

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;BNT162 B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATIO NO STUDY DRU
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		

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.

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 is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded 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 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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION NO STUDY DRUG
Sub To	tal:	19	11		10 01001 0100
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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Comparison of the suspect products on the case is placebo and none are Study drug, the event will be displayed under Placebo.

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.

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SOC	PT	BNT162B2;BNT162 B2S01;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			
oded Preferred T nent Grouping: Drug: If one of t	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		
Sub Total Congenital, familial and genetic disorders	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	l <u>i</u>	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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	Congenital rubella syndrome		1		
	Congenital skin dimples			1	
	Congenital ureteropelvic junction obstruction Craniosynostosis DiGeorge's syndrome Heart disease congenital Hypertrophic cardiomyopathy Microcephaly Mucopolysaccharido sis Newborn persistent pulmonary hypertension Patent ductus arteriosus Pectus excavatum Polydactyly Sex chromosome abnormality Sickle cell disease Syndactyly Syningomyelia Thanatophoric dwarfism Trisomy 21			1	
	Craniosynostosis			1	
	DiGeorge's syndrome		1		
	Heart disease congenital		1		
	Hypertrophic cardiomyopathy	2			
	Microcephaly		1		
	Mucopolysaccharido sis		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 Tota	al:	5	19	6	-1
Ear and labyrinth disorders	Deafness neurosensory	3			
	Sudden hearing loss	1			
	Vertigo	4	3		
Sub Tot	al:	8	3		
Endocrine disorders	Addison's disease	1			
	Goitre	1	2		
Sub Tot	al:	2	2		1
Sub Tot Endocrine disorders Sub Tot Eye disorders Sub Tot Eye disorders Sub Tot Gastrointestinal disorders coded Preferred Term di tment Grouping: y Drug: If one of the sus led Therapy: If one of the	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 Tot	al:	7	8	1	
Gastrointestinal	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			
	Entorecento Eosinophilic oesophagitis Food poisoning Gastric fistula Gastric ulcer Gastric ulcer haemorrhage Gastritis erosive Gastrointestinal disorder Gastrointestinal haemorrhage Gastrointestinal mucosa hyperaemia Gastrointestinal mucosa hyperaemia Gastrointestinal necrosis Gastrointestinal perforation Gastrointestinal perforation Gastrointestinal perforation Gastrooesophageal reflux disease Haemorrhoidal haemorrhoids Hiatus hernia Ileus	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	
	lleus	1	1		

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	Impaired gastric emptying		1		
	Incarcerated inguinal hemia		1		
	Infantile vomiting		1		
	Inguinal hemia	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		
	Infantile vomiting Inguinal hemia Intestinal ischaemia Intestinal obstruction Intestinal obstruction Intestinal perforation Intestinal ulcer perforation Intestinal ulcer perforation Intra-abdominal fluid collection Intra-abdominal haematoma Large intestine perforation Lower gastrointestinal haemorrhage Meconium plug syndrome Mesenteric panniculitis Nausea Neonatal intestinal perforation Obstructive pancreatitis	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		
oded Preferred Te ment Grouping: / Drug: If one of th ad Therapy: If one	Upper gastrointestinal haemorrhage	3		1	
	Volvulus	1	1		
	Vomiting	5			

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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		
coded Preferred Term disp tment Grouping: ly Drug: If one of the susp lad Therapy: If one of the susp	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
lepatobiliary 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			
	Jaundice cholestatic Jaundice cholestatic Portal vein thrombosis Portosplenomesenter ic venous thrombosis al: Anaphylactic reaction Anaphylactic shock Anaphylactic shock Anaphylactic shock Anaphylactic shock Anaphylactic shock Drug hypersensitivity Food allergy Hypersensitivity Kidney transplant rejection cal: Abdominal abscess Abdominal sepsis Abdominal wall abscess Abscess oral	1			
Sub Tot	al:	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 Tot	al:	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		
	Anal abscess Appendicitis Appendicitis perforated Arteriosclerotic gangrene Arthritis bacterial Asymptomatic bacteriuria Atypical pneumonia Bacteraemia Bacterial sepsis Brain abscess Bronchiolitis Bronchiolitis Bronchitis Campylobacter gastroenteritis Cellulitis Cholangitis infective Cholecystitis infection Colonic abscess Complicated appendicitis erm displayed as Verbatim Term he suspect products on the case e of the suspect products on the case	2			
	Colonic abscess		2		
	Complicated appendicitis	2	3		

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.

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 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.
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 Placebo.
Pre Randomization / No Study Drug: If the case optimizer the both the presence of the suspect products on the case is placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION NO STUDY DRUG
	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	
	infection Diabetic foot infection Diverticulitis Emphysematous cholecystitis Empyema Endocarditis Endometritis Enterovirus infection Epstein-Barr virus infection Escherichia urinary tract infection Exanthema subitum Extradural abscess Focal peritonitis Gangrene Gastroenteritis adenovirus Gastroenteritis bacterial Gastroenteritis norovirus Gastroenteritis rotavirus Gastroenteritis viral		1		
	Gastroenteritis rotavirus		4		
	Gastroenteritis viral		3		

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.

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 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.
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 Placebo.
Pre Randomization / No Study Drug: If the case optimizer the both the case optimizer to be support and the case optimizer to be

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.



SOC	PT	BNT162B2;BNT162 B2S01;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		
	Herpes zoster oticus HIV infection Infected skin ulcer Infection Infectious pleural effusion Influenza Intervertebral discitis Kidney infection Labyrinthitis Large intestine infection Liver abscess Localised infection Lower respiratory tract infection viral Lung abscess Lyme disease Mastoiditis Meningitis bacterial Meningitis viral Metapneumovirus infection transplayed as Verbatim Term		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		

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.

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 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.
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 Placebo.
On the case of the suspect products on the case is Placebo and none are Study Drug or Blinded Therapy, the event will be displayed under Placebo.
On the case of the suspect products on the case is Placebo and none are Study drug, the event will be displayed under Placebo.
On the case of the suspect products on the case is Placebo and none are Study drug, the event will be displayed under Placebo.
On the case of the case of the suspect are does not have any designated study drug.
Description: The case of the cas

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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	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			
	Otitis media acute Parainfluenzae virus infection Pelvic abscess Pelvic inflammatory disease Penile abscess Penile infection Peritoneal abscess Peritoneal abscess Peritoneal abscess Peritonitis Peritonsillar abscess Pharyngeal abscess Pharyngeal abscess Pharyngeal abscess Pharyngitis streptococcal Pneumonia Pneumonia Pneumonia Pneumonia bacterial Pneumonia bacterial Pneumonia pneumococcal Pneumonia Postoperative abscess		1	1	
	Postoperative abscess		1		

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.

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 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.
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.
Comparison of the suspect products on the case is placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;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		
	Prostate infection Pulmonary tuberculosis Pyelonephritis Pyelonephritis acute Renal abscess Respiratory syncytial virus bronchiolitis Respiratory syncytial virus infection Respiratory tract infection viral Rhinovirus infection Salmonellosis Sepsis Sepsis neonatal Septic arthritis staphylococcal Septic shock Shigella sepsis Sinusitis Skin candida Skin infection soft tissue infection		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			

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.

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 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.
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.
Compare the study Drug and the study Drug. Blocebo and none are Study drug, the event will be displayed under Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;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 Tota	al:	216	277	24	1
Sub Tota Injury, poisoning and procedural complications coded Preferred Term dis itment Grouping: by Drun: If one of the sus	Abdominal injury	1			

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.

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 is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded 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 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.



SOC	PT	BNT162B2;BNT162 B2S01;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			
	Anastomotic stenosis Animal bite Ankle fracture Arterial injury Arthropod bite Brain contusion Burns second degree Burns third degree Cervical vertebral fracture Chest injury Clavicle fracture Colon injury Concussion Craniocerebral injury Delayed recovery from anaesthesia Epiphyseal fracture Exposure via breast milk Facial bones fracture Fall Femur fracture Fibula fracture Fibula fracture art fracture Flail chest Foot fracture erm displayed as Verbatim Term he suspect products on the case e of the suspect products on the case	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 viə breəst milk	1			
	Facial bones fracture	2	2		
	Fəll	7	2		
	Femur fracture	3	3		
	Fibula fracture	2			
	Flail chest		1		
	Foot fracture	4	1	1	

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 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.
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.
Comparetor: If the case approximation of the Study Drug. Blocebo and none are Study drug, the event will be displayed under Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;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		
	Foreign body ingestion Fractured sacrum Fractured skull depressed Gastrointestinal anastomotic complication Gun shot wound Hand fracture Head injury Hip fracture Humerus fracture Infusion related reaction Injury Injury to brachial plexus due to birth trauma Intestinal anastomosis complication Jaw fracture Joint dislocation Ligament rupture Limb injury Lower limb fracture		1		
	Intestinal anastomosis complication	1			
	Jaw fracture	1			
	Joint dislocation	2			
	Ligament rupture	2	2		
	Limb injury	1			
	Lower limb fracture	1	2	1	

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.

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 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.
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 Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;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			
oded Preferred T ment Grouping:	Procedural haemorrhage		1		
	Procedural pain	2			
	Radius fracture	1		1	
	Rib fracture	6	3		
	Road traffic accident	4	1 1		
	Scapula fracture	1	1		

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.

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 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.
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 Placebo.
Or preventer: If the case extension of the Study Drug.
Comparison of No Study Drug.
Output: The case extension of the Study Drug.
Description: The case extension of the suspect products on the case is placebo.
Preventer: If the case extension of the suspect is placebo.
Description: The case extension of the case is placebo.
Preventer: If the case extension of the suspect is placebo.
Description: The case extension of the case is placebo.
Description: The case extension of the case extension of the case is placebo.
Description: The case extension of the case ext

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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION NO STUDY DRUG
	Skeletal injury	1 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		
coded Preferred T ment Grouping: / Drun: If one of t	Traumatic intracranial haemorrhage		2		
	Traumatic liver injury		2		
	Traumatic renal injury	1			
	Ulna fracture	2	1		
	Upper limb fracture	4	2		

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.

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 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.
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 Placebo.
Or preventer: If the case extension of the Study Drug.
Comparison of No Study Drug.
Output: The case extension of the suspect products on the case is placebo.
Pre Randomization / No Study Drug: If the case the Study Drug.
Description:
De

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.



SOC	PT	BNT162B2;BNT162 B2S01;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 1	Fotal:	146	218	17	•
nvestigations	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		
Sub Three stigations	Hepatic enzyme increased	2	1		
	Laboratory test abnormal	1			
	Ultrasound foetal abnormal		1		
	Urine output decreased	1			

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.

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 is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded 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 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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	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	
	Hyperkələemiə	1			
	Hypernətraemia			1	
	Hypervolaemia		1		
Sub Total Musculoskeletal and connective tissue disorders coded Preferred Term disp timent Grouping: by Drug: If one of the suspe ded Therapy: If one of the suspe	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	ł
Musculoskeletal and connective tissue disorders	Arthrəlgiə	4	2		
	Arthritis	3	1	1	
	Back pain	8	1		

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 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 one have any designated study drug, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case one have any designated study drug, the event will be displayed under Placebo.

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.



90C	PT	BNT162B2;BNT162 B2S01;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		
	Connective tissue disorder Costochondritis Intervertebral disc compression Intervertebral disc degeneration Intervertebral disc protrusion Kyphosis Lumbar spinal stenosis Muscular weakness Musculoskeletal chest pain Myalgia Myositis Osteoarthritis Osteochondritis Osteochondrosis Osteonecrosis Pain in extremity Pathological fracture Psoriatic arthropathy Rhabdomyolysis Rheumatoid arthritis		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			

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.

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 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.
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.
Comparison of the suspect products on the case is placebo and none are Study drug, the event will be displayed under Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;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		
Sub Tota Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Adrenal gland cancer		1		
	Adrenal neoplasm	1			
	Adrenocortical carcinoma	1			
	Anal cancer	1			
	Angiosarcoma	1			

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 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.



SOC	PT	BNT162B2;BNT162 B2S01;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			

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.

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 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.
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 Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	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	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		
	Colon cancer Colon cancer stage III Colon neoplasm Colorectal adenoma Cutaneous T-cell lymphoma Ductal adenocarcinoma of pancreas Endometrial adenocarcinoma Endometrial cancer Follicular lymphoma Gallbladder cancer Stage II Gastric cancer Gastrointestinal stromal tumour Glioblastoma Hepatic cancer Hepatic cancer Hepatic cancer Hepatic cancer Hepatic cancer metastatic Hormone receptor positive breast cancer	1	2		

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.

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 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 Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION NO STUDY DRUG
	Hypergammaglobulin aemia 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		
	proliferative breast lesion Invasive breast carcinoma Invasive ductal breast carcinoma Invasive lobular breast carcinoma Large intestine benign neoplasm Laryngeal papilloma Leukaemia Leydig cell tumour of the testis Lipoma Liposarcoma recurrent Lung adenocarcinoma Lung cancer metastatic Lung carcer metastatic Lung neoplasm malignant Lymphocytic leukaemia Malignant melanoma		1		
	Lung neoplasm malignant	3			
	Lymphocytic leukaemia		1		
	Malignant melanoma	2	5	1	

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.

Study Drug. In 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 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.
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.
Comparenter: If the case optimization are the Study Drug. Blogebo and none are Study drug, the event will be displayed under Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION NO STUDY DRUG
	Məlignant melənomə in situ			1	
	Məntle cell lymphomə	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		

Study Drug. In 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 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.
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.
Comparetor: If the case actioners the Study Drug. Blocebo actions purposed and bloce any designated study drug, the event will be displayed under Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;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	
	Non-Hodgkin's lymphoma recurrent Non-small cell lung cancer stage III Non-small cell lung cancer stage IV Ocular melanoma Oesophageal adenocarcinoma Oesophageal carcinoma Oropharyngeal cancer Oropharyngeal cancer recurrent Oropharyngeal squamous cell carcinoma Ovarian adenoma Ovarian cancer Ovarian cancer stage I Ovarian neoplasm Pancreatic carcinoma metastatic Pancreatic neoplasm Pancreatic neoplasm Pancreatic neoplasm		2		
	Ovarian adenoma	1			
	Ovarian cancer	3	1		
	Ovarian cancer stage	1			
	Ovarian neoplasm	1			
	Pancreatic carcinoma	5	2	1	
	Pancreatic carcinoma metastatic	1	2		
	Pancreatic neoplasm	1			

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.

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 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.
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 Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;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		
	endometrial carcinoma Papillary thyroid cancer Parathyroid tumour benign Penis carcinoma metastatic Pituitary tumour benign Plasma cell myeloma Pleural mesothelioma malignant Polycythaemia vera Prostate cancer Prostate cancer Prostate cancer Prostate cancer metastatic Prostate cancer stage II Rectal cancer metastatic Renal cancer recurrent Renal cell carcinoma Renal neoplasm Rhabdomyosarcoma Salivary gland cancer stage IV	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			

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.

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 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 one have any designated study drug, the event will be displayed under Placebo.
Pre Randomization / No Study Drug: If the case one have any designated study drug, the event will be displayed under Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION NO STUDY DRUG
	Sarcoma metastatic	1			
	Sebaceous carcinoma		1		
	Seminoma		1		
	Small cell carcinoma	1			
	Squamous cell carcinoma	1			
	Small cell carcinoma Squamous cell carcinoma Squamous cell carcinoma of the cervix Squamous cell carcinoma of the vagina Teratoma Teratoma Testis cancer Thyroid cancer Tongue cancer metastatic Tonsil cancer Transitional cell carcinoma Transitional cell carcinoma Transitional cell carcinoma recurrent Triple negative breast cancer Uterine leiomyoma Uterine leiomyoma Uterine leiomyoma Vascular neoplasm Total: Alcoholic seizure	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 T	otal:	191	115	26	
Nervous system disorders	Alcoholic seizure		1		

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.

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 is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded 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 Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, 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.



SOC	PT	BNT162B2;BNT162 B2S01;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 hæmorrhage	1	1		
	Cerebral infarction		1		
	Cerebral venous thrombosis		1		
	Cerebrovascular accident	28	11	1	
	Cervicogenic headache		1		
	Coma neonatal		1		
	Aphasia Aphasia Autonomic nervous system imbalance Basal ganglia haemorrhage Bell's palsy Brachial plexopathy Brain stem infarction Carotid artery aneurysm Carotid artery stenosis Cerebral haemorrhage Cerebral tunnel syndrome Cerebral venous thrombosis Cerebral venous thrombosis Cerebrovascular accident Cervicogenic headache Coma neonatal Dementia Alzheimer's type Dizziness		1	1	
	Dizziness	1	3		

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.

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 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.
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.
Compared to the case actions on the case is placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	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		

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.

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 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.
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.
Compared to the case optimization of the suspect products on the case is placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;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			
	Migraine Multifocal motor neuropathy Myasthenia gravis Myelitis transverse Neonatal seizure Nervous system disorder Neuropathy peripheral Optic neuritis Paraesthesia Peripheral nerve lesion Polyneuropathy Presyncope Psychogenic seizure Reversible cerebral vasoconstriction syndrome Sedation Seizure Serotonin syndrome Somnolence Spinal claudication	1			
	Sedation	1			
	Seizure	8	1		
	Serotonin syndrome	1			
	Somnolence	1			
	Spinal claudication	1			

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.

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 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.
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.
Comparetor: If the case approximation of the Study Drug. Blocebo and none are Study drug, the event will be displayed under Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATIO NO STUDY DRU
	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			
		17	14	4	
	Abortion spontaneous	"			
Sub Total: Pregnancy, puerperium and perinatal conditions	Abortion spontaneous Abortion spontaneous incomplete		1		

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 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.
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 Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;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		
	Cephalo-pelvic disproportion Ectopic pregnancy Failed induction of labour Failed trial of labour Foetal death Foetal distress syndrome Foetal distress syndrome Foetal growth restriction Foetal hypokinesia Gestational hypertension Haemorrhage in pregnancy Jaundice neonatal Low birth weight baby Meconium in armiotic fluid Meconium stain Omphalorrhexis Placental insufficiency Postpartum haemorrhage Pre-eclampsia Premature baby		1		
	Postpartum haemorrhage	1	3		
	Pre-eclampsia	1	6		
	Premature baby		1	1	

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.

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 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.
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.
Comparison of the suspect products on the case is placebo and none are Study drug, the event will be displayed under Placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION NO STUDY DRUG
	Premature delivery	1	1	1	
	Premature separation of placenta		4		
Sub Tota Psychiatric disorders	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 Tota	11:	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		
		1	2		

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 the study Drug, the event will be displayed under study Drug regardless of other suspect products on the case is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded 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 Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, 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.



SOC	PT	BNT162B2;BNT162 B2S01;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		
	Mənia	1			
	Mental disorder	2	1		
	Drug abuse Drug dependence Hallucination Major depression Mania Mental disorder Mental status changes Obsessive-compulsiv e disorder Panic attack Post-traumatic stress disorder Psychotic behaviour Suicidal behaviour Suicidal ideation Suicide attempt tal: Acute kidney injury Bladder prolapse End stage renal disease Glomerulonephritis Hydronephrosis Nephrolithiasis isplayed as Verbatim Term spect products on the case	2			
	Obsessive-compulsiv e 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 To	tal:	72	46	7	1
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		

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 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 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.



SOC	PT	BNT162B2;BNT162 B2S01;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		
	Uninary retention	4			
	Urinary tract obstruction	1			
	Vesicoureteric reflux		1		
Sub Tota		32	35	1	
Reproductive system and breast disorders	Abnormal utenne bleeding	1			
	Adenomyosis		2		
	Adnexal torsion	1	1	1	
	Benign prostatic hyperplasia	3		2	
	Breast hyperplasia		1	1	
Sub Tota Reproductive system and breast disorders	Endometrial thickening		1		
	Endometriosis	1	2		
	Heavy menstrual bleeding	3			

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.

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 is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded 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 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.



SOC	PT	BNT162B2;BNT162 B2S01;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	- T
Respiratory, thoracic and mediastinal disorders	oedema	1			
	Acute respiratory distress syndrome	3			
	Acute respiratory	11	7		
	failure				
		3	6		
	failure	3	6		1
	failure Asthma	3			1
	failure Asthma Asthmatic crisis				1
	failure Asthma Asthmatic crisis Atelectasis Bronchial		1		

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 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.
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 Placebo.
Or preventer: If the case action of the Study Drug.
Comparison of the suspect products on the case is placebo and none are Study drug, the event will be displayed under Placebo.
Or preventer: If the case action of the suspect products on the case is placebo.
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Preventer: If the case action

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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION NO STUDY DRUG
	Diaphragmatic paralysis	1			
	Dyspnoea	6	6		
	Dyspnoea exertional	1	2		
	Нурохіа	4	2		
	Interstitial lung disease	1	2		
	Hypoxia Interstitial lung disease Meconium aspiration syndrome Nasal septum deviation Negative pressure pulmonary oedema Neonatal hypoxia Neonatal pneumothorax Neonatal respiratory distress Neonatal respiratory distress syndrome Neonatal respiratory distress syndrome Neonatal respiratory distress syndrome Neonatal respiratory failure Neonatal respiratory Pleural effusion Pleural effusion Pleural effusion Pleural effusion Pleural effusion Pleural effusion Pleunonary embolism Pulmonary embolism Pulmonary fibrosis Pulmonary mass		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		

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.

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 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.
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.
Comparison of the suspect products on the case is placebo.

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.



SOC	PT	BNT162B2;BNT162 B2S01;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	1	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	I	1
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		second and a second second second	
Vascular disorders	Accelerated hypertension		1		
	Aneurysm	1			
	Aortic aneurysm	1	1	1	
	Aortic dissection	1	1		

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.

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 is Blinded Therapy and none are the Study Drug, then the event will be displayed under Blinded 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 Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, 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.



SOC	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZATION NO STUDY DRUG
	Aortic rupture	1	1		
	Aortic stenosis	1		2	
	Arteriosclerosis	1	3		
	Cyanosis		1	1	
	Cyanosis Deep vein thrombosis Embolism Haematoma Hypertension Hypertensive crisis Hypertensive crisis Hypertensive emergency Hypotension Hypotension Hypotension Hypotension Infarction Neonatal hypotension Neurogenic shock Orthostatic hypotension Penetrating aortic ulcer Peripheral artery occlusive disease Peripheral artery occlusion	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			
	lliac 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			

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.

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 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.
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.
Comparison of the suspect products on the case is placebo.

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.



	PT	BNT162B2;BNT162 B2S01;BNT162B2 OMI	BLINDED THERAPY	PLACEBO	PRE RANDOMIZAT NO STUDY D
	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 Tota	al:	45	38	6	I.
Total Number of Cases:	1	1, 16 1	1,054	127	2
Total Number of Events	;	1,501	1, 414	168	4
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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 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 Placebo.
Pre Randomization / No Study Drug: If the case does not have any designated study drug, the event will be displayed under Placebo.

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.