APPENDIX 2.1 - Cumulative Summary Tabulation of Serious Adverse Events from Clinical Trials

BNT162B2

Reporting Period: Through 18-JUN-2022
Total Number of Cases: 2,344
Total Number of Adverse Events (PT): 3,087
MedDRA Version: v.25.0J

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
Blood and lymphatic system disorders	Anaemia	9	2		
	Anaemia macrocytic	1			
	Blood loss anaemia	1			
	Coagulopathy	1	1		
	Febrile neutropenia	2			
	Iron deficiency anaemia	1			
	Lymphadenitis		1		
	Lymphadenopathy	1			
	Microcytic anaemia		1		
	Neutropenia		1		
	Pancytopenia	1			
	Red blood cell abnormality		1		
	Sickle cell anaemia with crisis		1		
	Splenic vein thrombosis	1			
	Thrombocytopenia	1	2		
	Thrombocytopenia neonatal		1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
Sub Total:		**19**	**11**		
Cardiac disorders	Accelerated idioventricular rhythm	1			
	Acute coronary syndrome	7	5		
	Acute left ventricular failure	1	2		
	Acute myocardial infarction	17	20	1	
	Angina pectoris	3	3		
	Angina unstable	5	3		
	Aortic valve incompetence			2	
	Arteriosclerosis coronary artery		1		
	Arteriospasm coronary	1	1		
	Atrial fibrillation	25	20	1	
	Atrial flutter	3			
	Atrioventricular block	1			
	Atrioventricular block complete		1		
	Atrioventricular block first degree	1			
	Bradycardia		2		
	Bradycardia foetal		1		
	Cardiac arrest	4	8	1	
	Cardiac disorder	1			
	Cardiac failure	1	1		
	Cardiac failure acute			1	
	Cardiac failure chronic			1	

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SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Cardiac failure congestive	11	6		
	Cardiomyopathy		1		
	Cardio-respiratory arrest	4	5		
	Cardiovascular disorder	1			
	Chronic left ventricular failure		1		
	Conduction disorder	1			
	Coronary artery disease	12	8	3	
	Coronary artery dissection		1		
	Coronary artery insufficiency		1		
	Coronary artery occlusion		4		
	Hypertensive heart disease		2		
	Ischaemic cardiomyopathy	1	1		
	Junctional ectopic tachycardia		1		
	Mitral valve incompetence	3			
	Mitral valve prolapse			1	
	Myocardial infarction	17	14	1	
	Myocardial ischaemia	1	1		
	Myocarditis	1			
	Myopericarditis	2			

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	Nonreassuring foetal heart rate pattern		2		
	Palpitations	2			
	Pericardial haemorrhage		1		
	Pericarditis	2	1		
	Postural orthostatic tachycardia syndrome	1			
	Prinzmetal angina	1			
	Sinus node dysfunction	1			
	Supraventricular extrasystoles	1			
	Supraventricular tachycardia	6			
	Tachyarrhythmia		1		
	Tachycardia	1	2		
	Ventricular arrhythmia	1			
	Ventricular extrasystoles	1	1		
	Ventricular fibrillation	1	1		
	Ventricular tachycardia	5	1		
Sub Total:		**148**	**124**	**12**	
Congenital, familial and genetic disorders	Ankyloglossia congenital		2		
	Atrial septal defect	1	3		
	BRCA1 gene mutation	1			
	Congenital bladder neck obstruction			1	

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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Congenital rubella syndrome		1		
	Congenital skin dimples			1	
	Congenital ureteropelvic junction obstruction			1	
	Craniosynostosis			1	
	DiGeorge's syndrome		1		
	Heart disease congenital		1		
	Hypertrophic cardiomyopathy	2			
	Microcephaly		1		
	Mucopolysaccharidosis		1		
	Newborn persistent pulmonary hypertension		1		
	Patent ductus arteriosus		1		
	Pectus excavatum	1			
	Polydactyly		1		
	Sex chromosome abnormality		1		
	Sickle cell disease		1		
	Syndactyly		1		
	Syringomyelia		1		
	Thanatophoric dwarfism			1	
	Trisomy 21		2		

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	Ventricular septal defect			1	
Sub Total:		**5**	**19**	**6**	
Ear and labyrinth disorders	Deafness neurosensory	3			
	Sudden hearing loss	1			
	Vertigo	4	3		
Sub Total:		**8**	**3**		
Endocrine disorders	Addison's disease	1			
	Goitre	1	2		
Sub Total:		**2**	**2**		
Eye disorders	Blindness unilateral		1		
	Choroidal neovascularisation		1		
	Diplopia	2	1		
	Eye haemorrhage			1	
	Eyelid ptosis	1			
	Optic ischaemic neuropathy	1			
	Papilloedema		1		
	Retinal artery occlusion		1		
	Retinal detachment	2			
	Retinal tear	1			
	Retinal vein thrombosis		1		
	Visual impairment		2		
Sub Total:		**7**	**8**	**1**	
Gastrointestinal disorders	Abdominal adhesions	1	1		

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	Abdominal compartment syndrome	1			
	Abdominal discomfort	1			
	Abdominal hernia	1	1		
	Abdominal pain	1	3		
	Abdominal pain upper	1	2		
	Abdominal wall haematoma		1		
	Acute abdomen			1	
	Allergic colitis		1		
	Allergic gastroenteritis		1		
	Anal fistula	1		1	
	Colitis	5	4		
	Colitis ischaemic	1	1		
	Colitis ulcerative	2			
	Constipation	4	4		
	Dental caries	1			
	Dental cyst	1			
	Diaphragmatic hernia	1			
	Diarrhoea	1	2		
	Diverticular perforation		2		
	Diverticulum intestinal			1	
	Duodenal obstruction		1		
	Duodenal perforation		1		
	Duodenal ulcer	1			

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	Duodenal ulcer perforation	1			
	Dysphagia	2	1		
	Enterocolitis		1		
	Eosinophilic oesophagitis	1			
	Food poisoning	1			
	Gastric fistula		1		
	Gastric ulcer	1			
	Gastric ulcer haemorrhage	1			
	Gastritis	1	2		
	Gastritis erosive	1			
	Gastrointestinal disorder	1			
	Gastrointestinal haemorrhage	4	4		
	Gastrointestinal mucosa hyperaemia		1		
	Gastrointestinal necrosis		1		
	Gastrointestinal pain	1			
	Gastrointestinal perforation	1			
	Gastrooesophageal reflux disease	3			
	Haemorrhoidal haemorrhage		1		
	Haemorrhoids		1		
	Hiatus hernia	1	2	1	
	Ileus	1	1		

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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Impaired gastric emptying		1		
	Incarcerated inguinal hernia		1		
	Infantile vomiting		1		
	Inguinal hernia	3		1	
	Intestinal ischaemia	1			
	Intestinal mass			1	
	Intestinal obstruction	11	2		
	Intestinal perforation		2		
	Intestinal strangulation		1		
	Intestinal ulcer perforation	1			
	Intra-abdominal fluid collection	2			
	Intra-abdominal haematoma	1			
	Large intestine perforation		2		
	Lower gastrointestinal haemorrhage	3	2		
	Meconium plug syndrome		1		
	Mesenteric panniculitis	1			
	Nausea	3			
	Neonatal intestinal perforation		1		
	Obstructive pancreatitis		2		

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	Oesophageal food impaction		1		
	Oesophageal spasm	1			
	Oesophageal stenosis	1			
	Oesophageal varices haemorrhage		1		
	Pancreatic cyst		1		
	Pancreatic pseudocyst		1		
	Pancreatitis	4	6		
	Pancreatitis acute	2	8	1	
	Pancreatitis necrotising	1			
	Peptic ulcer	1			
	Pneumoperitoneum		1		
	Rectal haemorrhage	1	1		
	Rectal perforation	1			
	Retroperitoneal haematoma		1		
	Salivary gland calculus			1	
	Small intestinal obstruction	5	15	1	
	Splenic artery aneurysm		1		
	Umbilical hernia		1		
	Upper gastrointestinal haemorrhage	3		1	
	Volvulus	1	1		
	Vomiting	5			

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SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
Sub Total:		**97**	**96**	**10**	
General disorders and administration site conditions	Asthenia		1		
	Chest discomfort	1			
	Chest pain	10	7	1	
	Condition aggravated	42	29	6	1
	Cyst	1			
	Death	8	5	1	
	Disease progression		2		
	Disease recurrence	5	1		
	Drowning	1			
	Drug ineffective	1			
	Drug withdrawal syndrome	2	1		
	Electrocution	1			
	Fatigue	1			
	Gait disturbance	1			
	Hypothermia		1		
	Impaired healing		1		
	Influenza like illness		1		
	Multiple organ dysfunction syndrome			2	
	Non-cardiac chest pain	3	8		
	Organ failure		1		
	Pain	1	2		
	Pyrexia	6	1		

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	Shoulder injury related to vaccine administration	1			
	Sudden cardiac death	1			
	Sudden death	2			
	Treatment noncompliance	1			
	Vascular stent occlusion		1		
Sub Total:		**89**	**62**	**10**	**1**
Hepatobiliary disorders	Acute hepatic failure		1		
	Alcoholic liver disease	1			
	Autoimmune hepatitis	1			
	Bile duct stone	4	2		
	Biliary colic	4	1		
	Biliary cyst	2			
	Biliary dyskinesia	1			
	Biliary fistula		1		
	Biliary obstruction	1			
	Cholangitis	3			
	Cholecystitis	6	2	1	
	Cholecystitis acute	7	9		
	Cholecystitis chronic	1	1		
	Cholelithiasis	14	8		
	Cholelithiasis obstructive	1			
	Cholestasis of pregnancy	1			
	Hepatic cirrhosis	1			

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	Hepatitis acute	2			
	Hepatocellular injury		1		
	Hyperbilirubinaemia neonatal	2	1	1	
	Jaundice cholestatic	1			
	Portal vein thrombosis	2			
	Portosplenomesenteric venous thrombosis	1			
Sub Total:		**56**	**27**	**2**	
Immune system disorders	Anaphylactic reaction	3	3		
	Anaphylactic shock		1		
	Anaphylactoid reaction	1			
	Drug hypersensitivity		1		
	Food allergy		1		
	Hypersensitivity		1		
	Kidney transplant rejection	1			
Sub Total:		**5**	**7**		
Infections and infestations	Abdominal abscess	1	3	1	
	Abdominal infection	2			
	Abdominal sepsis	1	1		
	Abdominal wall abscess	1			
	Abscess		1		
	Abscess limb	2	1		
	Abscess oral		1		

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	Acquired immunodeficiency syndrome	1	1		
	Adenovirus infection	2	1		
	Anal abscess		3		
	Appendicitis	21	31	4	
	Appendicitis perforated	4	5		
	Arteriosclerotic gangrene	1			
	Arthritis bacterial	1	2	1	
	Asymptomatic bacteriuria	1			
	Atypical pneumonia	1			
	Bacteraemia		1		
	Bacterial sepsis		1		
	Brain abscess		1		
	Bronchiolitis	2	7	1	
	Bronchitis	2	2		
	Campylobacter gastroenteritis	1	1		
	Cellulitis	7	7	1	
	Cholangitis infective	1			
	Cholecystitis infective	1			
	Clostridium difficile colitis	2	1		
	Clostridium difficile infection	2			
	Colonic abscess		2		
	Complicated appendicitis	2	3		

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	COVID-19	4	15	3	
	COVID-19 pneumonia	3	6		
	Device related infection	1	2		
	Diabetic foot infection		1		
	Diverticulitis	11	5	1	
	Emphysematous cholecystitis		1		
	Empyema		1		
	Endocarditis		1		
	Endometritis		1		
	Enterovirus infection		1		
	Epstein-Barr virus infection	1			
	Escherichia urinary tract infection		1		
	Exanthema subitum		1		
	Extradural abscess		1		
	Focal peritonitis	3	2		
	Gangrene	1	1		
	Gastroenteritis	11	10	1	
	Gastroenteritis adenovirus		1		
	Gastroenteritis bacterial			1	
	Gastroenteritis norovirus		1		
	Gastroenteritis rotavirus		4		
	Gastroenteritis viral		3		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Groin abscess	1			
	HCoV-NL63 infection		1		
	Herpes zoster	1			
	Herpes zoster oticus		1		
	HIV infection	2			
	Infected skin ulcer			1	
	Infection		1		
	Infectious pleural effusion		1		
	Influenza	1	1		
	Intervertebral discitis	1			
	Kidney infection	3			
	Labyrinthitis	1			
	Large intestine infection		1		
	Liver abscess	2	2		
	Localised infection		2		
	Lower respiratory tract infection	1	3		
	Lower respiratory tract infection viral		1		
	Lung abscess	1			
	Lyme disease		1		
	Mastoiditis	2			
	Measles		1		
	Meningitis	1			
	Meningitis bacterial	2	2		
	Meningitis viral	1			
	Metapneumovirus infection		2		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Neonatal pneumonia		3		
	Norovirus infection	1			
	Osteomyelitis	4	2		
	Otitis media acute		1		
	Parainfluenzae virus infection		1		
	Pelvic abscess	2	1		
	Pelvic inflammatory disease	1			
	Penile abscess	1			
	Penile infection	1			
	Peritoneal abscess		1		
	Peritonitis	4	3		
	Peritonsillar abscess	1	2		
	Pharyngeal abscess		1		
	Pharyngitis streptococcal			1	
	Pneumocystis jirovecii pneumonia		1		
	Pneumonia	27	26	1	
	Pneumonia aspiration	3	3		
	Pneumonia bacterial	1	1	1	
	Pneumonia klebsiella		1		
	Pneumonia pneumococcal	1			
	Pneumonia respiratory syncytial viral		1	1	
	Postoperative abscess		1		

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Treatment Grouping:
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Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Postoperative wound infection	2	3		
	Post procedural infection	2	1	1	
	Prostate infection	1	1		
	Pulmonary tuberculosis		1		
	Pyelonephritis	2	6		
	Pyelonephritis acute	2	2		
	Renal abscess		1		
	Respiratory syncytial virus bronchiolitis		8		
	Respiratory syncytial virus infection		2		
	Respiratory tract infection				1
	Respiratory tract infection viral		1		
	Rhinovirus infection	1	2		
	Salmonellosis		1		
	Sepsis	12	9	1	
	Sepsis neonatal		3		
	Septic arthritis staphylococcal	1			
	Septic shock	6	2		
	Shigella sepsis		1		
	Sinusitis	1			
	Skin candida		1		
	Skin infection	1			
	Soft tissue infection	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Staphylococcal bacteraemia		1		
	Staphylococcal infection	2	1		
	Staphylococcal sepsis	1	1		
	Streptococcal bacteraemia	1			
	Subacute endocarditis			1	
	Subcutaneous abscess		2		
	Subdiaphragmatic abscess	1			
	Suspected COVID-19		1		
	Tinea pedis		1		
	Tonsillitis		1		
	Tooth infection		1		
	Toxic shock syndrome	2			
	Upper respiratory tract infection		3		
	Urinary tract infection	11	11	2	
	Urosepsis	3	4		
	Vascular device infection	1			
	Viral infection		1		
	Wound infection	1			
Sub Total:		**216**	**277**	**24**	**1**
Injury, poisoning and procedural complications	Abdominal injury	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Accidental overdose	1	1		
	Acetabulum fracture		1		
	Alcohol poisoning		1		
	Anastomotic stenosis	1			
	Animal bite	2			
	Ankle fracture	7	3		
	Arterial injury	1			
	Arthropod bite	1			
	Brain contusion	1	1		
	Burns second degree	1	1		
	Burns third degree	1			
	Cervical vertebral fracture	4	1		
	Chest injury	1			
	Clavicle fracture		2		
	Colon injury		1		
	Concussion	1	1		
	Craniocerebral injury	3	4		
	Delayed recovery from anaesthesia			1	
	Epiphyseal fracture		1		
	Exposure via breast milk	1			
	Facial bones fracture	2	2		
	Fall	7	2		
	Femur fracture	3	3		
	Fibula fracture	2			
	Flail chest		1		
	Foot fracture	4	1	1	

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Forearm fracture		1		
	Foreign body		1		
	Foreign body in gastrointestinal tract	1			
	Foreign body ingestion		1		
	Fractured sacrum	1	2		
	Fractured skull depressed	1			
	Gastrointestinal anastomotic complication	1			
	Gun shot wound	3	2		
	Hand fracture	1	1		
	Head injury	2	2		
	Hip fracture	2	3	1	
	Humerus fracture	4	2	1	
	Infusion related reaction	1			
	Injury	2	2		
	Injury to brachial plexus due to birth trauma		1		
	Intestinal anastomosis complication	1			
	Jaw fracture	1			
	Joint dislocation	2			
	Ligament rupture	2	2		
	Limb injury	1			
	Lower limb fracture	1	2	1	

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
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Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Lumbar vertebral fracture	1	1		
	Maternal exposure before pregnancy	7	2	2	
	Maternal exposure during pregnancy	7	106	8	
	Maternal exposure timing unspecified		1		
	Meniscus injury		2		
	Multiple injuries		1		
	Muscle contusion	1			
	Muscle rupture	3			
	Muscle strain		1		
	Neck injury	1			
	Overdose	3	3		
	Patella fracture		1		
	Pelvic fracture	2	3		
	Postoperative ileus	2	1		
	Post procedural complication	1			
	Post procedural haematoma		1		
	Post-traumatic pain		1		
	Procedural dizziness	1			
	Procedural haemorrhage		1		
	Procedural pain	2			
	Radius fracture	1		1	
	Rib fracture	6	3		
	Road traffic accident	4	11		
	Scapula fracture	1	1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Skeletal injury	1			
	Skin laceration	1	1		
	Spinal column injury		1		
	Spinal cord injury	1			
	Spinal cord injury cervical		1		
	Spinal fracture	2			
	Splenic rupture		1		
	Stoma complication	1			
	Subdural haematoma	4	3		
	Suture related complication	1			
	Tendon injury		1		
	Tendon rupture	2			
	Thermal burn	1	1		
	Thoracic vertebral fracture	3	1		
	Tibia fracture	4	2		
	Toxicity to various agents	1	3		
	Traumatic haemothorax		2		
	Traumatic intracranial haemorrhage		2		
	Traumatic liver injury		2		
	Traumatic renal injury	1			
	Ulna fracture	2	1		
	Upper limb fracture	4	2		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Urethral injury		1		
	Urinary tract procedural complication			1	
	Venous injury		1		
	Wrist fracture	2	3		
Sub Total:		**146**	**218**	**17**	
Investigations	Alanine aminotransferase increased	1			
	Aspartate aminotransferase increased	1			
	Blood glucose abnormal		1		
	Blood glucose increased		1		
	Blood lactic acid	1			
	Blood pressure increased		1		
	Cardiac murmur		1		
	Foetal heart rate abnormal		1		
	Haemoglobin decreased		1		
	Hepatic enzyme increased	2	1		
	Laboratory test abnormal	1			
	Ultrasound foetal abnormal		1		
	Urine output decreased	1			
Sub Total:		**7**	**8**		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
Metabolism and nutrition disorders	Dehydration	3	4	1	
	Diabetes mellitus inadequate control		1		
	Diabetic ketoacidosis	6	3		
	Feeding intolerance		1		
	Fluid retention		2		
	Gout	1			
	Hyperglycaemia	3	1	1	
	Hyperkalaemia	1			
	Hypernatraemia			1	
	Hypervolaemia		1		
	Hypocalcaemia			1	
	Hypoglycaemia	1	4		
	Hypoglycaemia neonatal	1		1	
	Hypokalaemia	2	3		
	Hyponatraemia	6	2		
	Lactic acidosis	1			
	Malnutrition		1		
	Metabolic acidosis		1		
	Obesity	3	1		
	Type 2 diabetes mellitus	2	3		
Sub Total:		**30**	**28**	**5**	
Musculoskeletal and connective tissue disorders	Arthralgia	4	2		
	Arthritis	3	1	1	
	Back pain	8	1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Cervical spinal stenosis			1	
	Compartment syndrome		1		
	Connective tissue disorder		1		
	Costochondritis	1			
	Intervertebral disc compression		1		
	Intervertebral disc degeneration	2	1	2	
	Intervertebral disc protrusion	5	5		1
	Kyphosis	1			
	Lumbar spinal stenosis	3		1	
	Muscular weakness	1	3		
	Musculoskeletal chest pain		2		
	Myalgia	1	1		
	Myositis	1			
	Osteoarthritis	23	11	4	
	Osteochondritis		1		
	Osteochondrosis		1		
	Osteonecrosis		1		
	Pain in extremity	1	1		
	Pathological fracture	2			
	Psoriatic arthropathy			1	
	Rhabdomyolysis	1			
	Rheumatoid arthritis	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Rotator cuff syndrome		1		
	Spinal deformity	1			
	Spinal osteoarthritis	1		1	
	Spinal stenosis	4			
	Spondylolisthesis	1	2	1	
	Synovial cyst	1			
	Synovitis	1			
	Thoracic spinal stenosis	1		1	
Sub Total:		**68**	**37**	**13**	**1**
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Acute leukaemia		1		
	Acute lymphocytic leukaemia		1		
	Acute myeloid leukaemia	3	1		
	Adenocarcinoma	1			
	Adenocarcinoma gastric		1		
	Adenocarcinoma of colon	7	3		
	Adenocarcinoma pancreas	3	2		
	Adrenal gland cancer		1		
	Adrenal neoplasm	1			
	Adrenocortical carcinoma	1			
	Anal cancer	1			
	Angiosarcoma	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Basal cell carcinoma	1	1	2	
	B-cell lymphoma	1	1		
	B-cell small lymphocytic lymphoma stage IV		1		
	Benign hydatidiform mole		1		
	Biliary cancer metastatic		1		
	Biliary neoplasm	1			
	Bladder cancer	3	3	1	
	Bladder cancer recurrent	2			
	Bladder transitional cell carcinoma	2			
	Borderline serous tumour of ovary	2			
	Brain neoplasm	4	1		
	Breast cancer	12	7	3	
	Breast cancer female	1			
	Breast cancer in situ		1		
	Breast cancer metastatic	3	1		
	Breast cancer stage I	2	3		
	Breast cancer stage II	1			
	Bronchioloalveolar carcinoma	1			
	Carcinoid tumour pulmonary	1			
	Cervix carcinoma	1			
	Chordoma	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
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Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Chronic myeloid leukaemia		1		
	Clear cell renal cell carcinoma	1	1	1	
	Colon cancer	2	1		
	Colon cancer stage III	1			
	Colon neoplasm	1			
	Colorectal adenoma	1	1		
	Cutaneous T-cell lymphoma	1			
	Ductal adenocarcinoma of pancreas	1			
	Endometrial adenocarcinoma	3		1	
	Endometrial cancer	1	1		
	Follicular lymphoma	3	1		
	Gallbladder cancer stage II		1		
	Gastric cancer	1			
	Gastrointestinal stromal tumour	1			
	Glioblastoma	2	1		
	Hepatic adenoma	1			
	Hepatic cancer	2	1		
	Hepatic cancer metastatic		1		
	Hormone receptor positive breast cancer	1	2		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Hypergammaglobulinaemia benign monoclonal	1			
	Intraductal proliferative breast lesion	4	2		
	Invasive breast carcinoma	2			
	Invasive ductal breast carcinoma	9	5		
	Invasive lobular breast carcinoma	2	1		
	Large intestine benign neoplasm		1		
	Laryngeal papilloma	1			
	Leukaemia	1	1		
	Leydig cell tumour of the testis		1		
	Lipoma		1		
	Liposarcoma recurrent	1			
	Lung adenocarcinoma	4		2	
	Lung cancer metastatic		2		
	Lung carcinoma cell type unspecified stage II		1		
	Lung neoplasm malignant	3			
	Lymphocytic leukaemia		1		
	Malignant melanoma	2	5	1	

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Malignant melanoma in situ			1	
	Mantle cell lymphoma	1			
	Meningioma		2		
	Mesothelioma		1		
	Metastases to bone		1		
	Metastases to central nervous system		1		
	Metastases to liver		1		
	Metastases to lung		1		
	Metastases to lymph nodes	1	1	1	
	Metastatic gastric cancer	1			
	Metastatic malignant melanoma	1			
	Metastatic renal cell carcinoma	1			
	Metastatic squamous cell carcinoma		2		
	Mucinous breast carcinoma	1			
	Mucoepidermoid carcinoma of salivary gland	1			
	Myeloproliferative neoplasm	1			
	Neoplasm progression	1	1		
	Neoplasm recurrence	1	1		
	Nervous system neoplasm		1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Neuroendocrine carcinoma	1			
	Neuroendocrine tumour			1	
	Non-Hodgkin's lymphoma recurrent			1	
	Non-small cell lung cancer stage III	1			
	Non-small cell lung cancer stage IV		1		
	Ocular melanoma	1			
	Oesophageal adenocarcinoma	1			
	Oesophageal carcinoma	1			
	Oropharyngeal cancer		1		
	Oropharyngeal cancer recurrent			1	
	Oropharyngeal squamous cell carcinoma		2		
	Ovarian adenoma	1			
	Ovarian cancer	3	1		
	Ovarian cancer stage I	1			
	Ovarian neoplasm	1			
	Pancreatic carcinoma	5	2	1	
	Pancreatic carcinoma metastatic	1	2		
	Pancreatic neoplasm	1			

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Pancreatic neuroendocrine tumour		1		
	Papillary serous endometrial carcinoma			1	
	Papillary thyroid cancer	1	1	2	
	Parathyroid tumour benign			1	
	Penis carcinoma metastatic		1		
	Pituitary tumour benign	1	2	1	
	Plasma cell myeloma		1		
	Pleural mesothelioma malignant	1			
	Polycythaemia vera			1	
	Prostate cancer	23	9		
	Prostate cancer metastatic	2			
	Prostate cancer stage II	1			
	Rectal cancer metastatic	1			
	Renal cancer recurrent		1		
	Renal cell carcinoma		1		
	Renal neoplasm	1			
	Rhabdomyosarcoma	1			
	Salivary gland cancer stage IV	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Sarcoma metastatic	1			
	Sebaceous carcinoma		1		
	Seminoma		1		
	Small cell carcinoma	1			
	Squamous cell carcinoma	1			
	Squamous cell carcinoma of the cervix	1			
	Squamous cell carcinoma of the vagina	1			
	Teratoma			1	
	Testis cancer	1	1		
	Thyroid cancer	1			
	Tongue cancer metastatic	1			
	Tonsil cancer	1	1		
	Transitional cell carcinoma	5		1	
	Transitional cell carcinoma recurrent	1			
	Triple negative breast cancer		1		
	Uterine cancer		2		
	Uterine leiomyoma	4	4	1	
	Uterine leiomyosarcoma		1		
	Vascular neoplasm	1			
Sub Total:		**191**	**115**	**26**	
Nervous system disorders	Alcoholic seizure		1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Amnesia		1		
	Amyotrophic lateral sclerosis	1		1	
	Anticholinergic syndrome	1			
	Aphasia	2			
	Autonomic nervous system imbalance	1			
	Basal ganglia haemorrhage			1	
	Bell's palsy	1			
	Brachial plexopathy	1			
	Brain stem infarction	1			
	Carotid artery aneurysm	1			
	Carotid artery stenosis	1			
	Carpal tunnel syndrome		1		
	Cerebral haemorrhage	1	1		
	Cerebral infarction		1		
	Cerebral venous thrombosis		1		
	Cerebrovascular accident	28	11	1	
	Cervicogenic headache		1		
	Coma neonatal		1		
	Dementia Alzheimer's type		1	1	
	Dizziness	1	3		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Dural arteriovenous fistula	2			
	Dyskinesia	1			
	Embolic stroke	1			
	Encephalopathy	2			
	Encephalopathy neonatal		1		
	Epilepsy	1	2		
	Febrile convulsion	2	3		
	Generalised tonic-clonic seizure	1			
	Guillain-Barre syndrome			1	
	Haemorrhagic stroke	1	2		
	Headache	1			
	Hemiplegic migraine		1		
	Hepatic encephalopathy	2			
	Hypoaesthesia		1		
	Hypoxic-ischaemic encephalopathy		1		
	Idiopathic intracranial hypertension	1	2		
	Intracranial aneurysm	1	2		
	Intracranial hypotension	1			
	Intracranial pressure increased	1	1		
	Intraventricular haemorrhage	1	1		
	Ischaemic stroke	6	5		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Loss of consciousness	1			
	Lumbar radiculopathy		1		
	Migraine	1	1		
	Multifocal motor neuropathy	1			
	Myasthenia gravis	1			
	Myelitis transverse	1			
	Neonatal seizure		1		
	Nervous system disorder	1	1		
	Neuritis		1		
	Neuropathy peripheral	1	1		
	Optic neuritis	2	1		
	Paraesthesia	1	1		
	Peripheral nerve lesion	2			
	Polyneuropathy	1			
	Presyncope	3			
	Psychogenic seizure	1			
	Reversible cerebral vasoconstriction syndrome	1			
	Sedation	1			
	Seizure	8	1		
	Serotonin syndrome	1			
	Somnolence	1			
	Spinal claudication	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Spinal cord compression	1	1	1	
	Spinal cord haematoma	1			
	Status epilepticus		1		
	Status migrainosus	1			
	Subarachnoid haemorrhage	1	4	1	
	Superior sagittal sinus thrombosis		1		
	Syncope	16	10	1	
	Toxic encephalopathy	2	2		
	Toxic leukoencephalopathy		1		
	Transient global amnesia		1		
	Transient ischaemic attack	9	6		
	Uraemic encephalopathy		1		
Sub Total:		**126**	**82**	**8**	
Pregnancy, puerperium and perinatal conditions	Abortion complete	1			
	Abortion incomplete	1		1	
	Abortion missed	3			
	Abortion spontaneous	17	14	4	
	Abortion spontaneous incomplete		1		
	Anembryonic gestation	1			

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Arrested labour		1		
	Breech delivery		1		
	Caput succedaneum		1		
	Cephalo-pelvic disproportion		6		
	Ectopic pregnancy	1			
	Failed induction of labour		1		
	Failed trial of labour		1		
	Foetal death		2		
	Foetal distress syndrome	1	7		
	Foetal growth restriction		1		
	Foetal hypokinesia		3		
	Gestational hypertension	1	2		
	Haemorrhage in pregnancy		1		
	Jaundice neonatal	1	9	1	
	Low birth weight baby	1			
	Meconium in amniotic fluid		1		
	Meconium stain		1		
	Omphalorrhexis		1		
	Placental insufficiency		1		
	Postpartum haemorrhage	1	3		
	Pre-eclampsia	1	6		
	Premature baby		1	1	

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Premature delivery	1	1	1	
	Premature separation of placenta		4		
	Preterm premature rupture of membranes		1		
	Prolonged rupture of membranes		1		
	Retained placenta or membranes		1		
	Retained products of conception		1		
	Small for dates baby		1		
	Threatened labour	1			
	Weight decrease neonatal			1	
Sub Total:		**32**	**75**	**9**	
Psychiatric disorders	Acute psychosis	2			
	Affective disorder		1		
	Alcohol abuse	2	1	1	
	Alcoholism		2		
	Alcohol withdrawal syndrome	1	2		
	Anorexia nervosa	1			
	Anxiety	4			
	Bipolar disorder	2	3		
	Bipolar I disorder	3			
	Bipolar II disorder		1		
	Completed suicide	7	3		
	Conversion disorder		2		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Depression	10	8	2	
	Depression suicidal	1	1	1	
	Disorientation	1			
	Drug abuse	2	1		
	Drug dependence		2		
	Hallucination	1			
	Major depression	6	3		
	Mania	1			
	Mental disorder	2	1		
	Mental status changes	2			
	Obsessive-compulsive disorder	1			
	Panic attack		2		
	Post-traumatic stress disorder		1		
	Psychotic behaviour	1			
	Psychotic disorder	3	2		
	Suicidal behaviour	1			
	Suicidal ideation	13	8	2	
	Suicide attempt	5	2	1	
Sub Total:		**72**	**46**	**7**	
Renal and urinary disorders	Acute kidney injury	12	7		
	Bladder prolapse	1			
	End stage renal disease	1	1		
	Glomerulonephritis	1			
	Hydronephrosis			1	
	Nephrolithiasis	4	17		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Oliguria	1			
	Renal colic	3	1		
	Renal cyst		1		
	Renal failure	1			
	Renal failure neonatal		1		
	Renal infarct		1		
	Renal pain	1			
	Renal tubular necrosis		1		
	Renal vein thrombosis	1			
	Subcapsular renal haematoma		1		
	Ureterolithiasis	1	3		
	Urinary retention	4			
	Urinary tract obstruction	1			
	Vesicoureteric reflux		1		
Sub Total:		**32**	**35**	**1**	
Reproductive system and breast disorders	Abnormal uterine bleeding	1			
	Adenomyosis		2		
	Adnexal torsion	1	1	1	
	Benign prostatic hyperplasia	3		2	
	Breast hyperplasia		1	1	
	Endometrial thickening		1		
	Endometriosis	1	2		
	Heavy menstrual bleeding	3			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Infertility	1			
	Ovarian cyst		2		
	Ovarian mass		1		
	Pelvic fluid collection	1			
	Pelvic organ prolapse	1			
	Prostatitis		1		
	Rectocele			1	
	Testicular appendage torsion		1		
	Testicular necrosis	1			
	Uterine disorder		2		
	Uterine prolapse		1		
	Vaginal haemorrhage		1		
	Vaginal prolapse			1	
Sub Total:		**13**	**16**	**6**	
Respiratory, thoracic and mediastinal disorders	Acute pulmonary oedema	1			
	Acute respiratory distress syndrome	3			
	Acute respiratory failure	11	7		
	Asthma	3	6		
	Asthmatic crisis		1		1
	Atelectasis	1			
	Bronchial hyperreactivity		1		
	Bronchospasm	1	1		
	Chronic obstructive pulmonary disease	6	9		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Diaphragmatic paralysis	1			
	Dyspnoea	6	6		
	Dyspnoea exertional	1	2		
	Hypoxia	4	2		
	Interstitial lung disease	1	2		
	Meconium aspiration syndrome		2		
	Nasal septum deviation	1	1		
	Negative pressure pulmonary oedema		1		
	Neonatal hypoxia		1		
	Neonatal pneumothorax		1		
	Neonatal respiratory distress		3		
	Neonatal respiratory distress syndrome	1	1		
	Neonatal respiratory failure		2		
	Neonatal tachypnoea		2		
	Pleural effusion	4		1	
	Pleurisy	1			
	Pneumomediastinum		1		
	Pneumonitis		1		
	Pneumothorax	2	1		
	Pulmonary embolism	22	16	4	
	Pulmonary fibrosis	1			
	Pulmonary mass	1	1		

* Uncoded Preferred Term displayed as Verbatim Term (As Reported)
Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Pulmonary sarcoidosis	1			
	Pulmonary vein stenosis	1			
	Respiratory arrest		1		
	Respiratory distress		1		
	Respiratory failure	2	4		
Sub Total:		**76**	**77**	**5**	**1**
Skin and subcutaneous tissue disorders	Angioedema	1			
	Dermatomyositis	2			
	Diabetic foot	1			
	Mucocutaneous rash	1			
	Pemphigoid	1			
	Pruritus		1		
	Pustular psoriasis		1		
	Skin lesion	1			
	Vitiligo	1			
Sub Total:		**8**	**2**		
Social circumstances	Miscarriage of partner	1	1		
	Victim of crime	1			
Sub Total:		**2**	**1**		
Surgical and medical procedures	Drug therapy	1			
Sub Total:		**1**			
Vascular disorders	Accelerated hypertension		1		
	Aneurysm	1			
	Aortic aneurysm	1	1	1	
	Aortic dissection	1	1		

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Aortic rupture	1	1		
	Aortic stenosis	1		2	
	Arteriosclerosis	1	3		
	Cyanosis		1	1	
	Deep vein thrombosis	11	8	2	
	Embolism	1			
	Haematoma	1			
	Hypertension	5	5		
	Hypertensive crisis		2		
	Hypertensive emergency	3	1		
	Hypertensive urgency	2	3		
	Hypoperfusion		1		
	Hypotension	2	1		
	Hypovolaemic shock	1			
	Iliac artery dissection		1		
	Infarction	1			
	Neonatal hypotension		1		
	Neurogenic shock	1			
	Orthostatic hypotension	1	2		
	Penetrating aortic ulcer	1			
	Peripheral arterial occlusive disease	1			
	Peripheral artery occlusion	1			

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.

SOC	PT	BNT162B2;BNT162B2S01;BNT162B2OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION / NO STUDY DRUG
	Peripheral artery stenosis		1		
	Peripheral artery thrombosis	2			
	Shock		1		
	Shock haemorrhagic	1	1		
	Subgaleal haemorrhage		1		
	Thrombosis	3			
	Venous thrombosis limb	1	1		
Sub Total:		**45**	**38**	**6**	
Total Number of Cases:		**1,161**	**1,054**	**127**	**2**
Total Number of Events:		**1,501**	**1,414**	**168**	**4**

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Treatment Grouping:
Study Drug: If one of the suspect products on the case is the Study Drug, the event will be displayed under Study Drug regardless of other suspect products on the case.
Blinded Therapy: If one of the suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded Therapy.
Placebo: If one of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Pre Randomization / No Study Drug.
Comparator: If the case category is different than the Study Drug, Blinded Therapy, Placebo, Pre Randomization / No Study Drug, but the case contains suspect products designated as part of the study, the events will fall under Comparator.
Other Suspects: If none of the above categories are met, the event will fall under Other Suspects. Some examples include background drugs or non study drugs deemed as suspect.