

***** List of reported SAE's *****

-> group == arm A

ssoccd SOC code
 aeterm Event term
 affected Subjects affected number
 exposed Subjects exposed number
 occurrences Occurrences all number
 occurrel Occurrences causally related to treatment number
 fatality Fatalities number
 fatalrel Fatalities causally related to treatment number

	ssoccd	aeterm	affected	exposed	occurrences	occurrel	fatality	fatalrel
Blood and lymphatic system disorders	(weakness due to) anemia		1	73	1	1	.	.
Blood and lymphatic system disorders	Anemia		1	73	1	1	.	.
Blood and lymphatic system disorders	Febrile Neutropenia		2	73	2	2	.	.
Blood and lymphatic system disorders	Febrile neutropenia		11	73	17	15	.	.
Blood and lymphatic system disorders	Febrile neutropenia G3		1	73	1	1	.	.
Blood and lymphatic system disorders	Leukocytosis		1	73	1	.	1	.
Blood and lymphatic system disorders	Neutropenic fever		5	73	7	7	.	.
Blood and lymphatic system disorders	Neutropenic fever (second episode)		1	73	1	1	.	.
Blood and lymphatic system disorders	Neutropenic fever (third episode)		1	73	1	1	.	.
Cardiac disorders	Atrial fibrillation		2	73	2	.	.	.
Cardiac disorders	Cardiac decompensation		1	73	1	1	.	.
Cardiac disorders	Cardiac failure		1	73	1	.	.	.
Cardiac disorders	Decompensatio cordis		1	73	1	1	1	1
Cardiac disorders	Heart failure		1	73	1	.	1	.
Eye disorders	Retina detachment		1	73	1	1	.	.
Gastrointestinal disorders	Anal fissure		1	73	1	.	.	.
Gastrointestinal disorders	Constipation		1	73	1	1	.	.
Gastrointestinal disorders	Diarrhea with blood		1	73	1	.	.	.
Gastrointestinal disorders	Nausea		1	73	1	1	.	.
Gastrointestinal disorders	Rectal hemorrhage		1	73	1	.	.	.
Gastrointestinal disorders	Stomatitis		1	73	1	1	.	.
Gastrointestinal disorders	Upper gastrointestinal bleeding (hemorrhage)		1	73	1	1	.	.
General disorders and administration site conditions	Death because of AML		1	73	1	.	1	.
General disorders and administration site conditions	Disease progression		1	73	1	.	1	.
General disorders and administration site conditions	Fever		3	73	5	4	.	.
Hepatobiliary disorders	Cholecystitis		1	73	1	1	.	.
Immune system disorders	Allergic reaction		1	73	1	.	.	.
Infections and infestations	Anorectal infection		1	73	1	1	.	.
Infections and infestations	Aspergillus infection		1	73	1	.	1	.
Infections and infestations	Bladder infection		1	73	1	1	.	.
Infections and infestations	Bronchial infection		1	73	1	1	.	.
Infections and infestations	Catheter related infection		1	73	1	1	.	.
Infections and infestations	E. coli bacteraemia		1	73	1	.	.	.
Infections and infestations	Erysipelas		1	73	1	.	.	.
Infections and infestations	Eye infection		1	73	1	1	.	.
Infections and infestations	IMD		1	73	1	.	1	.
Infections and infestations	Infection (Neck-submandibolar) abscess		1	73	1	.	.	.
Infections and infestations	Infection e.c.i.		1	73	1	.	.	.
Infections and infestations	Infection lung		1	73	1	1	.	.
Infections and infestations	Infectious Enterocolitis (Cl Difficile)		1	73	1	.	.	.
Infections and infestations	Infectious enterocoliits (clostridium difficile)		1	73	1	.	.	.
Infections and infestations	Infective myositis (previous term: abdominal infection)		1	73	1	1	.	.
Infections and infestations	Influenza A		1	73	1	1	.	.
Infections and infestations	Laryngitis		1	73	1	.	.	.
Infections and infestations	Lower right lobe pneumonia		1	73	1	.	.	.
Infections and infestations	Lung abscess (lung infection)		1	73	1	1	.	.
Infections and infestations	Lung infection		3	73	4	4	1	1
Infections and infestations	Lung infection due to influenza B infection		1	73	1	1	.	.
Infections and infestations	Pneumonia		8	73	8	8	2	2
Infections and infestations	Pneumonie		1	73	1	.	.	.
Infections and infestations	Pulmonary infection		1	73	1	1	1	1
Infections and infestations	Pyelonefritis		1	73	1	1	.	.
Infections and infestations	Respiratory infection		1	73	1	1	.	.
Infections and infestations	Sepsis		5	73	5	3	4	3
Infections and infestations	Sepsis with staphylococcus haemolyticus		1	73	1	1	.	.
Infections and infestations	Skin Infection		1	73	1	.	.	.
Infections and infestations	Soft tissue infection		2	73	2	.	.	.
Infections and infestations	Staphylococcus epidermidis infection		1	73	1	1	.	.
Infections and infestations	Urinary tract infection		2	73	2	2	.	.

Injury, poisoning and procedural complications	Fall	1	73	1	.	.	.
Injury, poisoning and procedural complications	Spinal fracture	1	73	1	.	.	.
Investigations	Neutrophil count decreased	1	73	1	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	2nd malignancy CNS lymphoma	1	73	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	AML	1	73	1	.	1	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	AML progression	1	73	1	.	1	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Brain tumor. Second primary malignancy	1	73	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Rectum carcinoma	1	73	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Thyroid carcinoma	1	73	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Tumor pain	1	73	2	.	.	.
Nervous system disorders	Brain edema	1	73	1	.	.	.
Nervous system disorders	Intercranial hemorrhage	1	73	1	1	.	.
Nervous system disorders	Leuko encephalopathy	1	73	1	1	.	.
Nervous system disorders	Peripheral sensory neuropathy	1	73	1	1	.	.
Nervous system disorders	Radicular syndrome of nerve L2	1	73	1	.	.	.
Nervous system disorders	Seizure	1	73	1	.	.	.
Nervous system disorders	Stroke	1	73	1	.	1	.
Nervous system disorders	Syncope (Fainting)	1	73	1	1	.	.
Psychiatric disorders	Depression	1	73	2	.	.	.
Renal and urinary disorders	Acute on chronic kidney failure	1	73	1	1	.	.
Renal and urinary disorders	Chronic kidney disease	1	73	1	.	1	.
Reproductive system and breast disorders	Vaginal hemorrhage	1	73	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Acute fibrinous and organizing pneumonia (AFOP)	1	73	1	1	1	1
Respiratory, thoracic and mediastinal disorders	Hypoxia	1	73	1	.	1	.
Respiratory, thoracic and mediastinal disorders	Pneumonitis	3	73	4	3	2	1
Respiratory, thoracic and mediastinal disorders	Pulmonary Edema/congestion	1	73	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Pulmonary oedema	1	73	1	.	1	.
Skin and subcutaneous tissue disorders	Morbus sweet	1	73	1	.	.	.

-> group == arm B ibrutinib 560 mg/day

ssoccd SOC code
aeterm Event term
affected Subjects affected number
exposed Subjects exposed number
occurrences Occurrences all number
occurrel Occurrences causally related to treatment number
fatality Fatalities number
fatalrel Fatalities causally related to treatment number

	ssoccd	aeterm	affected	exposed	occurrences	occurrel	fatality	fatalrel
Blood and lymphatic system disorders	Anemia	1	71	1	1	1	.	.
Blood and lymphatic system disorders	Anemia due to progressive disease	1	71	1
Blood and lymphatic system disorders	Cytopenia (anemia G2, platelets decreased G3)	1	71	1	1	.	.	.
Blood and lymphatic system disorders	Febrile Neutropenia	5	71	5	5	.	.	.
Blood and lymphatic system disorders	Febrile Neutropenia grade 3	1	71	1	1	.	.	.
Blood and lymphatic system disorders	Febrile neutropenia	9	71	10	8	.	.	.
Blood and lymphatic system disorders	Neutropenic Fever	1	71	2	2	.	.	.
Blood and lymphatic system disorders	Neutropenic fever	7	71	9	6	.	.	.
Cardiac disorders	Atrial fibrillation	2	71	2	1	.	.	.
Cardiac disorders	Cardiac decompensation	1	71	1
Cardiac disorders	Heart failure	2	71	2	2	.	.	.
Cardiac disorders	Myocardial infarction	1	71	1	1	.	.	.
Endocrine disorders	Panhypopituitarism	1	71	1	1	.	.	.
Eye disorders	Submaculaire bleeding left eye	1	71	1	1	.	.	.
Gastrointestinal disorders	Acute pancreatitis	1	71	1
Gastrointestinal disorders	Entocolitis infection (due to champhylobacter positive in stool)	1	71	1
Gastrointestinal disorders	Hematemesis	1	71	1	1	1	1	1
Gastrointestinal disorders	Vomiting	1	71	1	1	.	.	.
General disorders and administration site conditions	Asthenia	1	71	1	1	.	.	.
General disorders and administration site conditions	Death	1	71	1	.	1	.	.
General disorders and administration site conditions	Fever	2	71	2	2	.	.	.
General disorders and administration site conditions	Fever of unknown origin	1	71	1
General disorders and administration site conditions	General malaise	1	71	1	1	.	.	.
General disorders and administration site conditions	Post interventional pain exarcerbation	1	71	1
General disorders and administration site conditions	Sudden death	1	71	1	.	1	.	.
Infections and infestations	(pneumonia) aspergillus pneumosepsis	1	71	1	1	1	1	1

Infections and infestations	Abdominal infection/Respiratory infection	1	71	1	1	1	1
Infections and infestations	Airway infection	1	71	1	.	.	.
Infections and infestations	Appendicitis	1	71	1	.	.	.
Infections and infestations	Bilateral Pneumonia	1	71	1	.	.	.
Infections and infestations	Bilateral pneumonia	1	71	1	.	.	.
Infections and infestations	Catheter infection	1	71	1	.	.	.
Infections and infestations	Catheter related infection	1	71	1	.	.	.
Infections and infestations	Cellulitis	1	71	1	.	.	.
Infections and infestations	Cerebral and pulmonal aspergillosis	1	71	1	1	.	.
Infections and infestations	Covid 19	1	71	1	.	.	.
Infections and infestations	Diverticulitis	1	71	1	1	.	.
Infections and infestations	E-Coli infection	1	71	1	1	.	.
Infections and infestations	Gastro-enteritis	1	71	1	.	.	.
Infections and infestations	Gram negative sepsis	1	71	1	.	1	.
Infections and infestations	Gum infection	1	71	1	.	.	.
Infections and infestations	Infected picc line with thrombus	1	71	1	.	.	.
Infections and infestations	Infection (erysipelas)	1	71	1	1	.	.
Infections and infestations	Invasive aspergillosis	1	71	1	1	.	.
Infections and infestations	Lower respiratory tract infection	1	71	1	.	.	.
Infections and infestations	Lung infection	3	71	3	3	2	2
Infections and infestations	Mucosal infection	1	71	1	1	.	.
Infections and infestations	Pneumonia	7	71	9	5	1	1
Infections and infestations	Pneumonia inflammation	1	71	1	.	.	.
Infections and infestations	Pulmonary Infection eci	1	71	1	1	1	1
Infections and infestations	Rash pustular	1	71	1	1	.	.
Infections and infestations	Rhinovirus respiratory infection	1	71	1	1	.	.
Infections and infestations	Sepsis	4	71	4	1	2	.
Infections and infestations	Sepsis (s. dysgalactiae)	1	71	1	.	.	.
Infections and infestations	Septic shock	1	71	1	.	.	.
Infections and infestations	Staphylococcus aureus infection	1	71	1	.	.	.
Infections and infestations	Streptococcus Dysgalactiae Bacteremia	1	71	1	1	.	.
Infections and infestations	Suspect Aspergillose invasive	1	71	1	1	.	.
Infections and infestations	Unspecified bacterial infection	1	71	1	.	.	.
Infections and infestations	Wound infection	1	71	1	.	.	.
Injury, poisoning and procedural complications	Chronic subdural bleeding (hematoma)	1	71	1	1	.	.
Injury, poisoning and procedural complications	Spinal fracture	1	71	1	.	.	.
Musculoskeletal and connective tissue disorders	Arthritis	1	71	1	.	.	.
Musculoskeletal and connective tissue disorders	Pain sacro-iliacal joint	1	71	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	AML Progression	1	71	1	.	1	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Bladder Carcinoma relapse	1	71	1	1	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Death due to PD	1	71	1	.	.	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Progression of AML	1	71	1	.	1	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Progressive disease	1	71	1	.	1	.
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Skin squamous cell carcinoma	1	71	1	.	.	.
Nervous system disorders	Intracerebral stroke	1	71	1	.	1	.
Nervous system disorders	Subarachnoidal hemorrhage	1	71	1	.	.	.
Nervous system disorders	Transient ischemic attack	1	71	1	.	.	.
Psychiatric disorders	Suicide attempt	1	71	1	.	.	.
Renal and urinary disorders	Hematuria and neutropenic fever	1	71	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Pleural effusion	1	71	1	.	.	.
Respiratory, thoracic and mediastinal disorders	Pneumonia	1	71	1	1	.	.
Respiratory, thoracic and mediastinal disorders	Pneumonitis	3	71	3	1	.	.
Respiratory, thoracic and mediastinal disorders	Upper respiratory tract inflammatory disease	1	71	1	.	.	.
Skin and subcutaneous tissue disorders	Skin infection: sweet syndrome	1	71	1	1	.	.
Vascular disorders	Vasovagal collaps	1	71	1	.	.	.