

Un-coded Adverse Events at Database Lock

At database lock (21.05.2019), some adverse events remained uncoded. This was due to unanswered queries that were raised to request information that would assist with medical coding of adverse events using MedDRA. As these coding queries were not resolved, the corresponding adverse events were not coded. The queries were generated for the following reasons:

- Further clarification of the event(s) was required in order to code the terms accurately.
- More than one adverse event was recorded in a single datapoint (row) and there was no suitable match in the MedDRA dictionary to capture a combination of the events.

Below is a list of the adverse events which were not be coded at the time of database lock.

PATIENT	VERBATIM TERM
0716	SOB AND FLU LIKE SYMPTOMS
0582	LETHARGY, TIREDNESS
0061	VASOVAGAL
0061	REFLUX
0137	HEAD ACHE AND COLD LIKE SYMPTOMS
0743	FACIAL FLUSHING WITH SWELLING
0130	NEUROLOGY, OTHER, FELT WOBBLY, NO LOSS OF CONSCIOUSNESS OR COLLAPSE. EXCESSIVE CAFFEINE CONSUMPTION AND WITHDRAWAL
0222	ABDOMINAL PAIN AND BLOATING
0556	FEVER AND RIGORS
0385	LIBIDO
0334	CONSTITUTIONAL – OTHER SENSITIVE TEETH AND GUMS
0334	ABDOMINAL PAIN AND DIARRHOEA
0563	DYSPNEA ON EXERTION CHEST INFECTION
0092	NAUSEA/TRAPPED WIND OCCASSIONAL
0176	PYOGENIC GRANULOMA/ HAEMANGIOMA
0176	HEADACHES AND TIREDNESS
0687	DRY/ITCHY EYES
0086	ANXIETY / ANGER
0303	COMMON COLD AND SORE THROAT
0610	REFLUX
0103	PAROTID LUMP
0316	SPLIT CONDOM - UNPROTECTIVE SEX
0533	ACHING LEGS (DULL) WITH PINS AND NEEDLES ON TOES (SHARP)
0521	ABDO PAIN AND CRAMPS
0315	SUSPICIOUS LEFT SUBMANDIBULAR GLAND.
0460	ATTENDED ACCIDENT AND EMERGENCY DEPT. WITH PROFUSE VOMITING AND DISTENSION,? STOMA NOT WORKING,? BOWEL OBSTRUCTION RESOLVED?
0142	PAIN IN AXILLAE AND RIGHT SIDE OF BREAST
0183	REFLUX
0767	OEDEMA OF EYES AND SCALP
0062	HYPERGLYCAEMIA/TYPE 2 DIABESTES
0650	ELEVATED AST ELEVATED LDH
0792	PAIN DOWN BOTH AXILLAE AND BREASTS
0309	GRADE 2 PLATELETS
0814	RED, DRY EYES
0168	COLD AND SORE THROAT
0378	EXCESSIVE MUCUS PRODUCTION
0054	COLLAPSE SECONDARY TO POSSIBLE ARRHYTHMIA, POSSIBLE SEIZURE.
0462	PLATELETS
0298	ACUTE CARDIAC EVENT
0439	FLAP TEAR OF THE BODY OF THE LATERAL MENISCUS AND FOCAL CHONDROPATHY OF THE FEMORAL END (KNEE)
0367	JOINT PAIN AND SWELLING
0292	SWELLING AND RASH BOTH LOWER LEGS.
0631	PAINFUL TEETH AND GUMS

0797	ACUTE CORONARY EVENT
0732	EPISODE OF COLLAPSE WITH ASSOCIATED HEADACHE: SAE
0190	GASTRO-TINTESTINAL-OTHER, LEFT UPPER GASTRIC DISCOMFORT WITH SOME NAUSEA
0424	TOOTH PAIN & INFECTION
0424	SWOLLEN GLANDS/ SORE THROAT
0461	RAISED CREATINE
0167	COMBINED GERM CELL TUMOUR SEMINOMA AND MALIGNANT TERATOMA
0120	PLATLETS GRADE 2
0120	PLATLETS GRADE 4
0011	PAIN -LOWER BACK AND LEFT HIP
0541	PERIANAL SPOTS/PAIN
0541	ANAL FISTULA/ PERIANAL ABSCESES
0296	PATIENT C/O URGENCY, RIGORS AND DYSURIA
0296	ABDOMINAL PAIN & DIARRHOEA C DIFF CULTURE ISOLATED IN STOOL
0296	ABDOMINAL PAIN & CRAMPING
0257	LEFT LEG OEDEMA AND PAIN
0605	REFLUX
0417	L3/L4 DISC PROLAPSE/ NERVE ROOT COMPRESSION AND ASSOCIATED POST LATERAL SPINAL CANAL STENOSIS
0349	PAIN LEFT CHEST AND DORSAL SPINE
0560	GASTRITIS/ENTEROCOLITIS
0029	RIGHT SHOULDER/GASTRIC PAIN
0696	ABDOMINAL PAIN/CRAMPING
0722	CORNEAL EROSION SECONDARY TO RIGHT LOWER EYELID ENTROPION
0720	AGITATION -MOOD SWINGS
0206	SORE THROAT/COUGH
0206	HEADACHE, DIZZINESS, AND ASSOCIATED MUSCLE SPASM