0%
Hand pain	4	0%
Hand swelling	1	0%
Head lice	2	0%
Headache	96	11%
Headache aggravated	2	0%
Heart injury	1	0%
Heartburn	5	1%
Hematemesis	2	0%
Hematochezia	1	0%
Hematuria	1	0%
Hepatomegaly	1	0%
Hyperchloremia	7	1%
Hyperchloremic acidosis	44	5%
Hyperglycemia	4	0%
Hyperkalemia	17	2%
Hypernatremia	4	0%
Hyperphosphatemia	1	0%
Hypertension	6	1%
Hypertriglyceridemia	1	0%
Hypocalcemia	2	0%
Hypoglycemia	48	6%
Hypoglycemic episode	4	0%
Hypokalemia	48	6%
Hypomagnesemia	4	0%
Hyponatremia	9	1%
Hypophosphatemia	15	2%
Hypotension	3	0%
Hypothermia	1	0%
Hypothyroidism	1	0%
Hypovolemic shock	1	0%
Hypoxia	1	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Lowest Level Term		
IgA increased	1	0%
Inconsolable crying	1	0%
Incontinence	1	0%
Increased TSH	1	0%
Infection	1	0%
Influenza A virus test positive	1	0%
Infusion site burning	1	0%
Infusion site extravasation	2	0%
Infusion site infiltration	2	0%
Infusion site pain	1	0%
Infusion site tenderness	1	0%
Injection site pain	1	0%
Insomnia	1	0%
Intermittent headache	1	0%
Irritability	4	0%
Irritable	1	0%
Itching	3	0%
Itchy rash	1	0%
Jaw spasm	1	0%
Junctional rhythm	1	0%
Knee pain	1	0%
Leg pain	1	0%
Lipase increased	2	0%
Low blood pressure	1	0%
Lower abdominal pain	1	0%
Lymphadenopathy	1	0%
Magnesium low	3	0%
Medication error	1	0%
Mental status changes	21	2%
Metapneumovirus infection	1	0%
Middle ear effusion	1	0%
Mouth pain	3	0%
Muscle ache	1	0%
Nasal congestion	3	0%
Nausea	14	2%
Nausea aggravated	1	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Lowest Level Term		
Neck pain	1	0%
Nose bleeds	1	0%
Oral candida	1	0%
Oral intake reduced	1	0%
Oral thrush	2	0%
Oral ulceration	1	0%
Osmolality decreased	1	0%
Otitis media	3	0%
Pain	2	0%
Pain in hand	1	0%
Pain injection site	1	0%
Painful L arm	1	0%
Painful arm	4	0%
Pancreatitis	1	0%
Periorbital cellulitis	1	0%
Pharyngitis	4	0%
Pharyngitis streptococcal	1	0%
Pharynx redness of	1	0%
Phlebitis	1	0%
Phosphate low	2	0%
Pneumonia	1	0%
Pneumothorax	1	0%
Poor peripheral perfusion	2	0%
Postoperative hemorrhage	1	0%
Postural hypotension	1	0%
Potassium increased	1	0%
Potassium low	6	1%
Premature ventricular contractions	2	0%
Pruritis	1	0%
Pruritus	1	0%
Pulmonary edema	1	0%
Pyuria	2	0%
Raised liver function tests	1	0%
Rash	10	1%
Rash trunk	1	0%
Rectal pain	1	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Lowest Level Term		
Red throat	1	0%
Renal injury	1	0%
Rhinorrhea	1	0%
Rib pain	2	0%
Seizures	1	0%
Shivering	1	0%
Shoulder pain	1	0%
Sinusitis	1	0%
Skin breakdown	1	0%
Skin candida	1	0%
Skin warm	1	0%
Slurred speech	1	0%
Sodium low	1	0%
Somnolence	1	0%
Sore throat	27	3%
Sore tongue	1	0%
Sores mouth	1	0%
Streptococcal pharyngitis	1	0%
Streptococcal sore throat	1	0%
Streptococcus identification test positive	1	0%
Stridor	1	0%
Suicidal ideation	2	0%
Swallowing difficult	1	0%
Swelling of face	1	0%
Swelling of fingers	1	0%
Syncope	1	0%
Tachycardia	8	1%
Tachypnea	1	0%
Throat pain	12	1%
Tongue pain	2	0%
Tooth infection	1	0%
Tooth pain	2	0%
UTI	1	0%
Upper back pain	1	0%
Upper respiratory infection	1	0%
Urethritis	1	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Lowest Level Term		
Urinary casts	2	0%
Urinary incontinence	1	0%
Urinary tract infection	6	1%
Urine analysis abnormal	1	0%
Urine candida	1	0%
Urine output decreased	1	0%
Urine uric acid crystals present	1	0%
Urticaria	1	0%
Vaginal discharge	2	0%
Vaginal itching	1	0%
Vaginal yeast infection	2	0%
Vaginitis	2	0%
Vomiting	10	1%
Vulvovaginal candida	1	0%
Vulvovaginitis	1	0%
WBC increased	1	0%
Wheezing	2	0%
Wide complex tachycardia	1	0%
Wrist pain	1	0%
Yeast infection	2	0%
MedDRA Preferred Term		
Abdominal distension	1	0%
Abdominal pain	23	3%
Abdominal pain lower	1	0%
Abdominal pain upper	2	0%
Abdominal tenderness	1	0%
Abscess	1	0%
Acidosis	9	1%
Acidosis hyperchloraemic	44	5%
Acute respiratory distress syndrome	1	0%
Agitation	2	0%
Alkalosis	1	0%
Amylase increased	1	0%
Anxiety	1	0%
Arthralgia	2	0%
Back pain	4	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Preferred Term		
Bacteraemia	1	0%
Blood bicarbonate decreased	3	0%
Blood chloride increased	1	0%
Blood creatine phosphokinase decreased	1	0%
Blood glucose decreased	10	1%
Blood glucose increased	1	0%
Blood immunoglobulin A increased	1	0%
Blood ketone body increased	1	0%
Blood magnesium decreased	3	0%
Blood osmolarity decreased	1	0%
Blood phosphorus decreased	4	0%
Blood potassium decreased	6	1%
Blood potassium increased	1	0%
Blood pressure increased	1	0%
Blood sodium decreased	3	0%
Blood sodium increased	1	0%
Blood thyroid stimulating hormone increased	1	0%
Blood urea decreased	1	0%
Bradycardia	5	1%
Brain oedema	20	2%
Candida infection	3	0%
Candiduria	1	0%
Cardiac arrest	1	0%
Cardiac murmur	1	0%
Catheter site inflammation	6	1%
Catheter site pain	9	1%
Cellulitis	2	0%
Cerebral infarction	1	0%
Chest discomfort	2	0%
Chest pain	9	1%
Chills	3	0%
Clostridium difficile colitis	1	0%
Coagulopathy	1	0%
Coma scale abnormal	6	1%
Complication associated with device	2	0%
Confusional state	1	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Preferred Term		
Constipation	20	2%
Cough	7	1%
Crying	1	0%
Crystal urine present	1	0%
Decubitus ulcer	1	0%
Dehydration	1	0%
Diabetic ketoacidosis	1	0%
Diarrhoea	2	0%
Dizziness	6	1%
Dry skin	1	0%
Dysarthria	1	0%
Dyspepsia	6	1%
Dysphagia	1	0%
Dyspnoea	1	0%
Ear pain	3	0%
Electrocardiogram QT prolonged	1	0%
Electrocardiogram T wave peaked	1	0%
Epistaxis	2	0%
Eye irritation	1	0%
Eye pain	2	0%
Facial pain	1	0%
Flushing	1	0%
Fungal infection	2	0%
Gastrointestinal sounds abnormal	1	0%
Gastrooesophageal reflux disease	3	0%
Gingival pain	1	0%
Glossodynia	3	0%
Haematemesis	2	0%
Haematochezia	1	0%
Haematuria	1	0%
Headache	100	11%
Heart injury	1	0%
Hepatomegaly	1	0%
Hyperchloraemia	7	1%
Hyperglycaemia	4	0%
Hyperkalaemia	17	2%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Preferred Term		
Hypernatraemia	4	0%
Hyperphosphataemia	1	0%
Hypertension	6	1%
Hypertriglyceridaemia	1	0%
Hypocalcaemia	2	0%
Hypoglycaemia	52	6%
Hypokalaemia	48	6%
Hypomagnesaemia	4	0%
Hyponatraemia	9	1%
Hypophagia	1	0%
Hypophosphataemia	15	2%
Hypotension	4	0%
Hypothermia	1	0%
Hypothyroidism	1	0%
Hypovolaemic shock	1	0%
Hypoxia	1	0%
Incontinence	1	0%
Infection	1	0%
Influenza A virus test positive	1	0%
Infusion site extravasation	4	0%
Infusion site pain	3	0%
Injection site pain	2	0%
Insomnia	1	0%
Irritability	5	1%
Lice infestation	2	0%
Lipase increased	2	0%
Liver function test increased	1	0%
Lymphadenopathy	1	0%
Medication error	1	0%
Mental status changes	21	2%
Metapneumovirus infection	1	0%
Middle ear effusion	1	0%
Mouth ulceration	1	0%
Musculoskeletal chest pain	2	0%
Musculoskeletal pain	1	0%
Myalgia	1	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Preferred Term		
Nasal congestion	4	0%
Nausea	15	2%
Neck pain	1	0%
Nodal rhythm	1	0%
Ocular hyperaemia	1	0%
Oedema peripheral	1	0%
Oesophageal discomfort	1	0%
Oesophagitis	1	0%
Oral candidiasis	4	0%
Oral pain	3	0%
Oropharyngeal pain	39	4%
Orthostatic hypotension	1	0%
Otitis media	3	0%
Pain	4	0%
Pain in extremity	11	1%
Pancreatitis	1	0%
Pancreatitis acute	1	0%
Periorbital cellulitis	1	0%
Peripheral coldness	1	0%
Peripheral swelling	2	0%
Pharyngeal erythema	2	0%
Pharyngitis	4	0%
Pharyngitis streptococcal	3	0%
Phlebitis	1	0%
Pneumonia	1	0%
Pneumonia aspiration	1	0%
Pneumothorax	1	0%
Poor peripheral circulation	2	0%
Post procedural haemorrhage	1	0%
Proctalgia	1	0%
Pruritus	5	1%
Pulmonary oedema	1	0%
Pyrexia	37	4%
Pyuria	2	0%
Rash	11	1%
Rash erythematous	1	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Preferred Term		
Rash pruritic	1	0%
Renal injury	1	0%
Rhinorrhoea	1	0%
Seizure	1	0%
Sinusitis	1	0%
Skin candida	3	0%
Skin disorder	1	0%
Skin warm	1	0%
Somnolence	1	0%
Stomatitis	1	0%
Streptococcus test positive	2	0%
Stridor	1	0%
Suicidal ideation	2	0%
Swelling face	1	0%
Syncope	1	0%
Tachycardia	9	1%
Tachypnoea	1	0%
Throat irritation	1	0%
Tooth infection	1	0%
Toothache	2	0%
Trismus	1	0%
Upper respiratory tract infection	1	0%
Urethritis	1	0%
Urinary casts	2	0%
Urinary incontinence	1	0%
Urinary tract infection	7	1%
Urine analysis abnormal	1	0%
Urine output decreased	1	0%
Urticaria	1	0%
Vaginal discharge	2	0%
Vaginal infection	2	0%
Ventricular extrasystoles	2	0%
Vision blurred	5	1%
Vomiting	12	1%
Vulvovaginal candidiasis	2	0%
Vulvovaginal mycotic infection	2	0%

(Continued)

AELOG Summaries

	N	Percent
MedDRA Preferred Term		
Vulvovaginal pruritus	1	0%
Vulvovaginitis	1	0%
Wheezing	2	0%
White blood cell count increased	1	0%
MedDRA System Organ Class		
Blood and lymphatic system disorders	2	0%
Cardiac disorders	18	2%
Ear and labyrinth disorders	4	0%
Endocrine disorders	1	0%
Eye disorders	9	1%
Gastrointestinal disorders	107	12%
General disorders and administration site conditions	87	10%
Hepatobiliary disorders	1	0%
Infections and infestations	54	6%
Injury, poisoning and procedural complications	3	0%
Investigations	62	7%
Metabolism and nutrition disorders	221	25%
Musculoskeletal and connective tissue disorders	23	3%
Nervous system disorders	131	15%
Psychiatric disorders	33	4%
Renal and urinary disorders	4	0%
Reproductive system and breast disorders	3	0%
Respiratory, thoracic and mediastinal disorders	66	8%
Skin and subcutaneous tissue disorders	24	3%
Vascular disorders	17	2%

AELOG Summaries

	N	Min	Max	Mean	SD	Q1	Med	Q3
MedDRA Lowest Level Term ID Number	870	10000057	10070215	10025807	15,645	10017924	10021005	10037844
AE End Day (relative to randomization)	831	0	33	2	2	1	1	2
AE Start Day (relative to randomization)	870	0	20	1	2	0	1	1