Supplementary Table S2 The comprehensive detailed information of all AEs at the PTs level identified by ROR algorithms.

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| Preferred Terms | SOC | Case Number | ROR\_95 (95% two side CI) |
| heterochromia iridis | Eye disorders | 7 | 2710.62 (1080.27-6801.52) |
| choroidal dystrophy | Eye disorders | 9 | 1619.79 (763.31-3437.27) |
| iris atrophy | Eye disorders | 15 | 824.25 (476.67-1425.26) |
| enophthalmos | Eye disorders | 8 | 774.87 (367.59-1633.41) |
| alveolar soft part sarcoma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 4 | 744.6 (260.29-2130.04) |
| chorioretinal atrophy | Eye disorders | 15 | 522.97 (306.74-891.62) |
| brain stem glioma | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 5 | 386.82 (155.59-961.7) |
| arteriosclerotic retinopathy | Vascular disorders | 3 | 327.61 (101.8-1054.29) |
| proteus test positive | Investigations | 4 | 314.12 (114.28-863.47) |
| nephroblastoma | Renal and urinary disorders | 3 | 221.62 (69.67-704.95) |
| febrile bone marrow aplasia | General disorders and administration site conditions | 30 | 187.8 (130.08-271.12) |
| iris adhesions | Eye disorders | 7 | 171.06 (80.43-363.81) |
| lenticular opacities | Eye disorders | 6 | 168.65 (74.67-380.89) |
| chorioretinal disorder | Eye disorders | 3 | 132.19 (41.97-416.36) |
| cerebral cyst | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 8 | 117.13 (58.02-236.44) |
| ocular toxicity | Eye disorders | 7 | 103.03 (48.68-218.06) |
| cataract subcapsular | Eye disorders | 5 | 99.77 (41.12-242.07) |
| intracranial tumour haemorrhage | Nervous system disorders | 3 | 97.86 (31.19-307.04) |
| neuroblastoma | Endocrine disorders | 3 | 96.6 (30.79-303.06) |
| small cell lung cancer stage unspecified | Respiratory, thoracic and mediastinal disorders | 12 | 81.84 (46.18-145.03) |
| acute interstitial pneumonitis | Respiratory, thoracic and mediastinal disorders | 3 | 81.02 (25.87-253.74) |
| vitreous haemorrhage | Eye disorders | 18 | 73.73 (46.2-117.68) |
| monocyte count decreased | Investigations | 5 | 71.22 (29.43-172.38) |
| bone marrow depression | Blood and lymphatic system disorders | 8 | 71.19 (35.37-143.25) |
| scleritis | Immune system disorders | 7 | 65.5 (31.03-138.23) |
| acute febrile neutrophilic dermatosis | Skin and subcutaneous tissue disorders | 12 | 61.86 (34.95-109.5) |
| malignant ascites | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 3 | 54.01 (17.3-168.65) |
| subileus | Gastrointestinal disorders | 7 | 50.92 (24.15-107.36) |
| retinal ischaemia | Eye disorders | 3 | 47.54 (15.24-148.32) |
| conjunctival oedema | Eye disorders | 4 | 43.8 (16.35-117.32) |
| white blood cells urine positive | Investigations | 4 | 43.42 (16.21-116.3) |
| thrombocythaemia | Blood and lymphatic system disorders | 3 | 43.18 (13.85-134.66) |
| protein total decreased | Investigations | 10 | 41.42 (22.2-77.31) |
| autonomic neuropathy | Nervous system disorders | 3 | 41.06 (13.17-128.02) |
| neutrophil count decreased | Investigations | 103 | 41.41 (33.92-50.54) |
| platelet transfusion | Surgical and medical procedures | 3 | 39.14 (12.56-122.01) |
| ovarian cancer metastatic | Reproductive system and breast disorders | 3 | 37.49 (12.03-116.83) |
| haematotoxicity | Blood and lymphatic system disorders | 23 | 37 (24.49-55.9) |
| red blood cell count decreased | Investigations | 62 | 34.68 (26.9-44.7) |
| ocular vascular disorder | Eye disorders | 3 | 33.12 (10.63-103.17) |
| blood phosphorus increased | Investigations | 5 | 29.75 (12.34-71.75) |
| vith nerve paralysis | Nervous system disorders | 3 | 27.8 (8.93-86.56) |
| hypoproteinaemia | Hepatobiliary disorders | 3 | 26.96 (8.66-83.91) |
| blood chloride decreased | Investigations | 5 | 26.08 (10.82-62.87) |
| ileus | Gastrointestinal disorders | 22 | 24.61 (16.14-37.5) |
| packed red blood cell transfusion | Surgical and medical procedures | 3 | 22.29 (7.17-69.35) |
| carbohydrate antigen 125 increased | Investigations | 6 | 21.44 (9.6-47.86) |
| blood culture positive | Investigations | 6 | 20.87 (9.35-46.6) |
| neutropenic sepsis | Blood and lymphatic system disorders | 12 | 20.73 (11.74-36.61) |
| radiation pneumonitis | Respiratory, thoracic and mediastinal disorders | 3 | 20.36 (6.55-63.34) |
| conjunctival hyperaemia | Eye disorders | 6 | 20.3 (9.09-45.31) |
| retinopathy | Vascular disorders | 7 | 20.31 (9.65-42.72) |
| metastases to meninges | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 3 | 20.15 (6.48-62.66) |
| hospice care | Surgical and medical procedures | 13 | 19.88 (11.51-34.33) |
| aspergillosis | Infections and infestations | 3 | 18.02 (5.8-56.05) |
| hydronephrosis | Renal and urinary disorders | 10 | 17.84 (9.57-33.24) |
| large intestine perforation | Injury, poisoning and procedural complications | 9 | 16.81 (8.72-32.38) |
| renal tubular disorder | Renal and urinary disorders | 4 | 16.46 (6.16-43.98) |
| pulmonary toxicity | Respiratory, thoracic and mediastinal disorders | 8 | 16.13 (8.05-32.34) |
| white blood cell count decreased | Investigations | 127 | 17.13 (14.3-20.51) |
| conjunctival haemorrhage | Eye disorders | 6 | 16.01 (7.17-35.73) |
| febrile neutropenia | General disorders and administration site conditions | 63 | 16.3 (12.67-20.95) |
| cardiac dysfunction | Cardiac disorders | 3 | 15.63 (5.03-48.6) |
| metastases to central nervous system | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 15 | 15.71 (9.44-26.13) |
| cerebellar syndrome | Nervous system disorders | 3 | 15.58 (5.01-48.45) |
| venous thrombosis | Vascular disorders | 5 | 14.99 (6.22-36.1) |
| rash vesicular | Skin and subcutaneous tissue disorders | 5 | 14.73 (6.12-35.47) |
| platelet count decreased | Investigations | 113 | 15.49 (12.8-18.73) |
| protein urine present | Investigations | 5 | 14.46 (6.01-34.84) |
| pyelonephritis | Renal and urinary disorders | 8 | 13.67 (6.82-27.4) |
| anaemia | Blood and lymphatic system disorders | 187 | 14.79 (12.71-17.2) |
| pulmonary haemorrhage | Vascular disorders | 9 | 13.25 (6.88-25.52) |
| disease progression | General disorders and administration site conditions | 123 | 13.73 (11.43-16.48) |
| pancytopenia | Blood and lymphatic system disorders | 50 | 12.76 (9.63-16.9) |
| performance status decreased | General disorders and administration site conditions | 5 | 12.48 (5.18-30.04) |
| blood test abnormal | Investigations | 12 | 12.51 (7.09-22.08) |
| thrombocytopenia | Blood and lymphatic system disorders | 101 | 13 (10.64-15.89) |
| blood lactic acid increased | Investigations | 5 | 12.24 (5.08-29.48) |
| orthopnoea | Respiratory, thoracic and mediastinal disorders | 3 | 12.22 (3.93-37.98) |
| hypomagnesaemia | Metabolism and nutrition disorders | 12 | 12.26 (6.94-21.64) |
| hyperammonaemia | Hepatobiliary disorders | 5 | 11.87 (4.93-28.59) |
| bone marrow disorder | Blood and lymphatic system disorders | 3 | 11.77 (3.79-36.58) |
| deafness neurosensory | Nervous system disorders | 3 | 11.59 (3.73-36.02) |
| optic ischaemic neuropathy | Eye disorders | 3 | 11.33 (3.65-35.2) |
| escherichia infection | Infections and infestations | 6 | 11.13 (4.99-24.82) |
| posterior reversible encephalopathy syndrome | Nervous system disorders | 8 | 10.74 (5.36-21.52) |
| blood urea increased | Investigations | 14 | 10.48 (6.19-17.75) |
| hepatic lesion | Hepatobiliary disorders | 3 | 9.87 (3.18-30.68) |
| papule | Skin and subcutaneous tissue disorders | 4 | 9.88 (3.7-26.37) |
| mucosal inflammation | General disorders and administration site conditions | 18 | 9.89 (6.22-15.74) |
| gastrointestinal toxicity | Gastrointestinal disorders | 3 | 9.71 (3.13-30.18) |
| neutropenia | Blood and lymphatic system disorders | 86 | 9.98 (8.04-12.39) |
| leukopenia | Blood and lymphatic system disorders | 34 | 9.39 (6.69-13.19) |
| recurrent cancer | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 3 | 9.22 (2.97-28.63) |
| lymphopenia | Blood and lymphatic system disorders | 9 | 9.15 (4.75-17.63) |
| blood albumin decreased | Investigations | 5 | 9.01 (3.74-21.7) |
| ileus paralytic | Gastrointestinal disorders | 3 | 8.81 (2.84-27.37) |
| failure to thrive | Pregnancy, puerperium and perinatal conditions | 4 | 8.66 (3.24-23.12) |
| periorbital oedema | Immune system disorders | 4 | 8.49 (3.18-22.68) |
| oesophageal pain | Gastrointestinal disorders | 3 | 8.42 (2.71-26.15) |
| blood creatine increased | Investigations | 3 | 8.15 (2.62-25.33) |
| ascites | Cardiac disorders | 18 | 8.12 (5.1-12.92) |
| gastrointestinal perforation | Gastrointestinal disorders | 3 | 8.04 (2.59-24.97) |
| metastatic neoplasm | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 3 | 7.91 (2.55-24.57) |
| neoplasm progression | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 24 | 7.98 (5.33-11.94) |
| malignant neoplasm progression | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 57 | 7.88 (6.05-10.26) |
| blood lactate dehydrogenase increased | Investigations | 9 | 7.63 (3.96-14.7) |
| blood magnesium decreased | Investigations | 4 | 7.59 (2.85-20.27) |
| hypotonia | Nervous system disorders | 7 | 7.36 (3.5-15.47) |
| atelectasis | Respiratory, thoracic and mediastinal disorders | 5 | 7.28 (3.03-17.53) |
| haemodialysis | Surgical and medical procedures | 7 | 7.17 (3.41-15.07) |
| ovarian cancer | Reproductive system and breast disorders | 7 | 6.93 (3.3-14.57) |
| full blood count decreased | Investigations | 9 | 6.92 (3.59-13.32) |
| drug toxicity | Injury, poisoning and procedural complications | 13 | 6.93 (4.01-11.95) |
| haemoglobin decreased | Investigations | 50 | 6.82 (5.15-9.03) |
| interstitial lung disease | Immune system disorders | 22 | 6.53 (4.29-9.95) |
| metastases to bone | Musculoskeletal and connective tissue disorders | 7 | 6.45 (3.07-13.55) |
| haematocrit decreased | Investigations | 10 | 6.43 (3.45-11.98) |
| hypoalbuminaemia | Hepatobiliary disorders | 3 | 6.38 (2.05-19.81) |
| ischaemia | Vascular disorders | 3 | 6.36 (2.05-19.75) |
| blood sodium decreased | Investigations | 9 | 6.37 (3.31-12.27) |
| cholestasis | Hepatobiliary disorders | 8 | 6.36 (3.18-12.75) |
| septic shock | Vascular disorders | 18 | 6.36 (4-10.12) |
| pleural effusion | Respiratory, thoracic and mediastinal disorders | 29 | 6.25 (4.33-9.02) |
| platelet count increased | Investigations | 6 | 6.17 (2.77-13.76) |
| hydrocephalus | Nervous system disorders | 3 | 6.14 (1.98-19.07) |
| lipase increased | Investigations | 4 | 6.12 (2.29-16.32) |
| diarrhoea haemorrhagic | Gastrointestinal disorders | 4 | 6.06 (2.27-16.16) |
| hypoxia | Respiratory, thoracic and mediastinal disorders | 15 | 6.06 (3.64-10.07) |
| small intestinal obstruction | Gastrointestinal disorders | 5 | 6.02 (2.5-14.49) |
| bone marrow failure | Blood and lymphatic system disorders | 12 | 6.04 (3.42-10.65) |
| tachypnoea | Respiratory, thoracic and mediastinal disorders | 6 | 5.85 (2.62-13.04) |
| necrosis | General disorders and administration site conditions | 3 | 5.83 (1.88-18.11) |
| general physical health deterioration | General disorders and administration site conditions | 43 | 5.86 (4.33-7.93) |
| flank pain | General disorders and administration site conditions | 4 | 5.71 (2.14-15.25) |
| encephalitis | Infections and infestations | 3 | 5.62 (1.81-17.44) |
| acute respiratory distress syndrome | Immune system disorders | 8 | 5.61 (2.8-11.23) |
| dehydration | Metabolism and nutrition disorders | 54 | 5.7 (4.34-7.47) |
| hyponatraemia | Metabolism and nutrition disorders | 24 | 5.55 (3.71-8.31) |
| cyst | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 5 | 5.47 (2.27-13.16) |
| acute myeloid leukaemia | Blood and lymphatic system disorders | 7 | 5.45 (2.59-11.45) |
| eyelid oedema | Immune system disorders | 6 | 5.4 (2.42-12.04) |
| retinal detachment | Injury, poisoning and procedural complications | 4 | 5.32 (1.99-14.2) |
| agranulocytosis | Blood and lymphatic system disorders | 6 | 5.23 (2.35-11.67) |
| conjunctivitis | Eye disorders | 6 | 5.16 (2.31-11.5) |
| petechiae | Blood and lymphatic system disorders | 4 | 5.04 (1.89-13.44) |
| electrolyte imbalance | Metabolism and nutrition disorders | 4 | 4.98 (1.87-13.3) |
| transfusion | Surgical and medical procedures | 4 | 4.83 (1.81-12.88) |
| inappropriate antidiuretic hormone secretion | Metabolism and nutrition disorders | 4 | 4.76 (1.78-12.7) |
| diplopia | Nervous system disorders | 10 | 4.77 (2.56-8.88) |
| rash pustular | Skin and subcutaneous tissue disorders | 3 | 4.75 (1.53-14.74) |
| blood bilirubin increased | Investigations | 11 | 4.75 (2.62-8.59) |
| lymphocyte count decreased | Investigations | 6 | 4.72 (2.12-10.52) |
| blood potassium increased | Investigations | 6 | 4.72 (2.12-10.52) |
| dermatitis | Skin and subcutaneous tissue disorders | 6 | 4.71 (2.11-10.5) |
| anorexia | Metabolism and nutrition disorders | 82 | 4.85 (3.89-6.05) |
| metastases to liver | Hepatobiliary disorders | 6 | 4.68 (2.1-10.44) |
| blood calcium decreased | Investigations | 4 | 4.64 (1.74-12.37) |
| hiccups | Respiratory, thoracic and mediastinal disorders | 3 | 4.59 (1.48-14.26) |
| retinal haemorrhage | Eye disorders | 3 | 4.49 (1.45-13.96) |
| fistula | Musculoskeletal and connective tissue disorders | 3 | 4.43 (1.43-13.77) |
| malnutrition | Metabolism and nutrition disorders | 3 | 4.42 (1.42-13.71) |
| intestinal perforation | Gastrointestinal disorders | 4 | 4.41 (1.65-11.77) |
| c-reactive protein increased | Investigations | 9 | 4.42 (2.29-8.51) |
| second primary malignancy | Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 3 | 4.38 (1.41-13.59) |
| urine output decreased | Investigations | 3 | 4.37 (1.41-13.56) |
| multi-organ failure | General disorders and administration site conditions | 9 | 4.37 (2.27-8.41) |
| pneumothorax | Respiratory, thoracic and mediastinal disorders | 5 | 4.35 (1.81-10.47) |
| mental status changes | Psychiatric disorders | 11 | 4.2 (2.32-7.6) |
| aspartate aminotransferase increased | Investigations | 18 | 4.2 (2.64-6.68) |
| sinus tachycardia | Cardiac disorders | 5 | 4.1 (1.7-9.87) |
| peritonitis | Infections and infestations | 5 | 4.06 (1.69-9.77) |
| polyneuropathy | Nervous system disorders | 3 | 4.03 (1.3-12.51) |
| myelodysplastic syndrome | Blood and lymphatic system disorders | 5 | 3.96 (1.65-9.54) |
| circulatory collapse | Vascular disorders | 6 | 3.88 (1.74-8.65) |
| sepsis | Infections and infestations | 32 | 3.92 (2.76-5.55) |
| respiratory failure | Metabolism and nutrition disorders | 23 | 3.86 (2.56-5.83) |
| blood alkaline phosphatase increased | Investigations | 8 | 3.78 (1.89-7.58) |
| hypokalaemia | Metabolism and nutrition disorders | 12 | 3.76 (2.13-6.63) |
| haematuria | Renal and urinary disorders | 11 | 3.71 (2.05-6.72) |
| sudden death | General disorders and administration site conditions | 4 | 3.7 (1.39-9.88) |
| intestinal obstruction | Gastrointestinal disorders | 9 | 3.67 (1.91-7.07) |
| hepatic failure | Hepatobiliary disorders | 10 | 3.65 (1.96-6.8) |
| blood creatinine increased | Investigations | 19 | 3.64 (2.31-5.71) |
| hypophagia | Metabolism and nutrition disorders | 6 | 3.6 (1.62-8.03) |
| respiratory distress | Respiratory, thoracic and mediastinal disorders | 8 | 3.54 (1.77-7.1) |
| pyrexia | General disorders and administration site conditions | 89 | 3.65 (2.95-4.52) |
| eating disorder | Metabolism and nutrition disorders | 6 | 3.5 (1.57-7.8) |
| alanine aminotransferase increased | Investigations | 17 | 3.38 (2.1-5.46) |
| blood potassium decreased | Investigations | 7 | 3.35 (1.59-7.03) |
| bacterial infection | Infections and infestations | 4 | 3.29 (1.23-8.79) |
| hemiparesis | Nervous system disorders | 5 | 3.29 (1.37-7.91) |
| haematemesis | Gastrointestinal disorders | 7 | 3.27 (1.56-6.88) |
| body temperature increased | Investigations | 5 | 3.21 (1.34-7.73) |
| blood count abnormal | Investigations | 6 | 3.16 (1.42-7.04) |
| renal failure acute | Renal and urinary disorders | 14 | 3.16 (1.87-5.35) |
| product use in unapproved indication | Injury, poisoning and procedural complications | 47 | 3.11 (2.33-4.16) |
| vomiting | Gastrointestinal disorders | 115 | 3.18 (2.63-3.84) |
| cellulitis | Infections and infestations | 11 | 2.94 (1.62-5.31) |
| pneumonitis | Respiratory, thoracic and mediastinal disorders | 5 | 2.84 (1.18-6.83) |
| disorientation | Psychiatric disorders | 10 | 2.79 (1.5-5.2) |
| death | General disorders and administration site conditions | 247 | 3.04 (2.66-3.47) |
| abdominal pain | Gastrointestinal disorders | 47 | 2.75 (2.06-3.68) |
| pneumonia | Respiratory, thoracic and mediastinal disorders | 63 | 2.66 (2.07-3.42) |
| nausea | Gastrointestinal disorders | 169 | 2.76 (2.36-3.23) |
| lethargy | General disorders and administration site conditions | 13 | 2.52 (1.46-4.35) |
| ill-defined disorder | General disorders and administration site conditions | 10 | 2.5 (1.34-4.66) |
| confusional state | Psychiatric disorders | 34 | 2.47 (1.76-3.47) |
| white blood cell count increased | Investigations | 7 | 2.37 (1.13-4.99) |
| pulmonary embolism | Vascular disorders | 22 | 2.37 (1.55-3.6) |
| epistaxis | Vascular disorders | 14 | 2.31 (1.37-3.92) |
| tachycardia | Cardiac disorders | 16 | 2.23 (1.36-3.64) |
| dyspnoea | Respiratory, thoracic and mediastinal disorders | 97 | 2.25 (1.83-2.76) |
| abdominal distension | Gastrointestinal disorders | 17 | 2.2 (1.36-3.55) |
| lung neoplasm malignant | Respiratory, thoracic and mediastinal disorders | 10 | 2.19 (1.18-4.08) |
| asthenia | General disorders and administration site conditions | 61 | 2.18 (1.69-2.82) |
| constipation | Gastrointestinal disorders | 32 | 2.14 (1.51-3.03) |
| therapeutic response decreased | General disorders and administration site conditions | 11 | 2.04 (1.13-3.68) |
| fatigue | General disorders and administration site conditions | 117 | 2.07 (1.72-2.49) |
| renal failure | Renal and urinary disorders | 27 | 2.02 (1.38-2.95) |