

# **Dossier zur Nutzenbewertung gemäß § 35a SGB V**

*Gozetotid (Locametz®)*

Novartis Pharma GmbH

## **Modul 4 A**

*Identifizierung von Patienten mit einem PSMA-positiven, progredienten, metastasierten, kastrationsresistenten Prostatakarzinom (mCRPC), bei denen eine auf PSMA abzielende Therapie angezeigt ist*

## **Anhang 4-H Kaplan-Meier-Kurven**

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**Anhang 4-H: Kaplan-Meier-Kurven**

**Anhang 1: Unerwünschte Ereignisse nach System Organ Class und Preferred Term**

**Anhang 1.1: UE jeglichen Schweregrads**

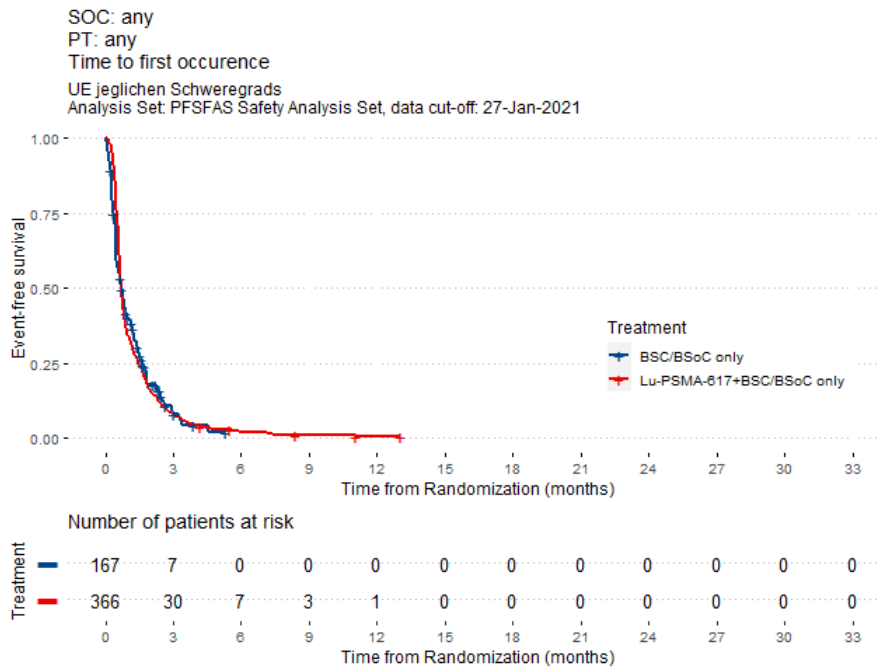


Abbildung 1: UE jeglichen Schweregrads: Time to first occurrence of SOC: any; PT: any

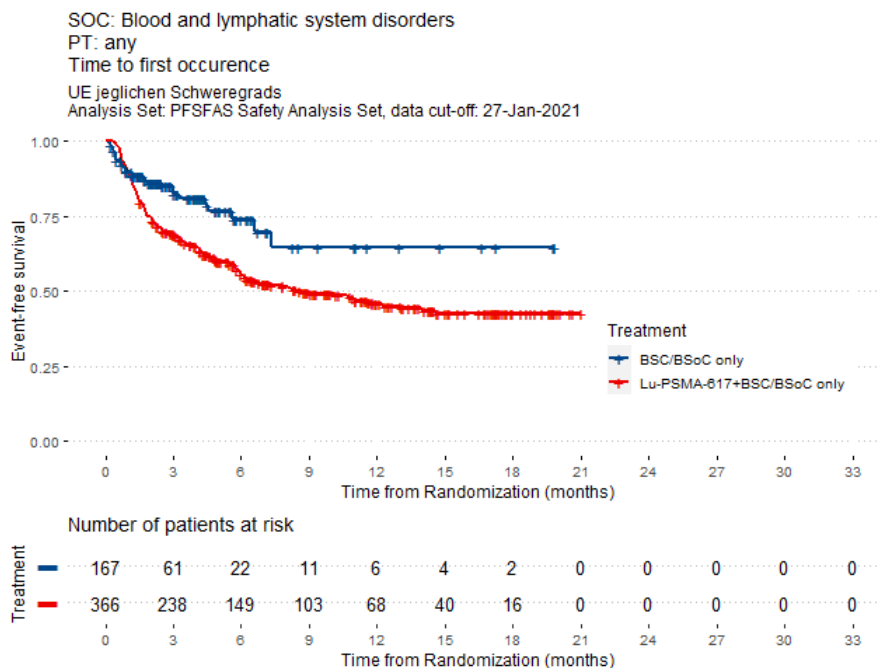


Abbildung 2: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: any

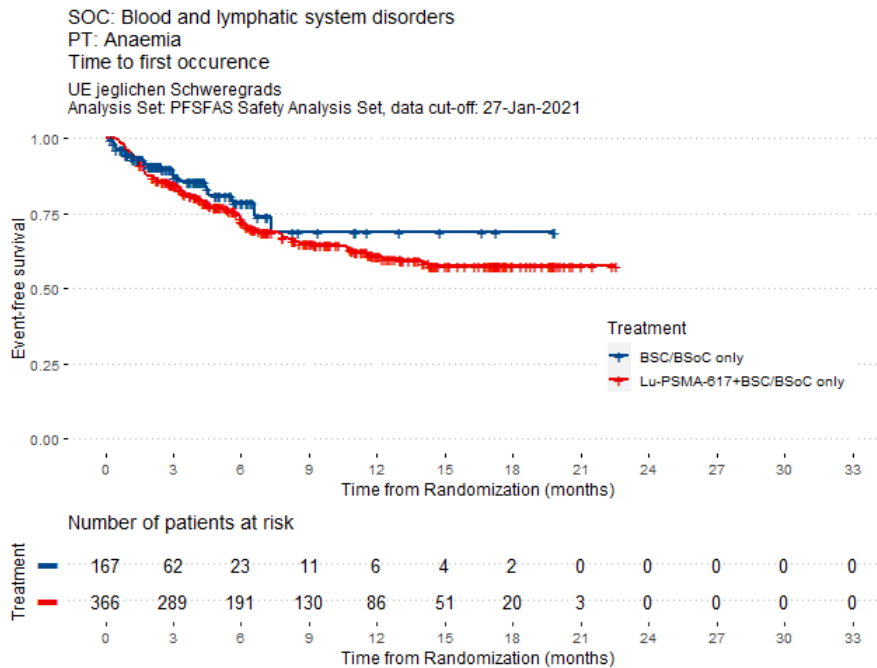


Abbildung 3: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Anaemia

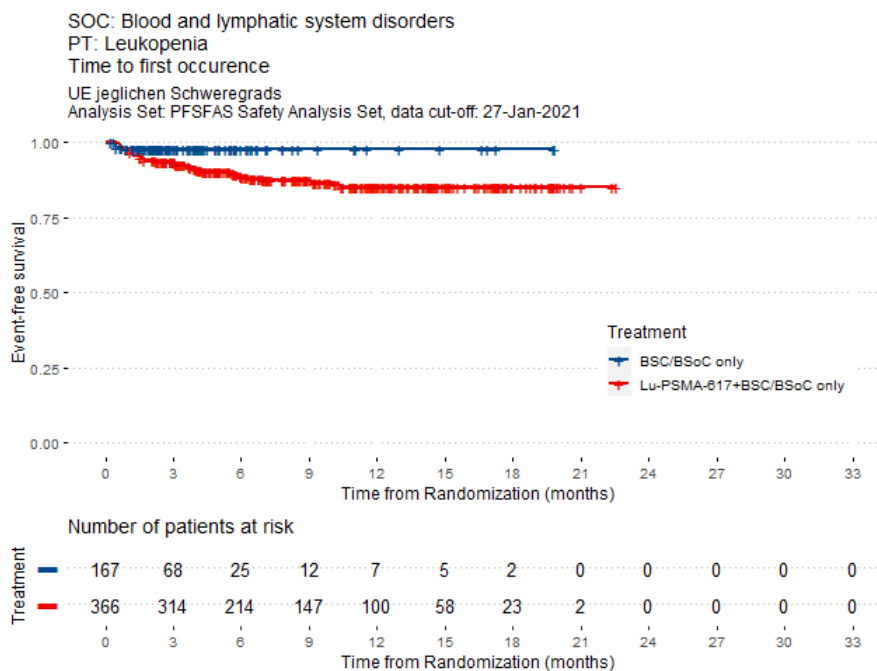


Abbildung 4: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Leukopenia

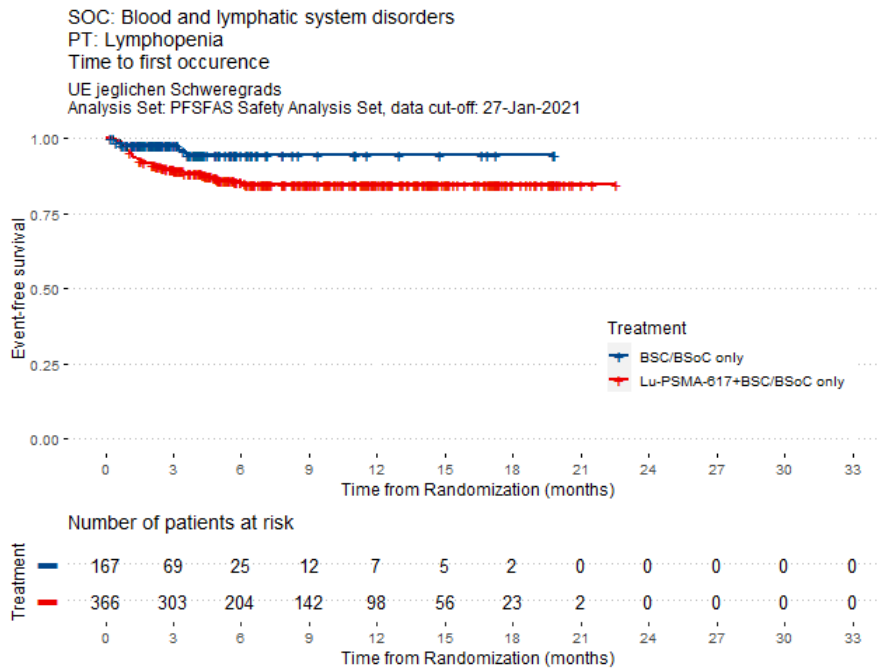


Abbildung 5: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Lymphopenia

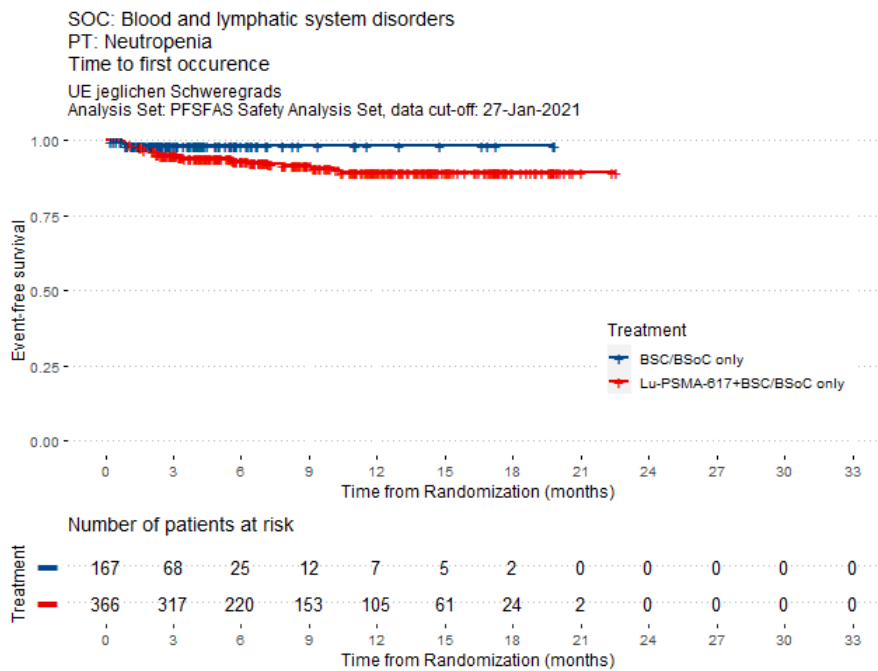


Abbildung 6: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Neutropenia

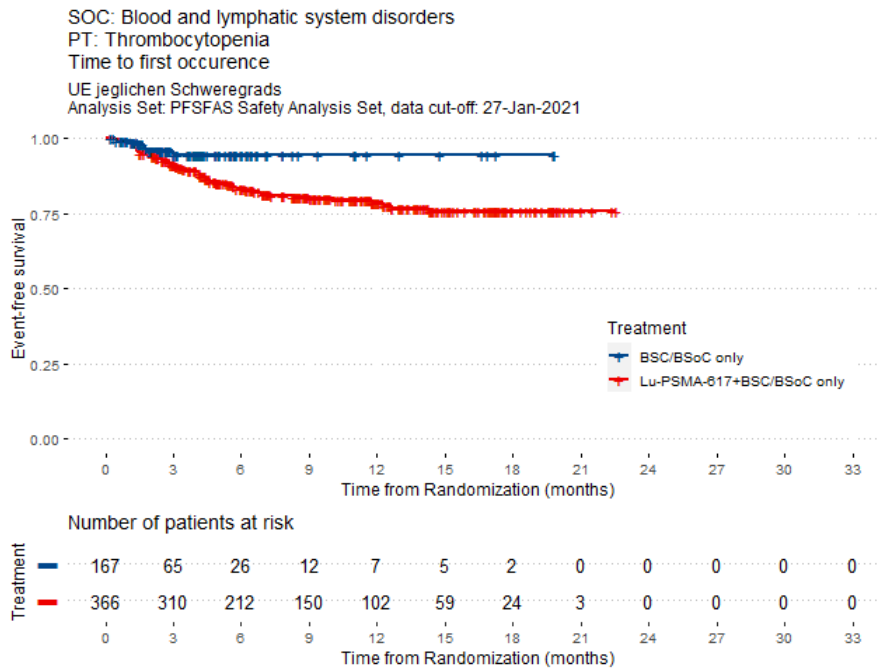


Abbildung 7: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Thrombocytopenia

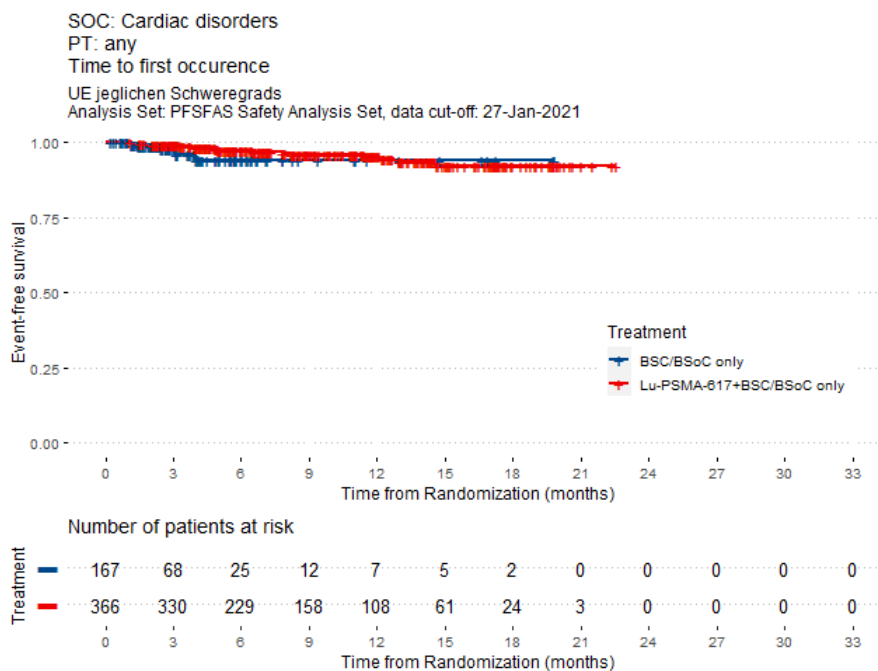


Abbildung 8: UE jeglichen Schweregrads: Time to first occurrence of SOC: Cardiac disorders; PT: any

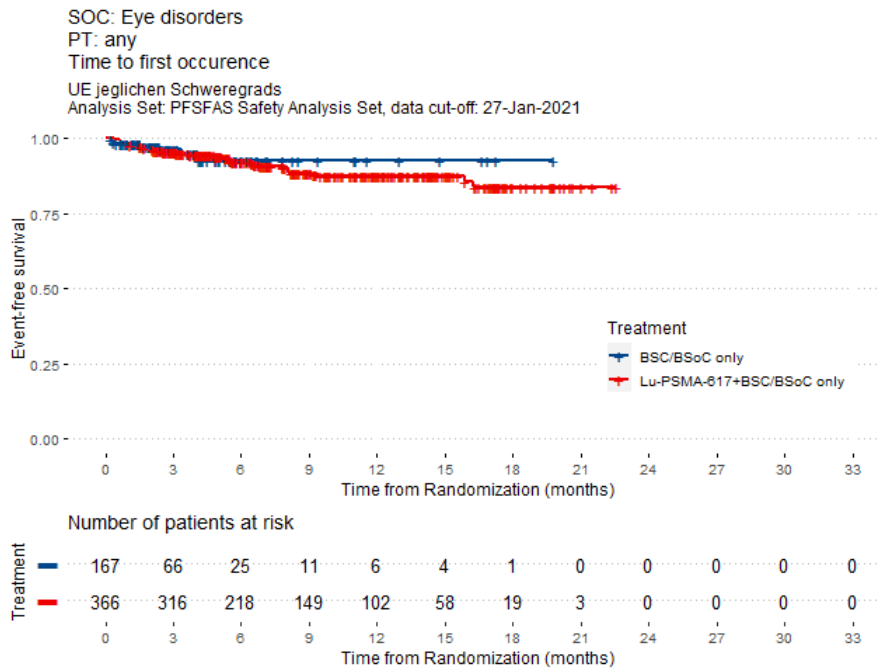


Abbildung 9: UE jeglichen Schweregrads: Time to first occurrence of SOC: Eye disorders; PT: any

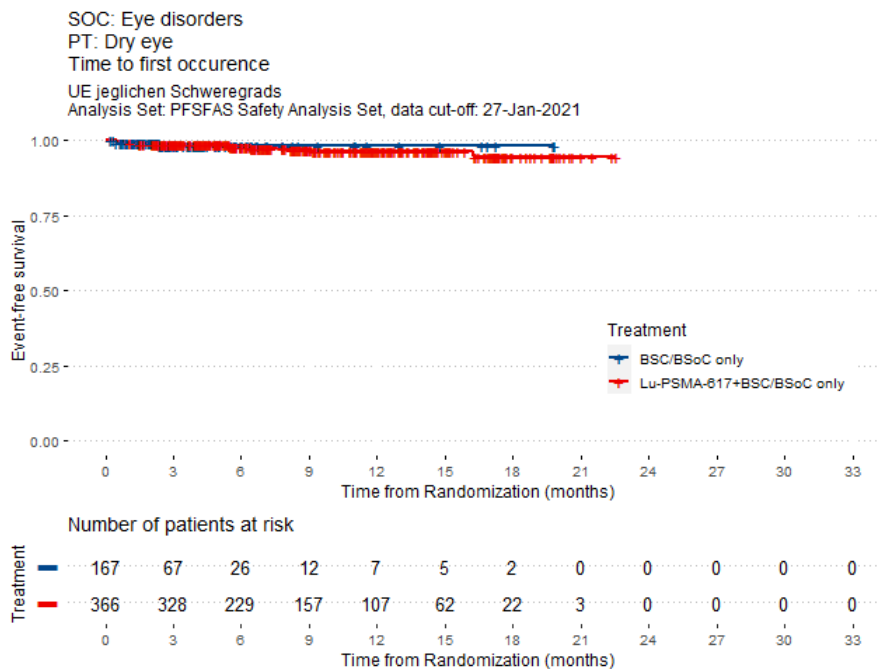


Abbildung 10: UE jeglichen Schweregrads: Time to first occurrence of SOC: Eye disorders; PT: Dry eye



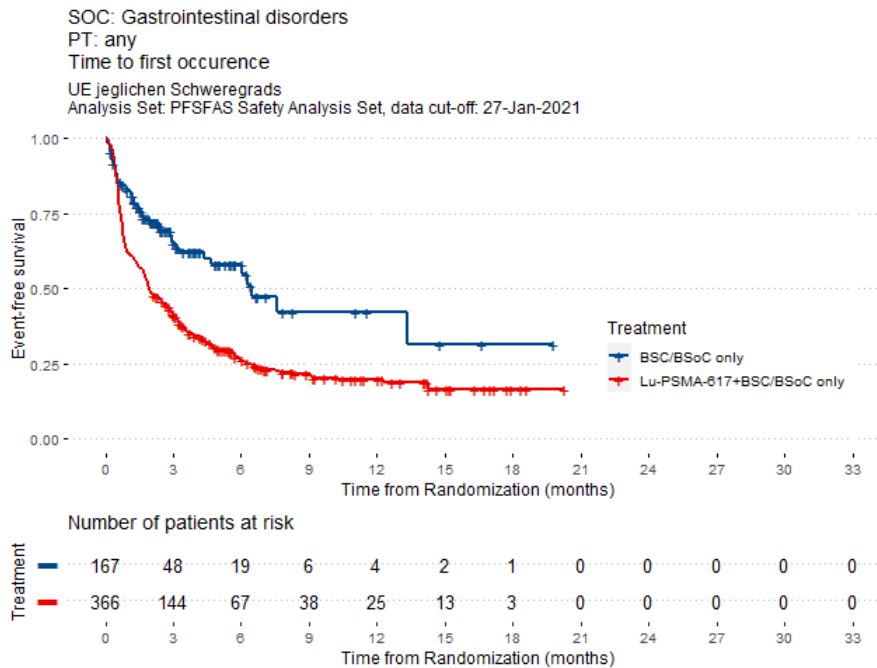


Abbildung 11: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: any

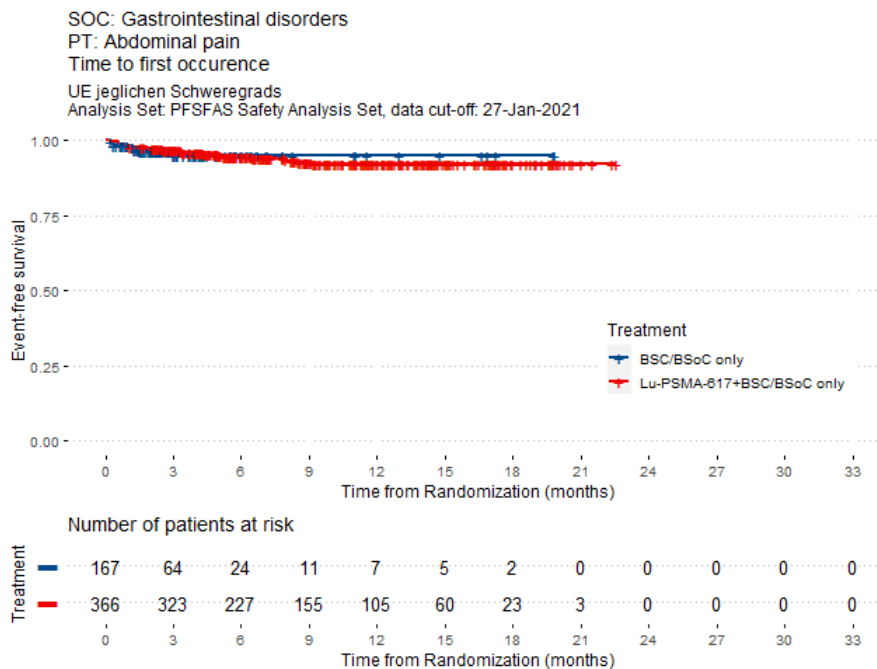


Abbildung 12: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Abdominal pain

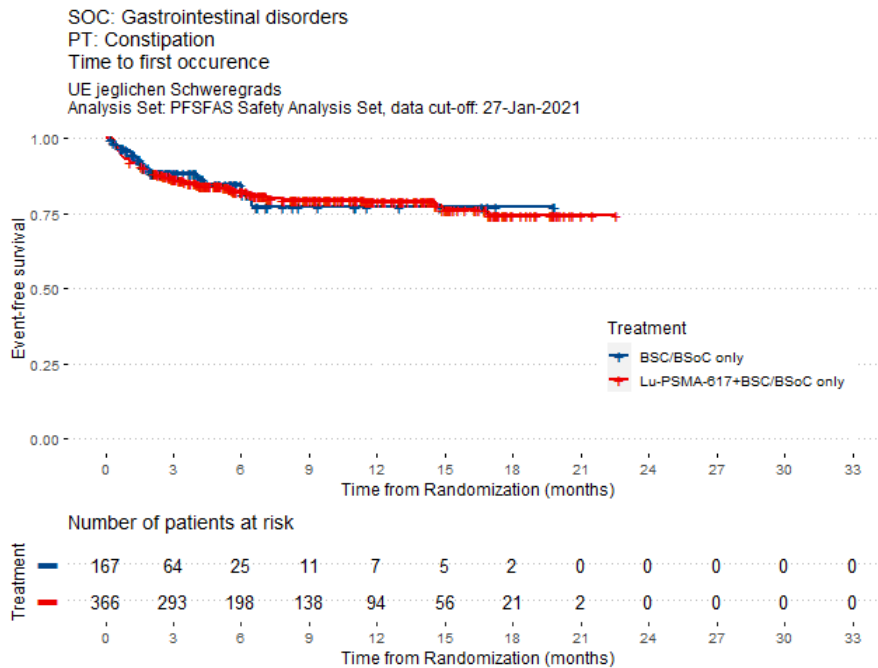


Abbildung 13: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Constipation

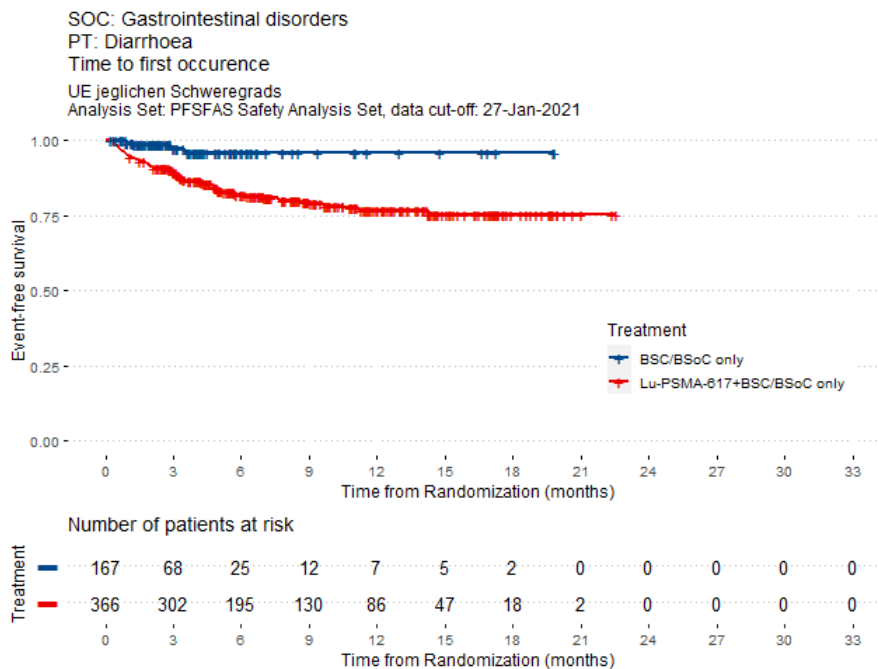


Abbildung 14: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Diarrhoea

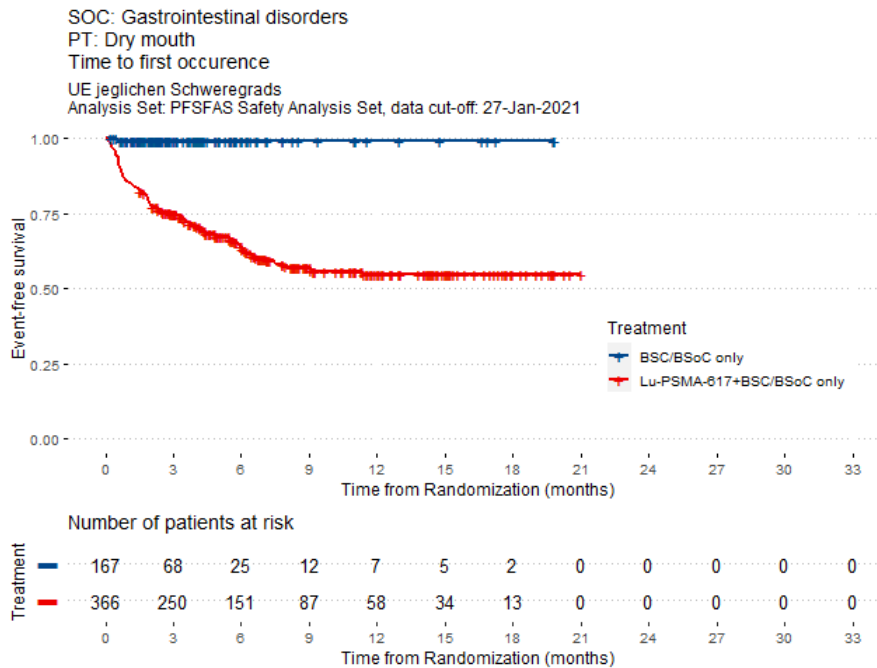


Abbildung 15: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Dry mouth

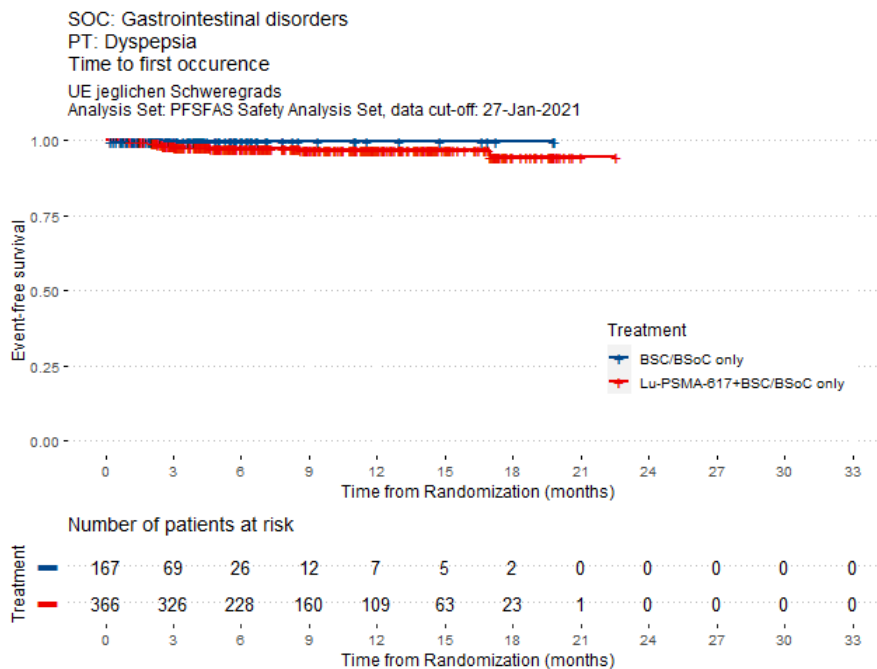


Abbildung 16: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Dyspepsia

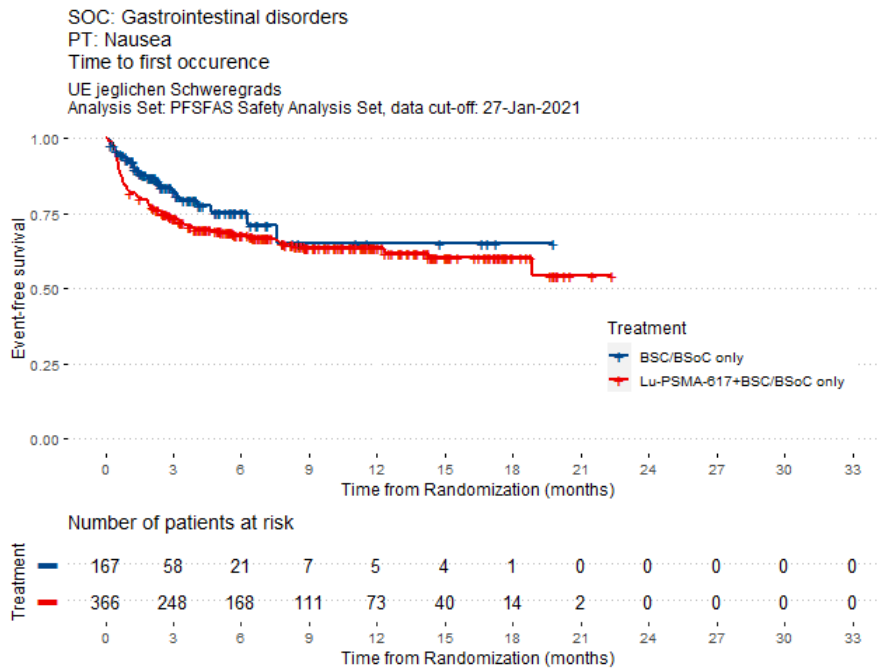


Abbildung 17: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Nausea

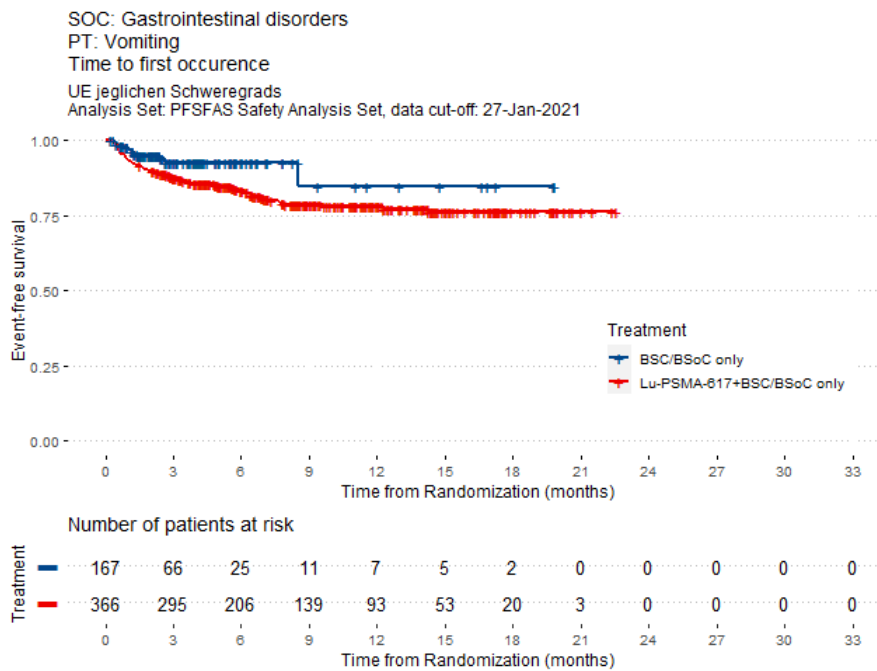


Abbildung 18: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Vomiting

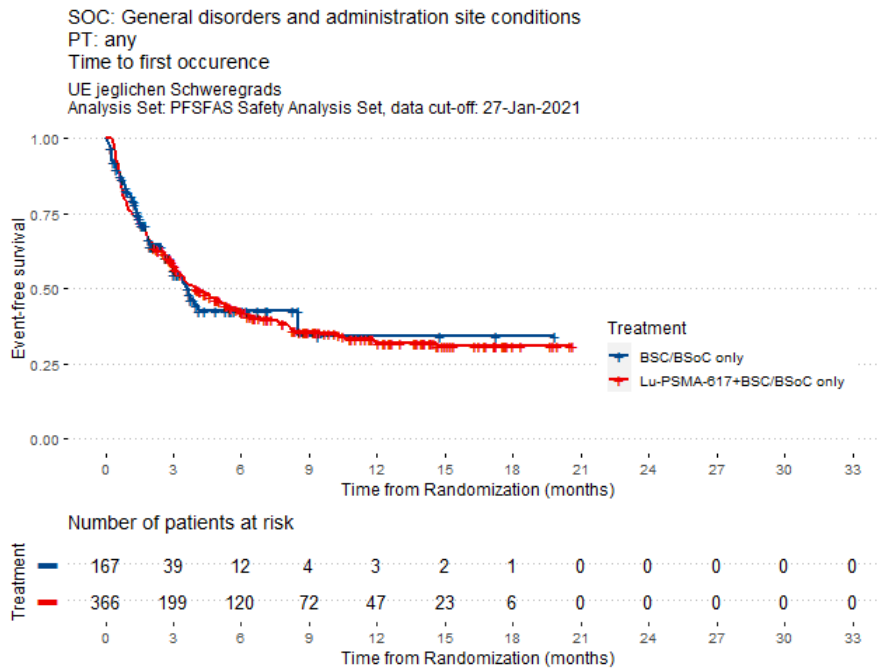


Abbildung 19: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: any

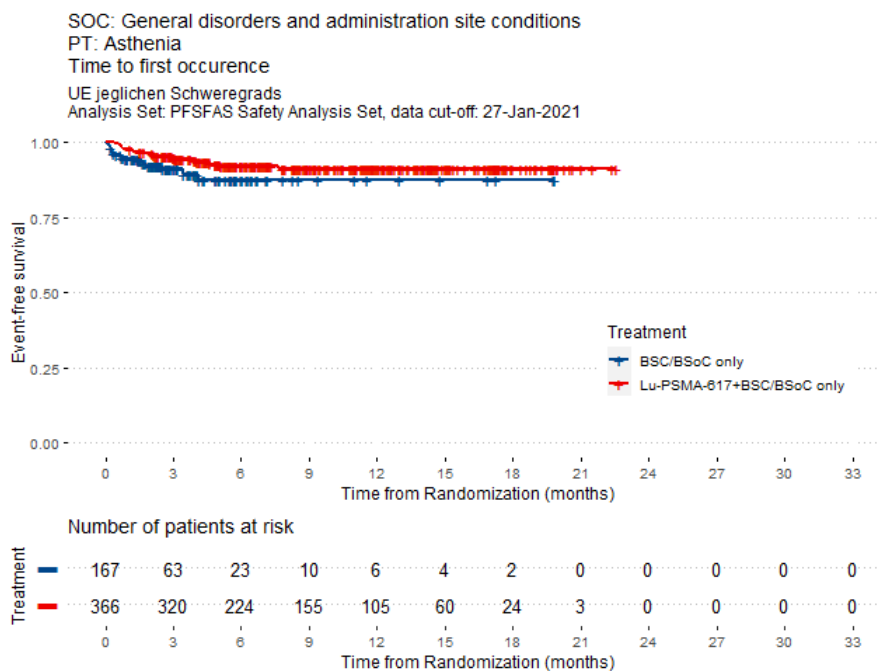


Abbildung 20: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Asthenia

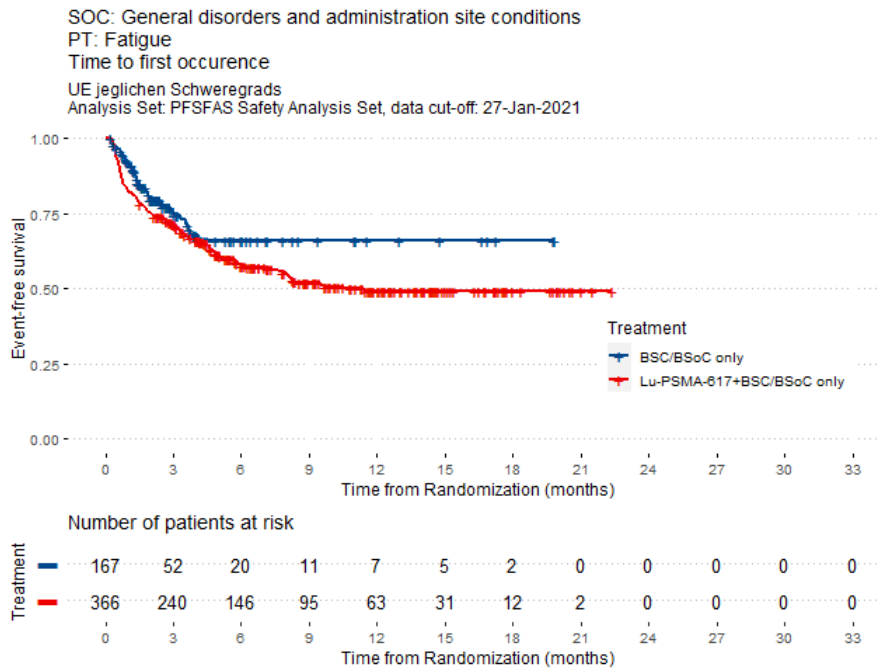


Abbildung 21: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Fatigue

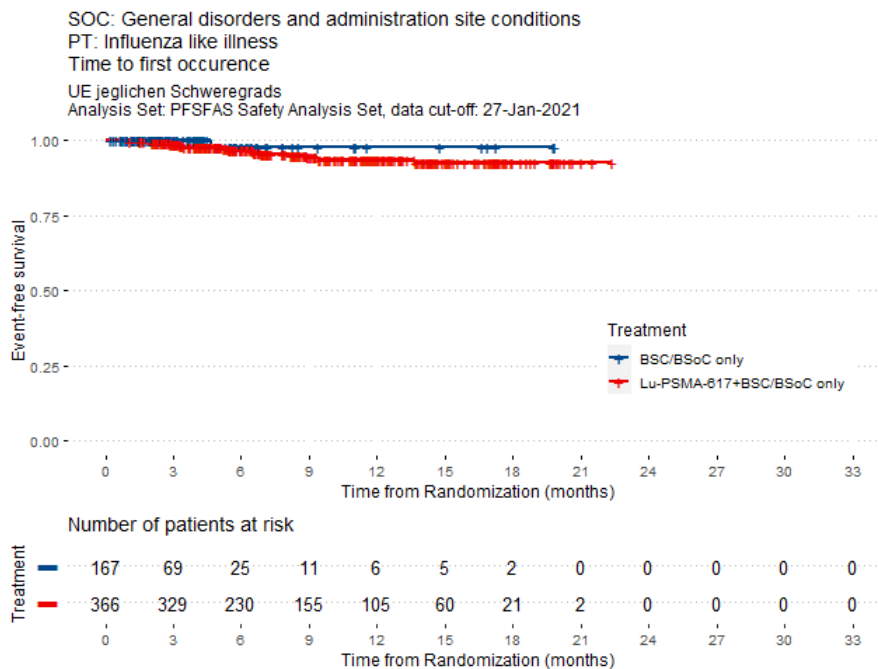


Abbildung 22: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Influenza like illness

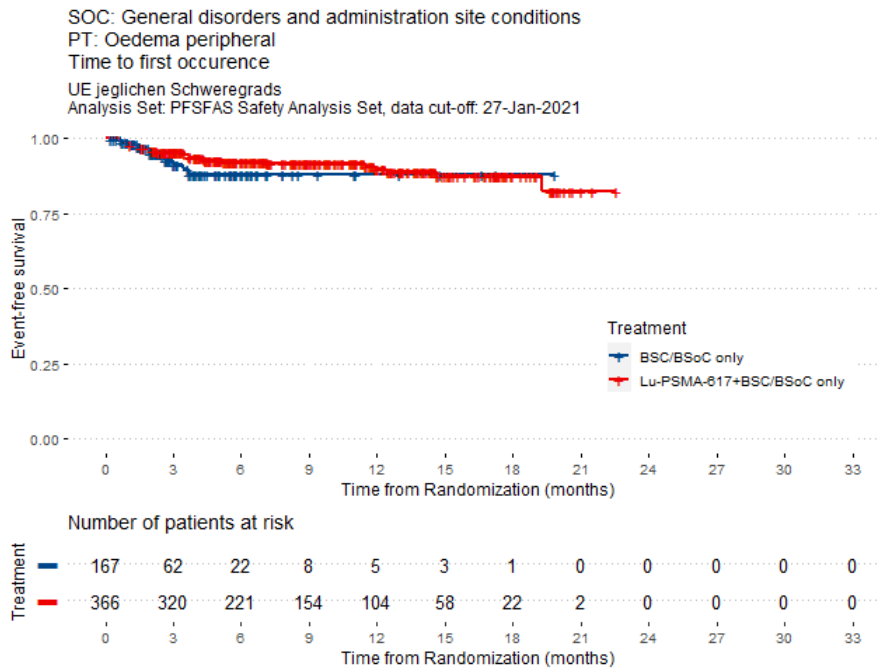


Abbildung 23: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Oedema peripheral

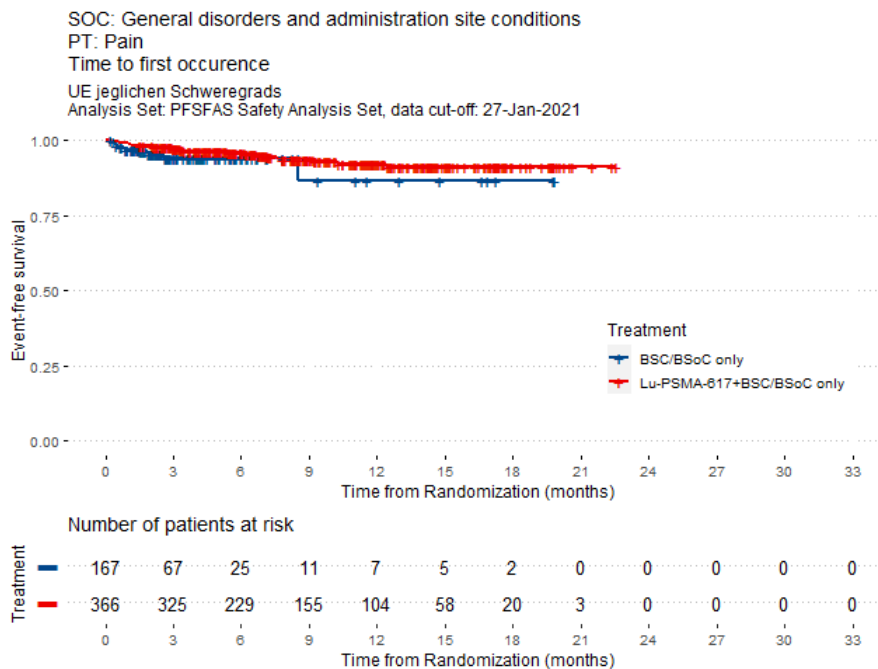


Abbildung 24: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Pain

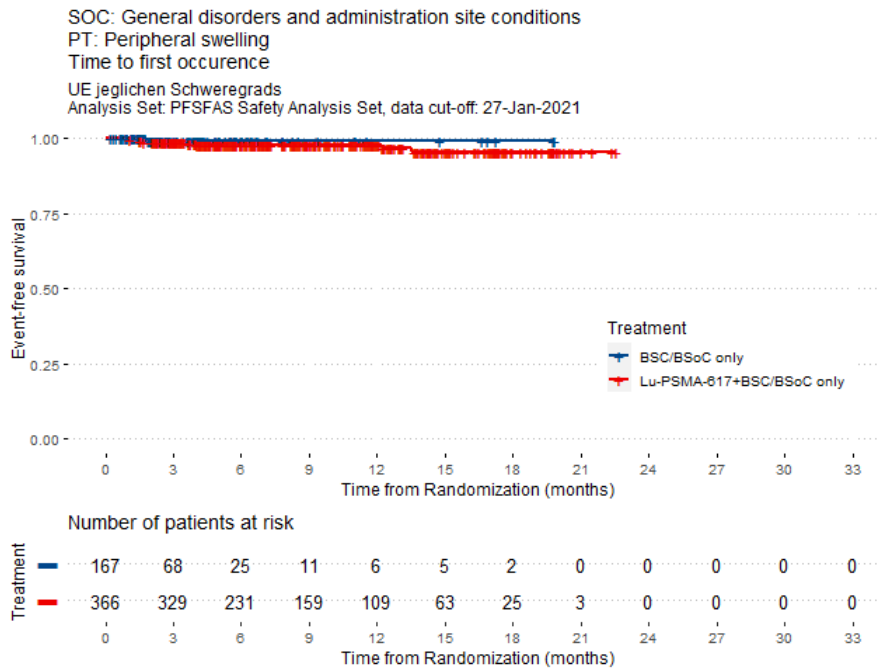


Abbildung 25: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Peripheral swelling

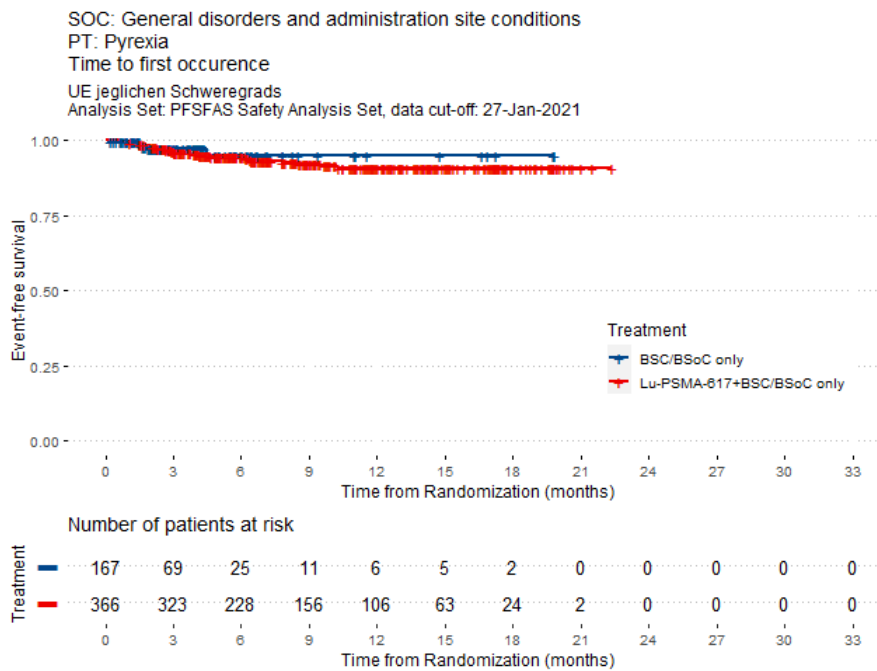


Abbildung 26: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Pyrexia



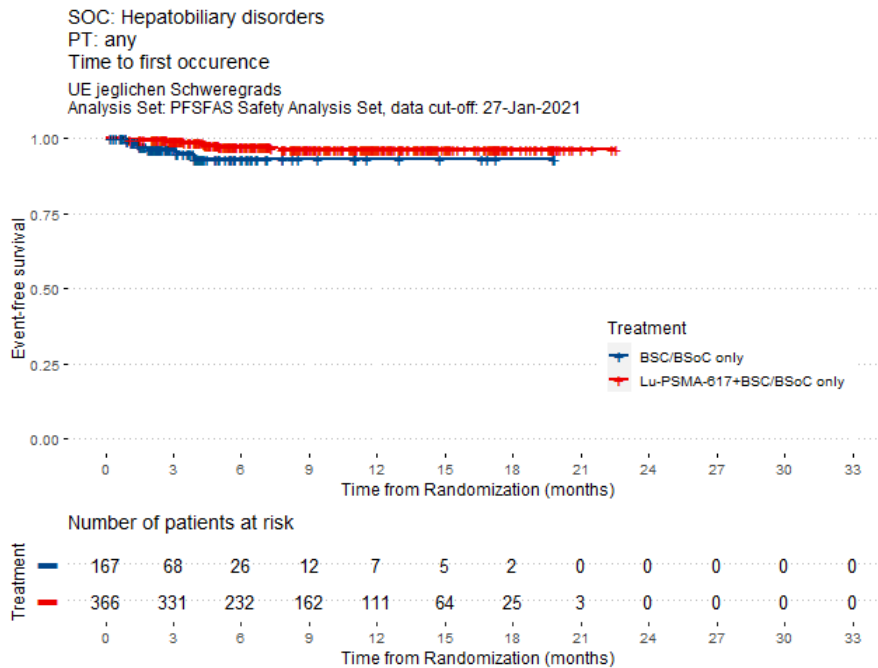


Abbildung 27: UE jeglichen Schweregrads: Time to first occurrence of SOC: Hepatobiliary disorders; PT: any

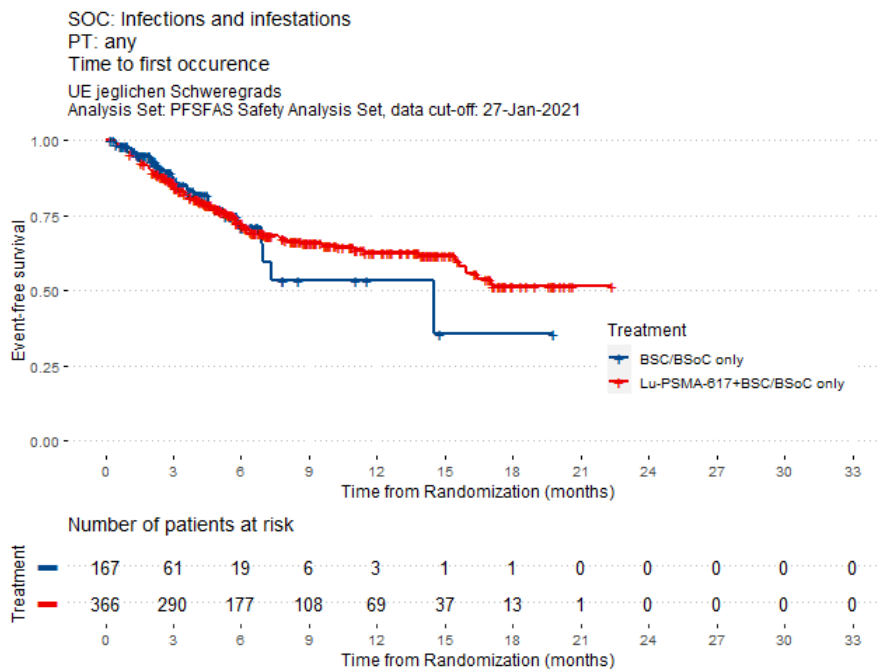


Abbildung 28: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: any

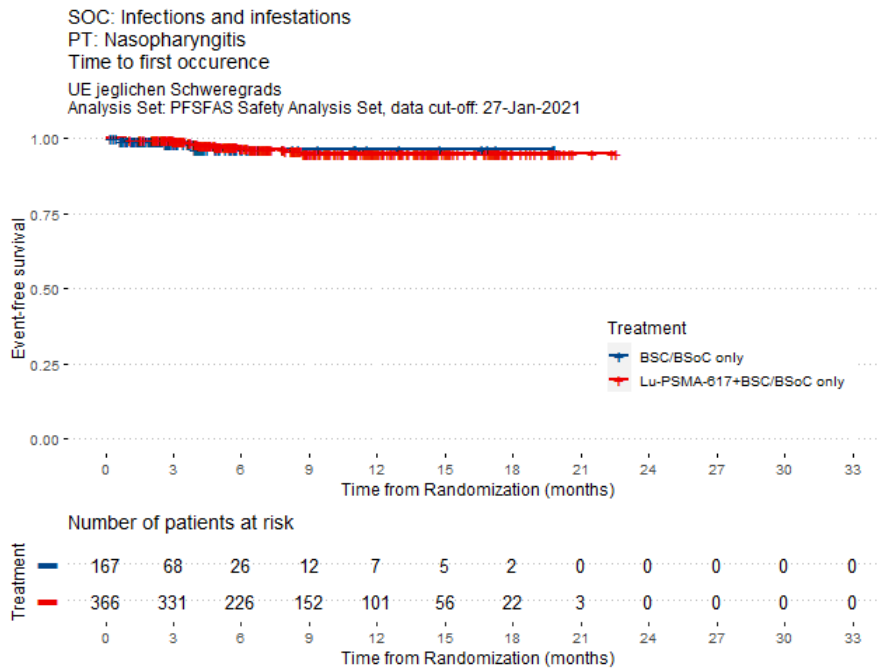


Abbildung 29: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Nasopharyngitis

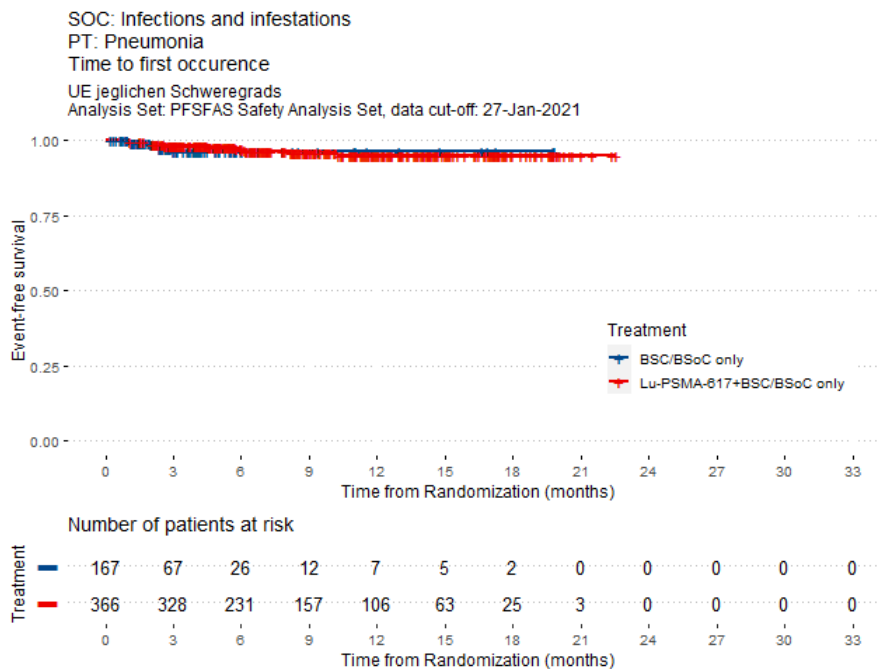


Abbildung 30: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Pneumonia

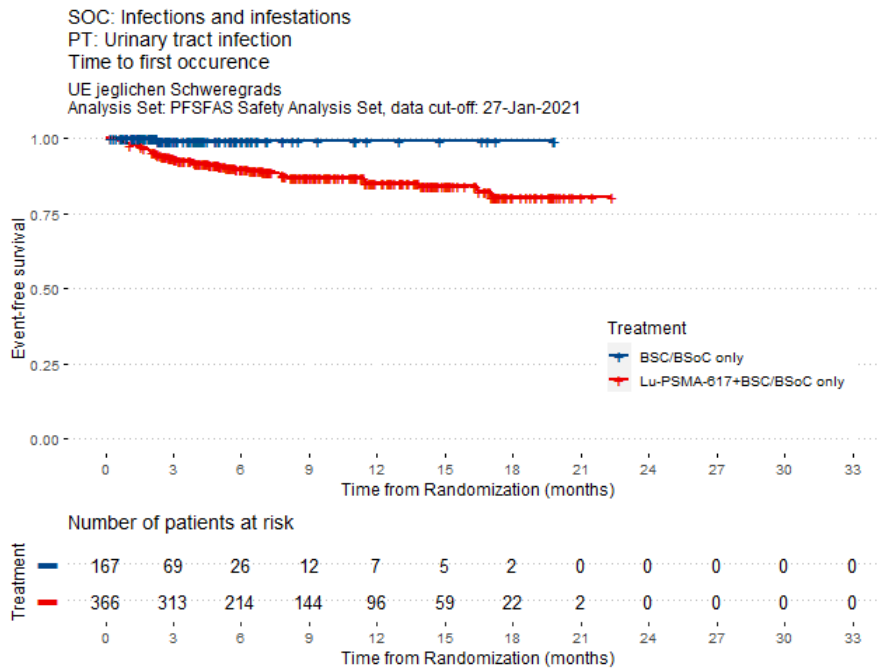


Abbildung 31: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Urinary tract infection

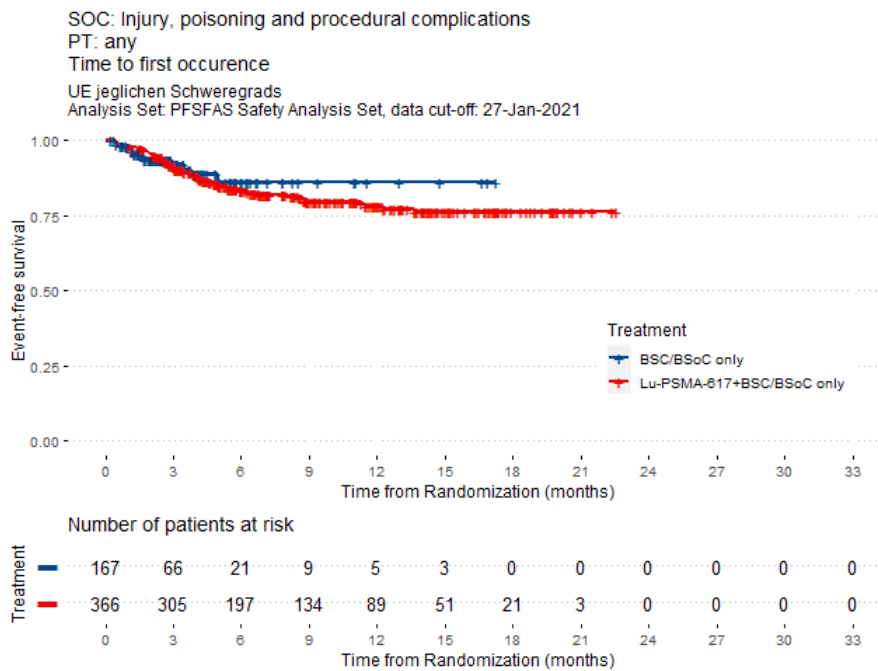


Abbildung 32: UE jeglichen Schweregrads: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: any

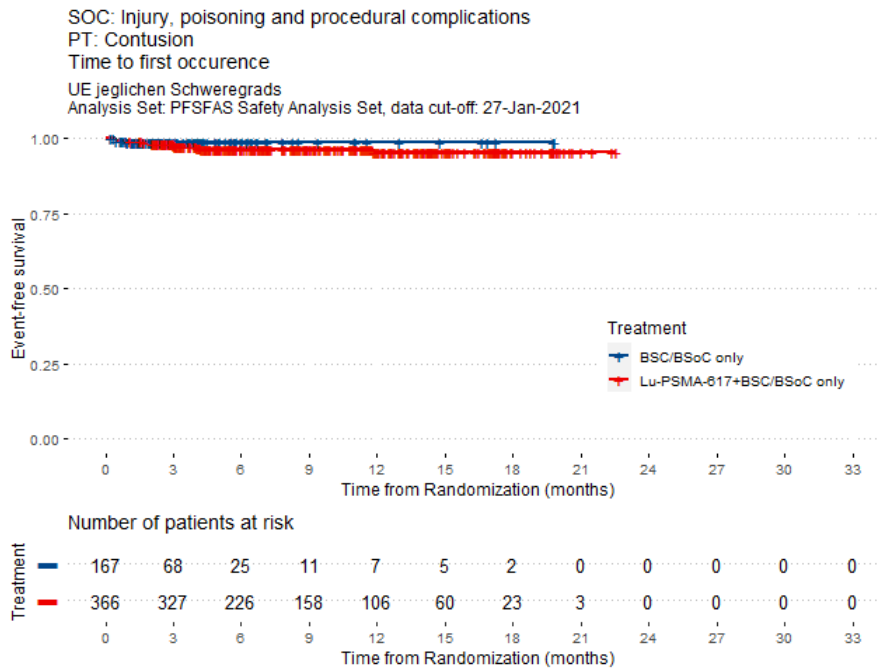


Abbildung 33: UE jeglichen Schweregrads: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: Contusion

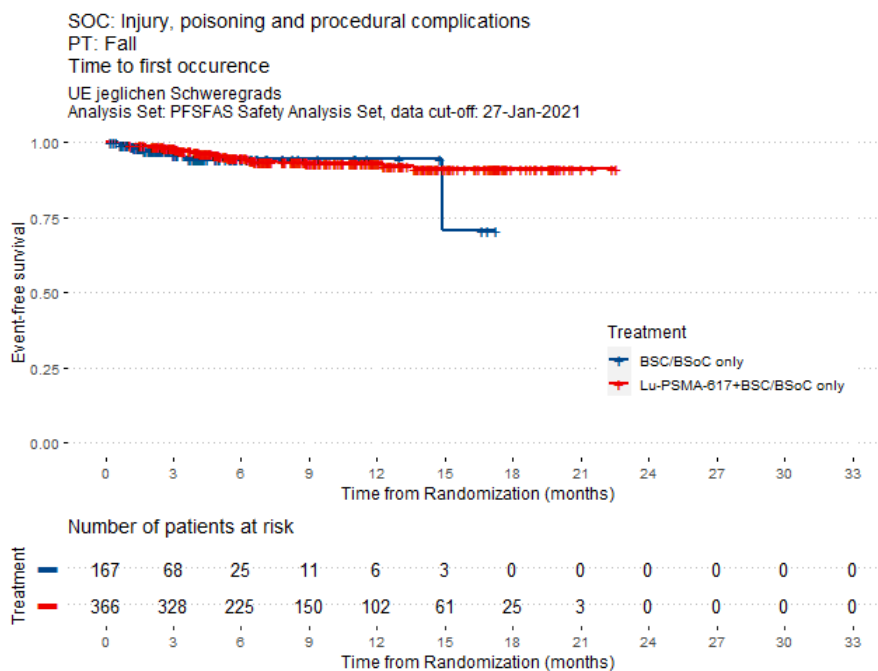


Abbildung 34: UE jeglichen Schweregrads: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: Fall

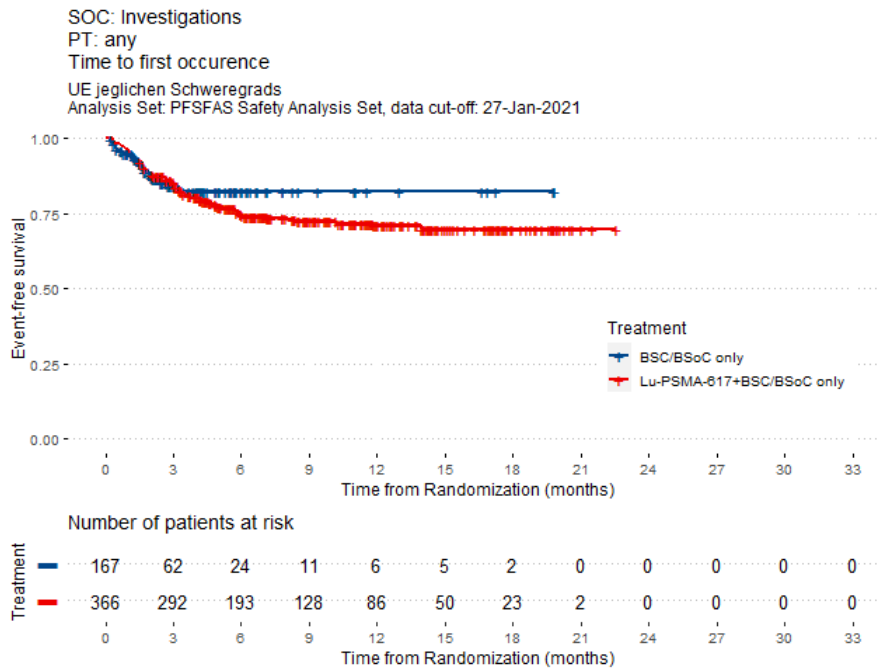


Abbildung 35: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: any

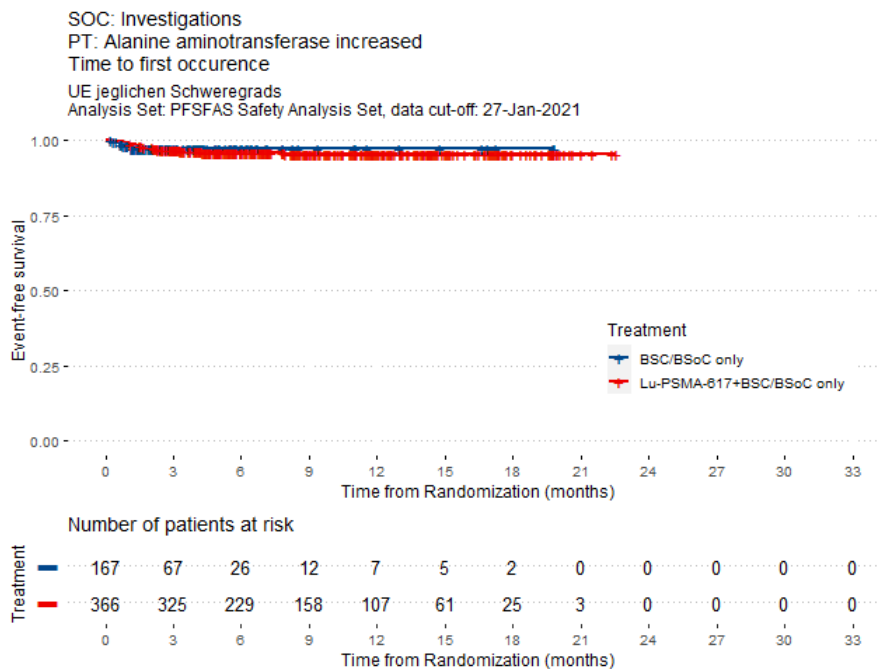


Abbildung 36: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: Alanine aminotransferase increased

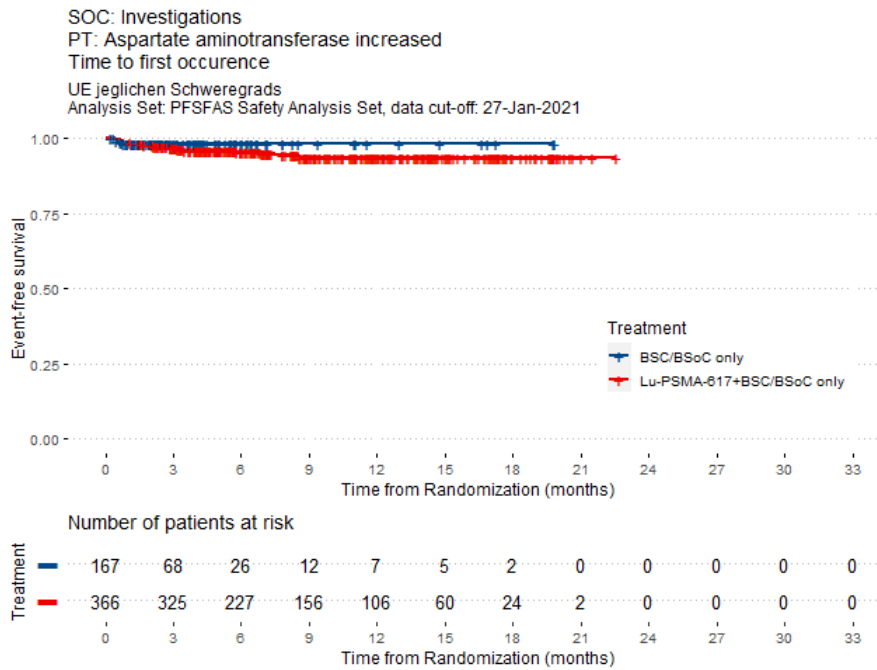


Abbildung 37: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: Aspartate aminotransferase increased

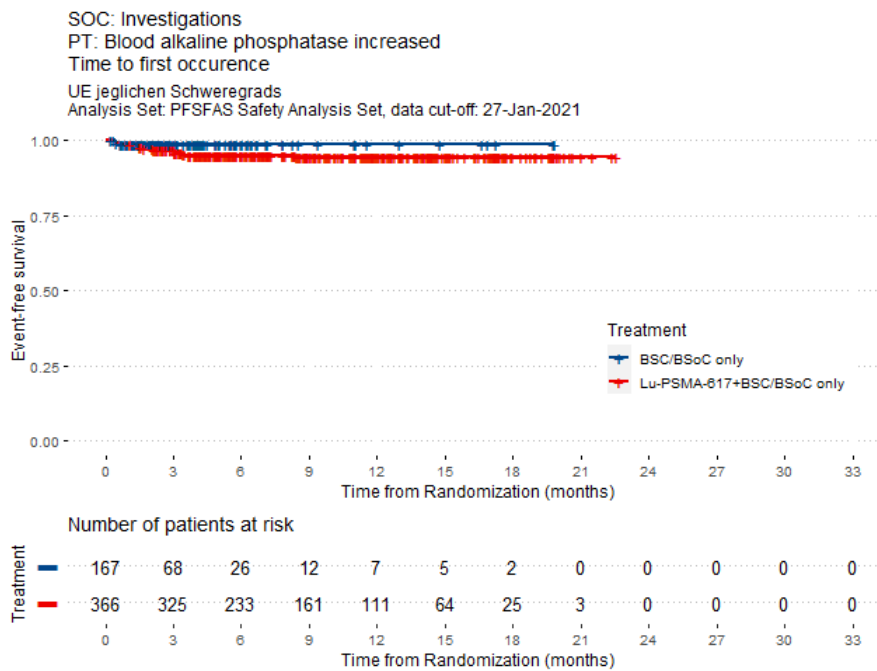


Abbildung 38: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: Blood alkaline phosphatase increased

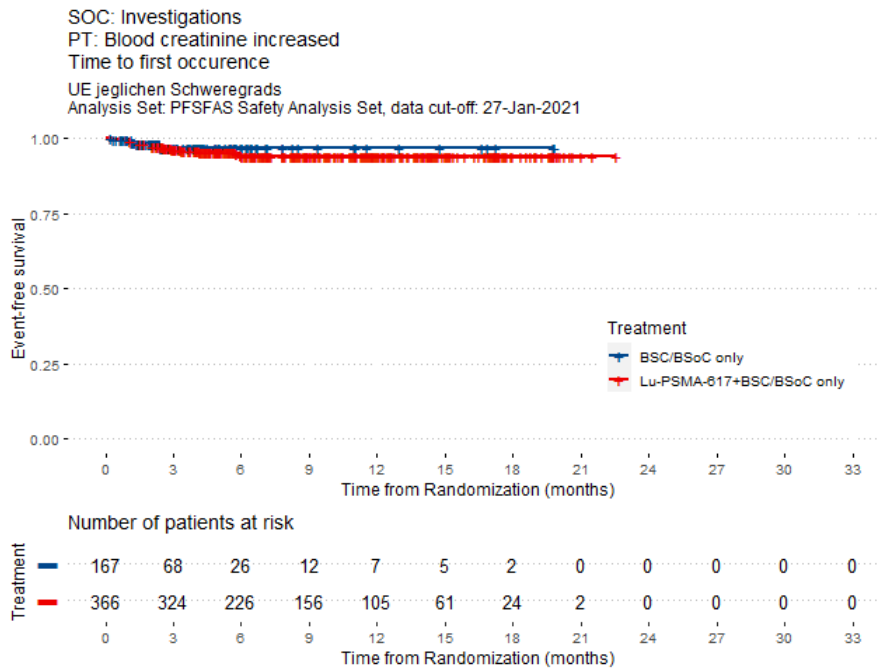


Abbildung 39: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: Blood creatinine increased

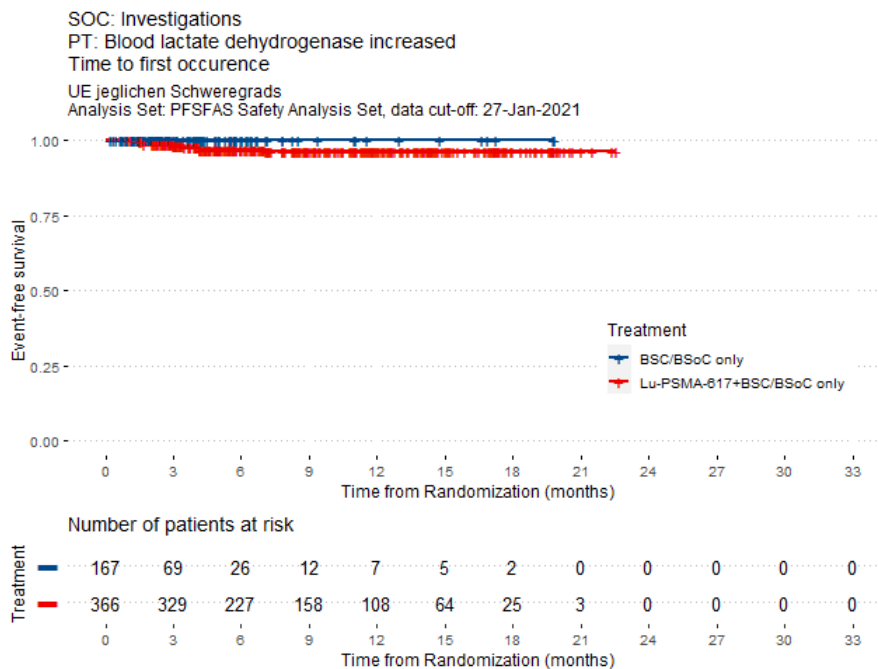


Abbildung 40: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: Blood lactate dehydrogenase increased

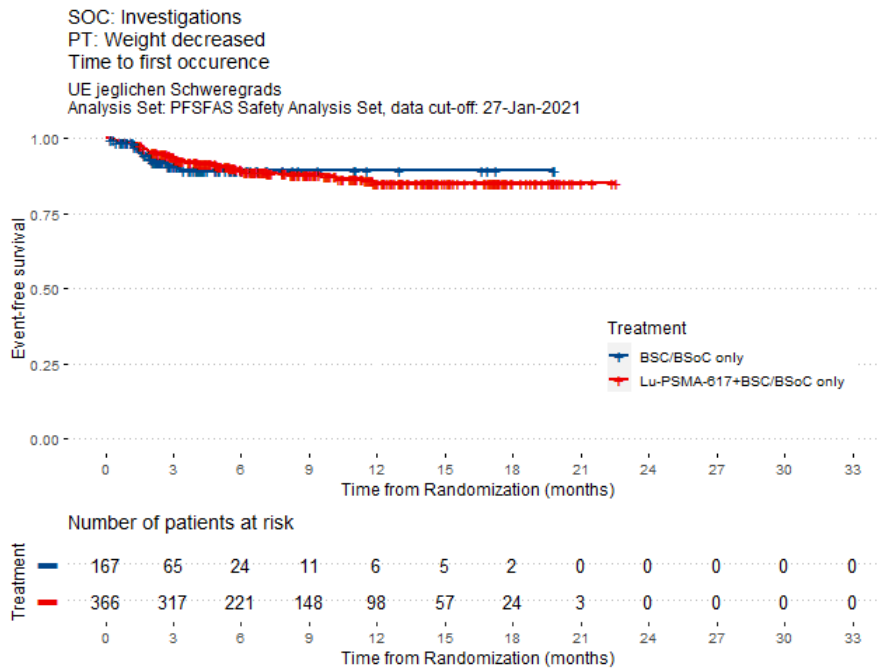


Abbildung 41: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: Weight decreased

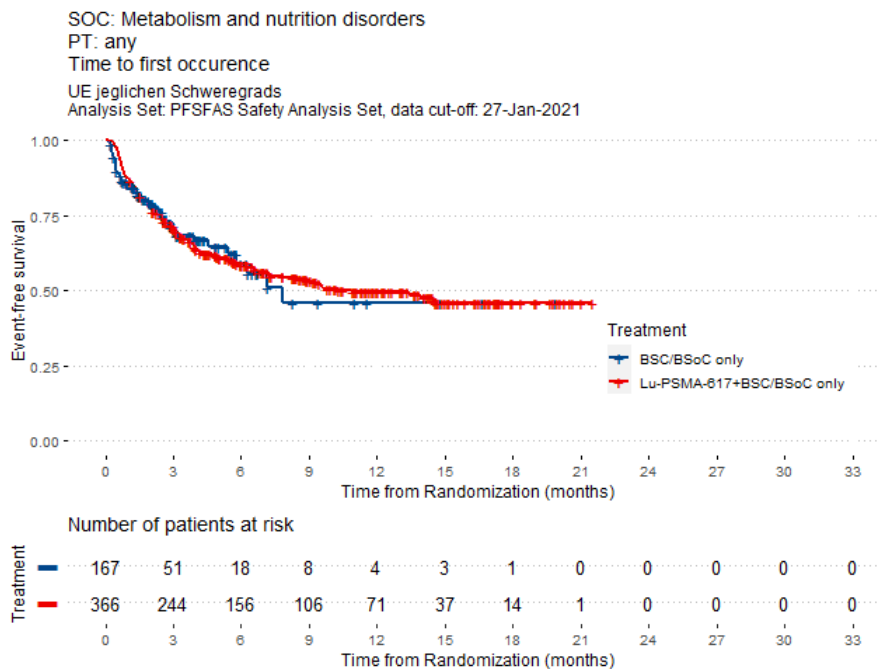


Abbildung 42: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: any



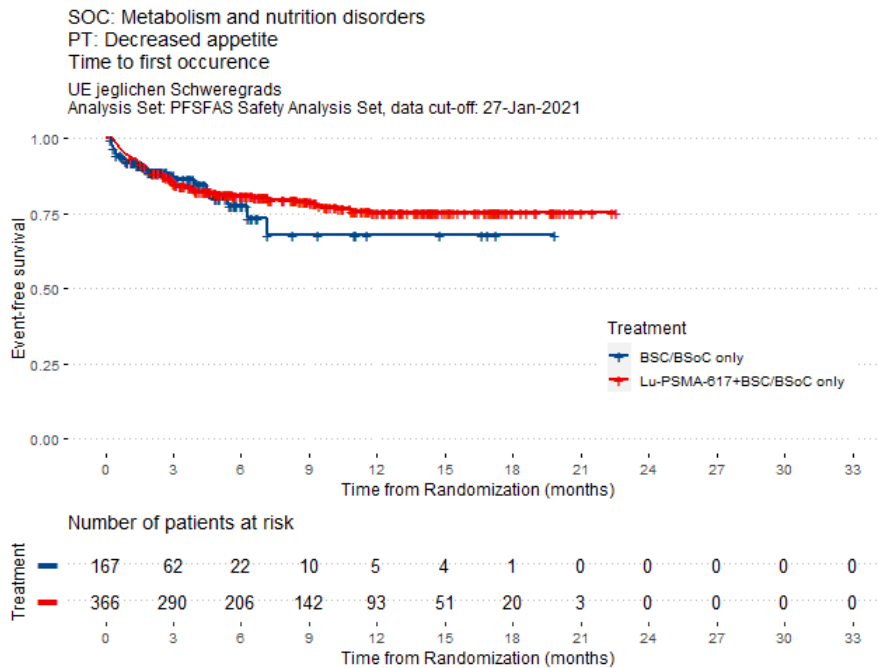


Abbildung 43: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Decreased appetite

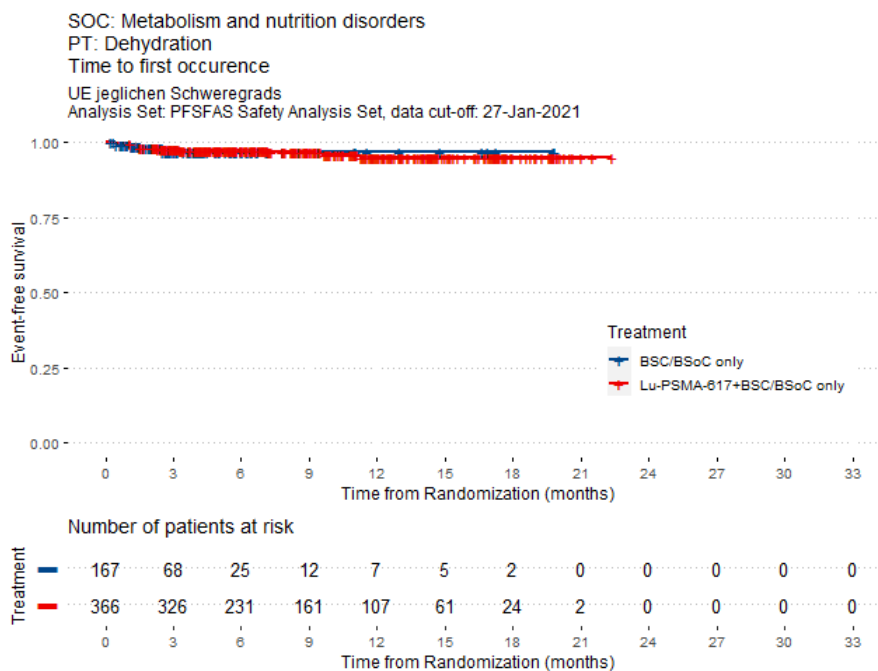


Abbildung 44: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Dehydration

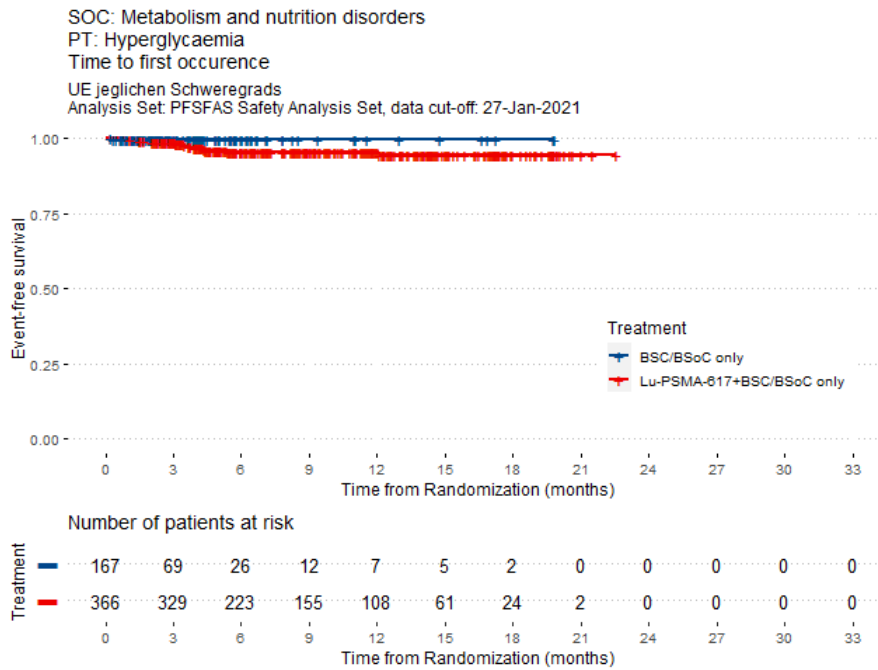


Abbildung 45: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hyperglycaemia

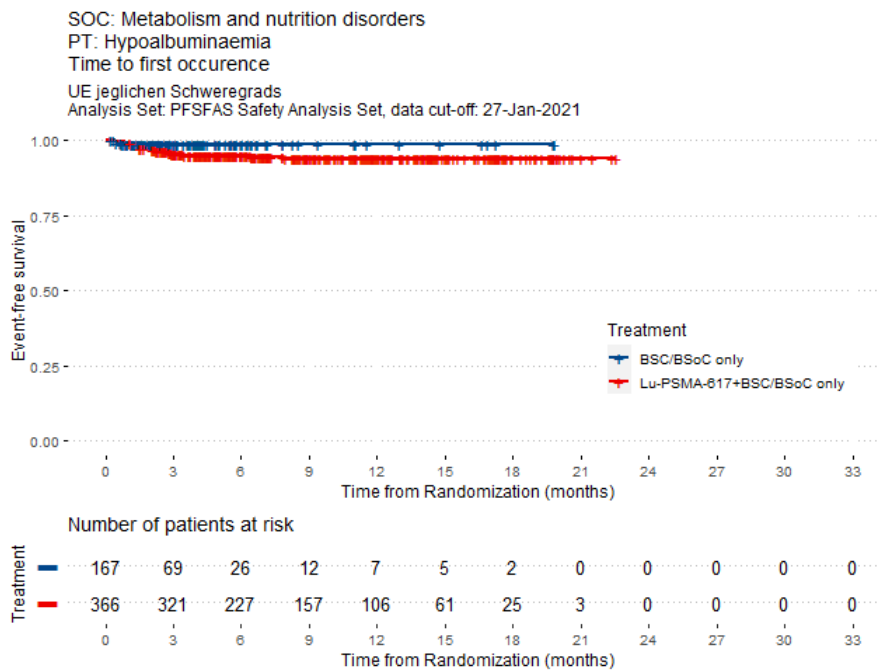


Abbildung 46: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypoalbuminaemia

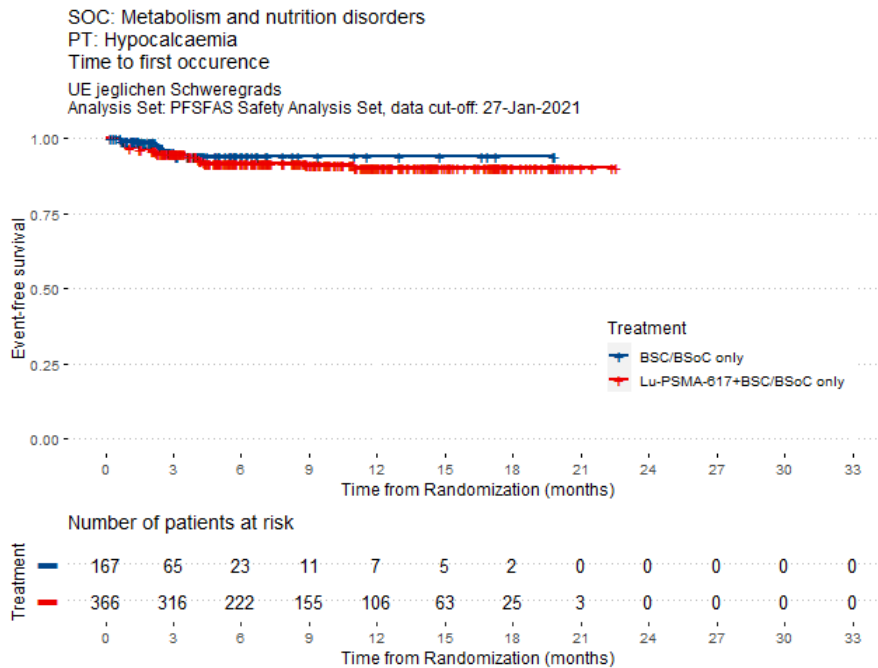


Abbildung 47: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypocalcaemia

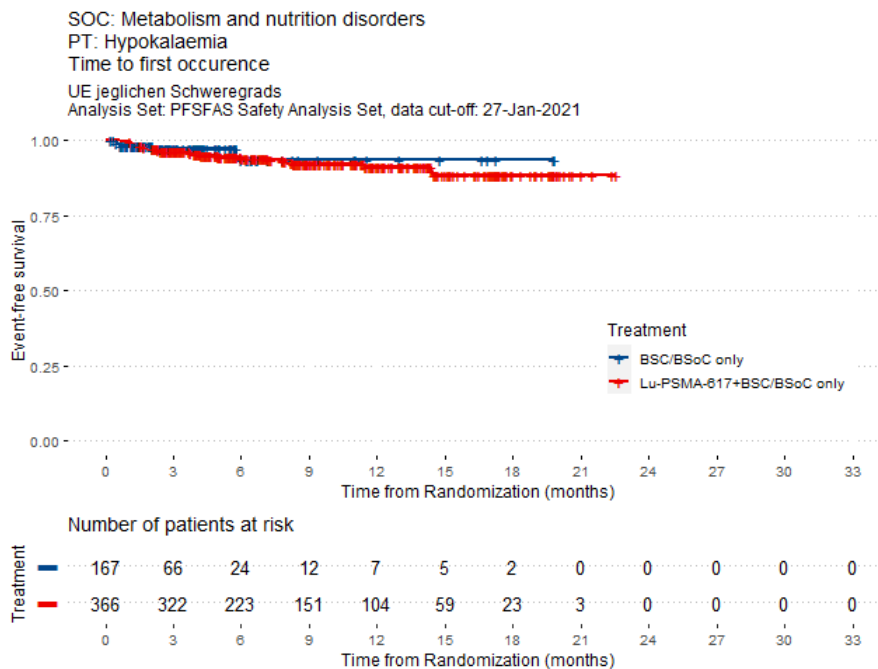


Abbildung 48: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

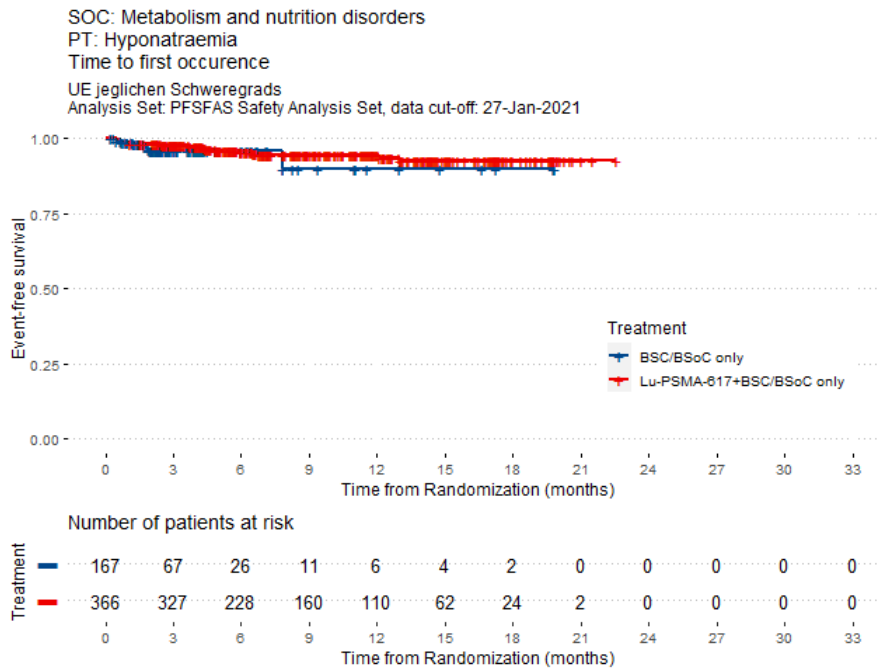


Abbildung 49: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hyponatraemia

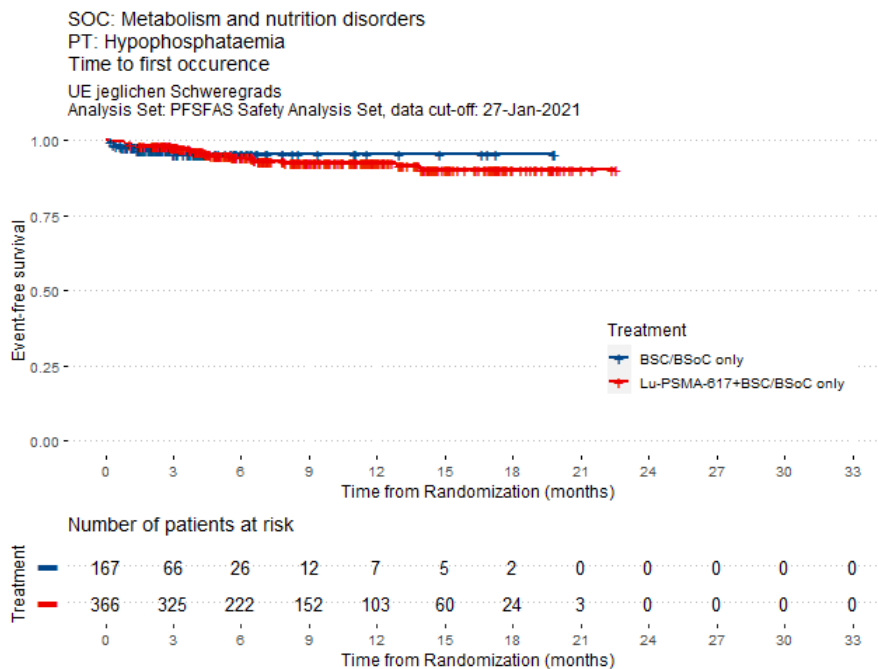


Abbildung 50: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypophosphataemia

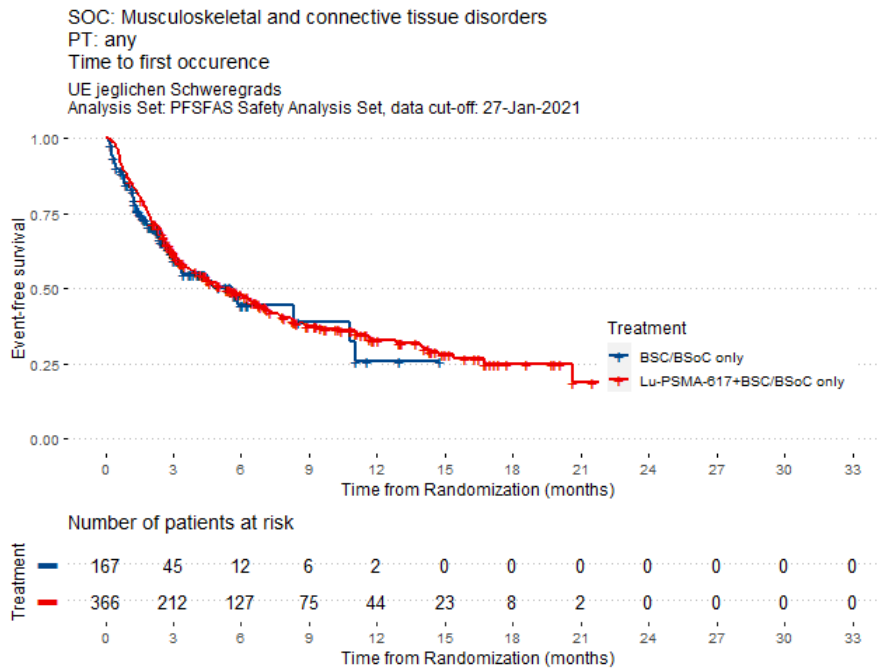


Abbildung 51: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: any

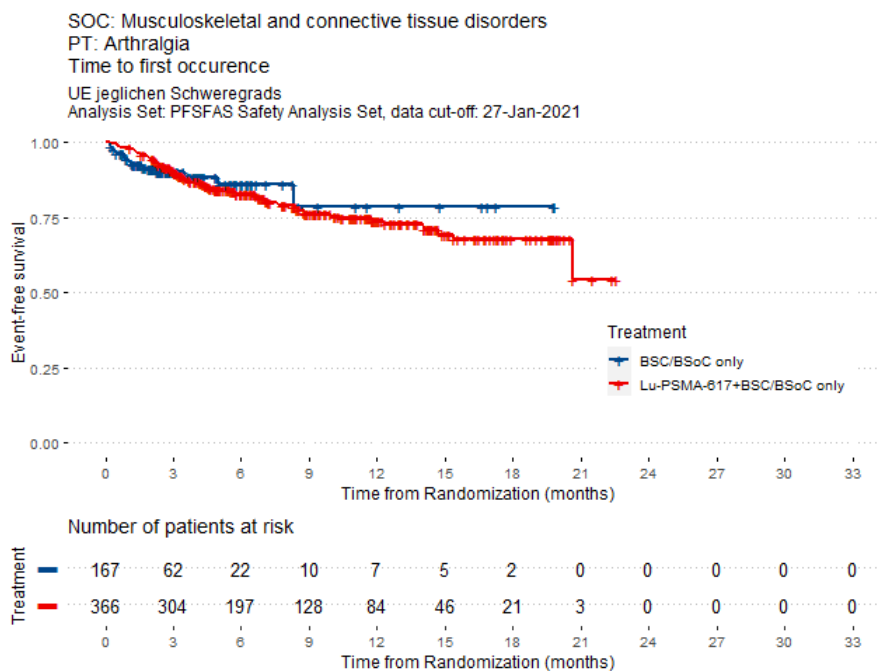


Abbildung 52: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Arthralgia

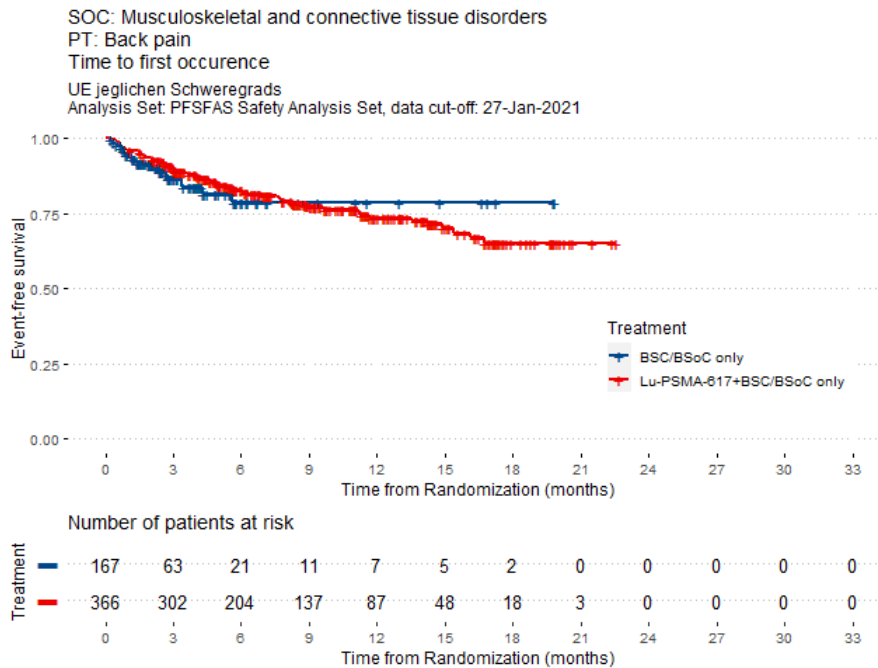


Abbildung 53: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Back pain

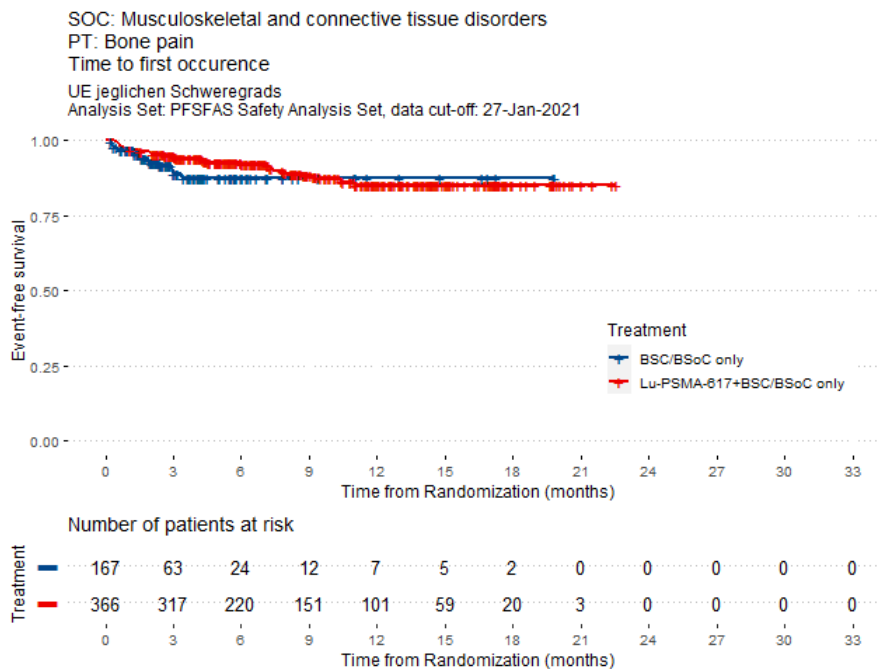


Abbildung 54: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Bone pain

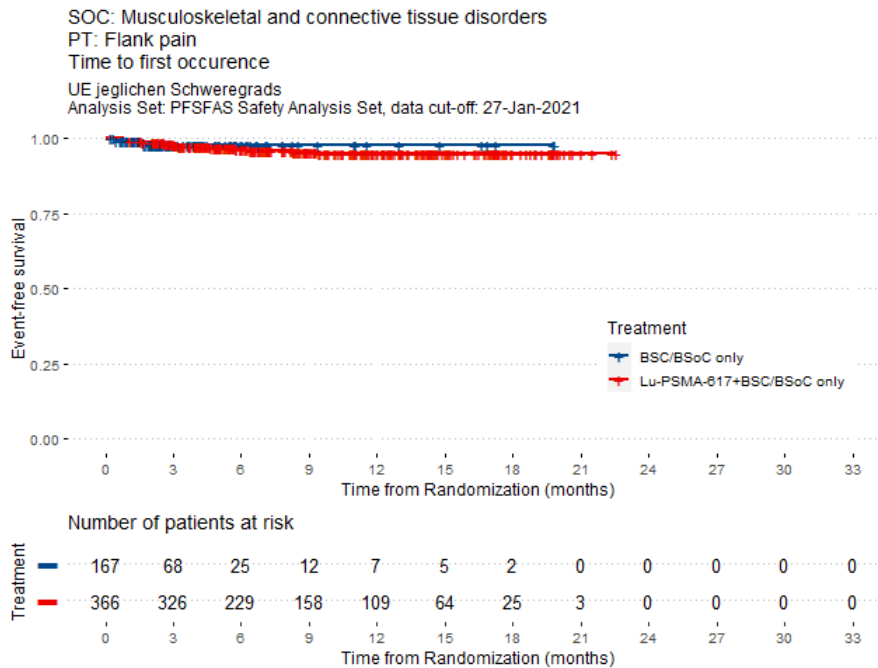


Abbildung 55: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Flank pain

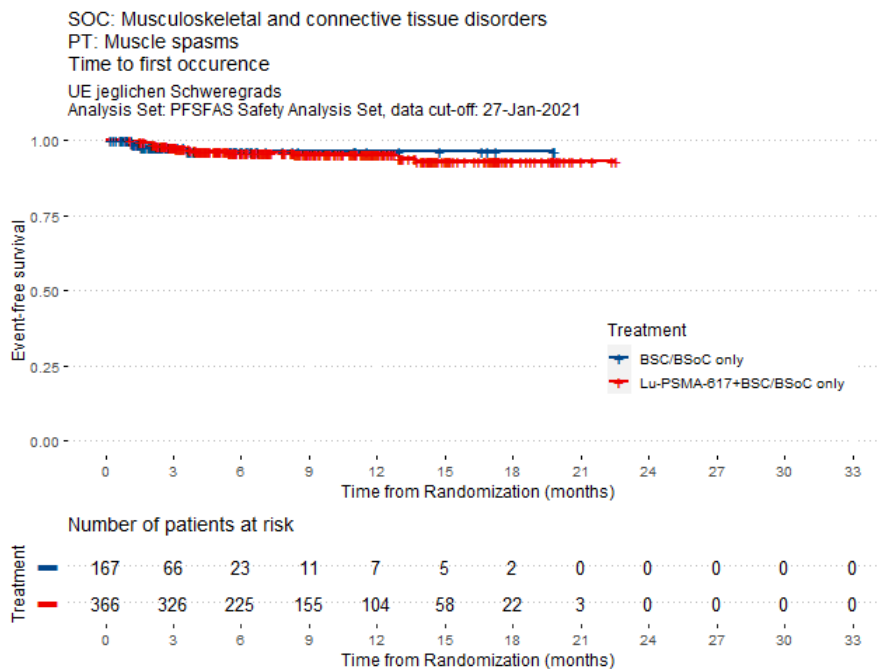


Abbildung 56: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Muscle spasms

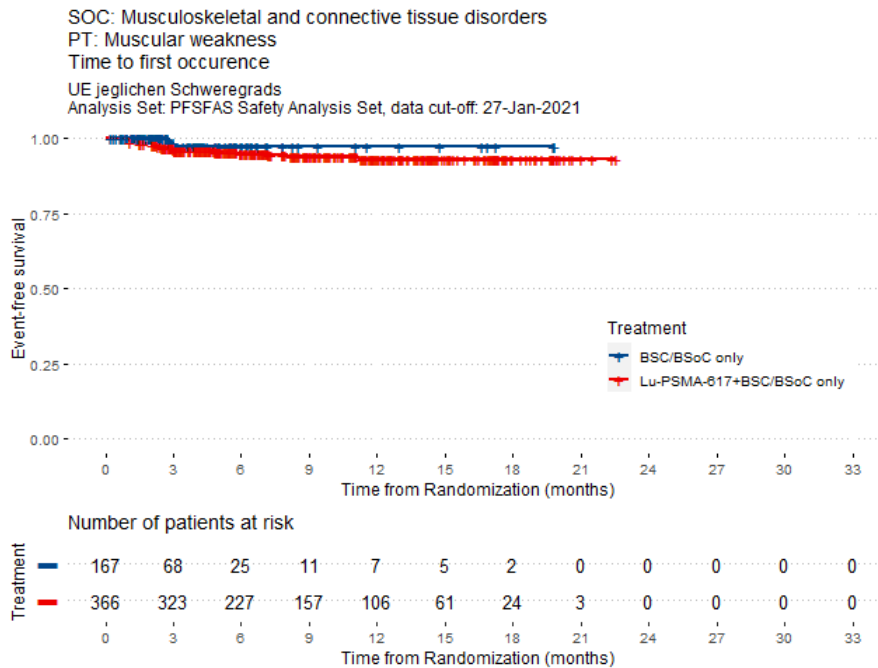


Abbildung 57: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Muscular weakness

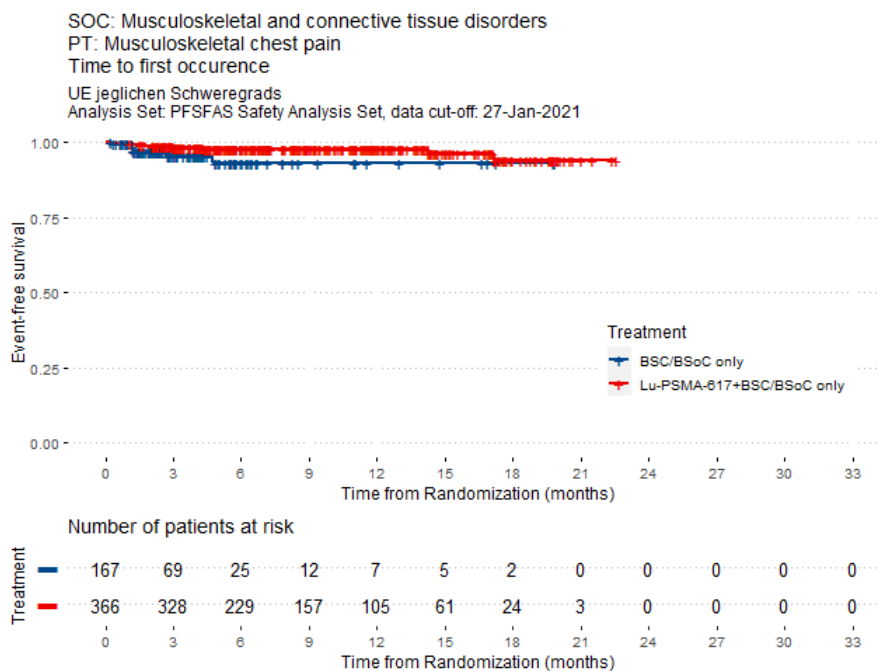


Abbildung 58: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Musculoskeletal chest pain



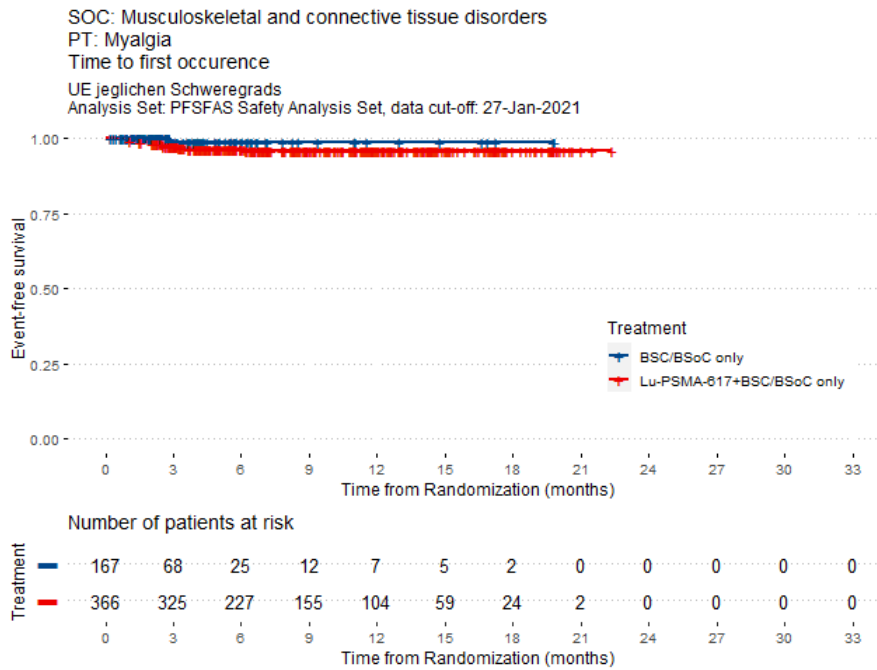


Abbildung 59: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Myalgia

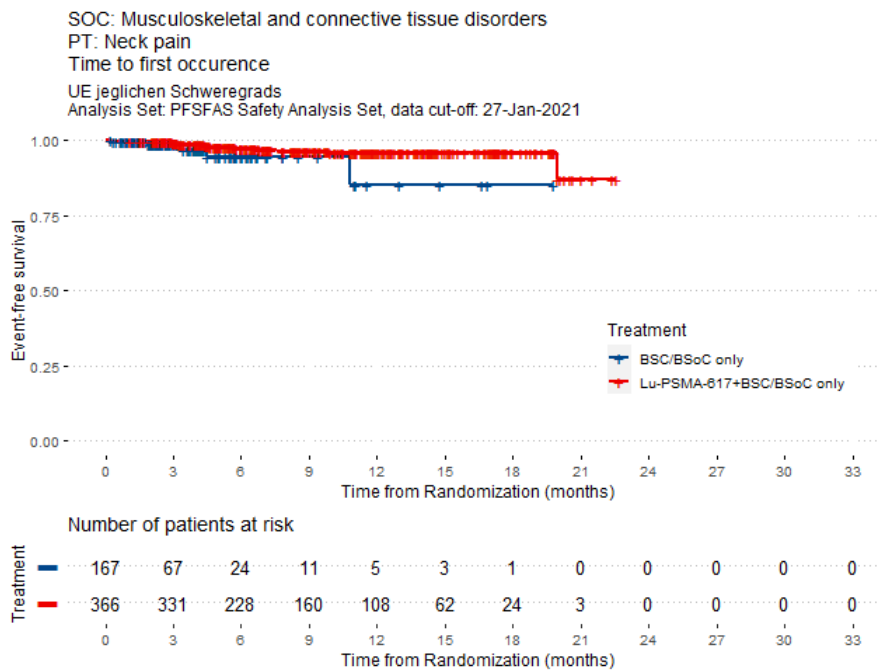


Abbildung 60: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Neck pain

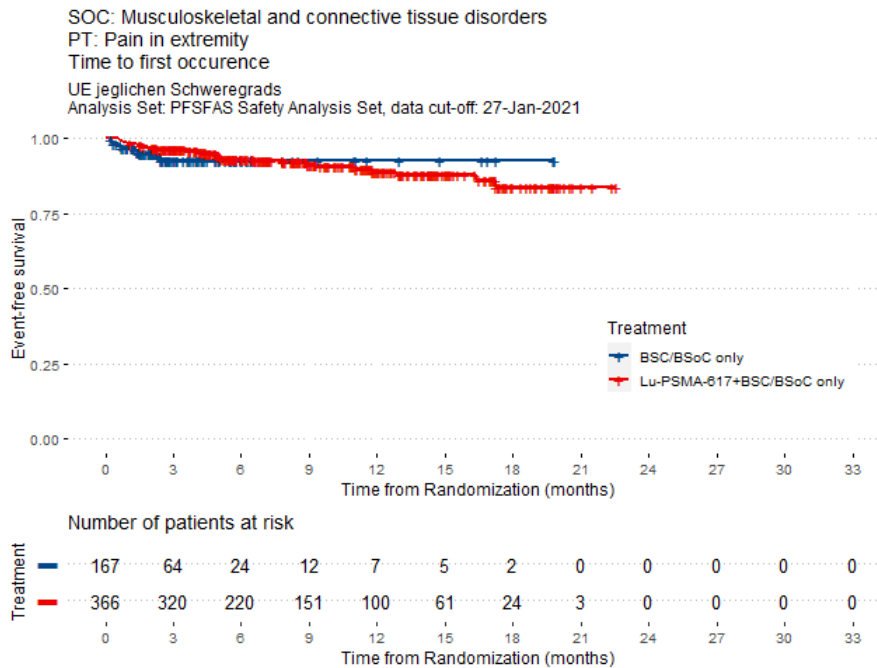


Abbildung 61: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Pain in extremity

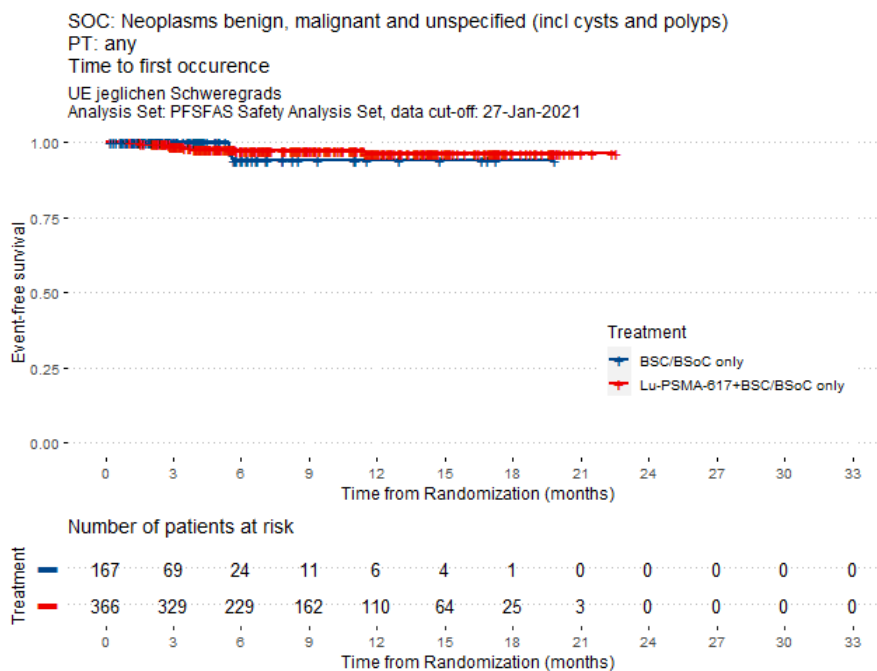


Abbildung 62: UE jeglichen Schweregrads: Time to first occurrence of SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: any

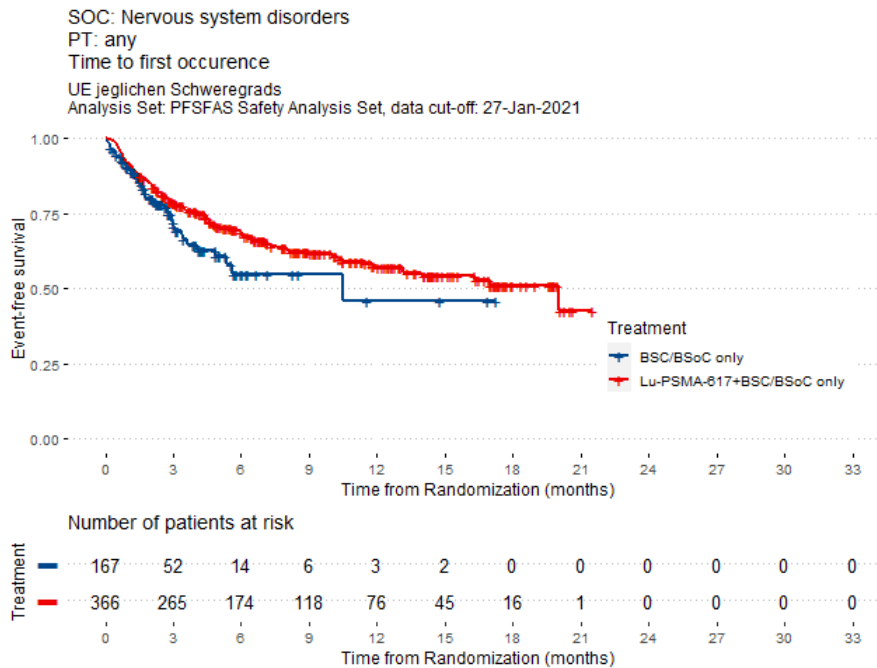


Abbildung 63: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: any

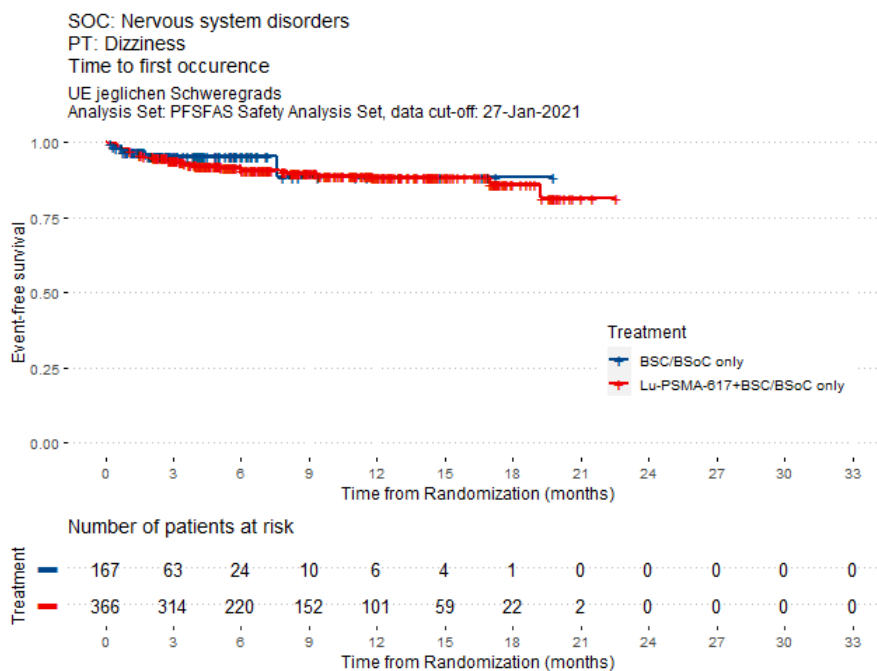


Abbildung 64: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Dizziness

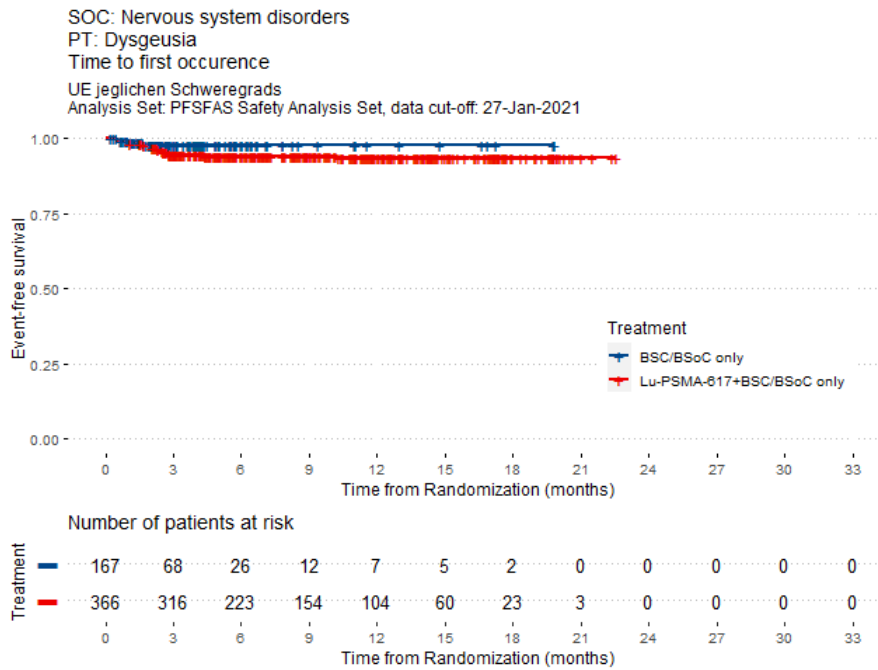


Abbildung 65: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Dysgeusia

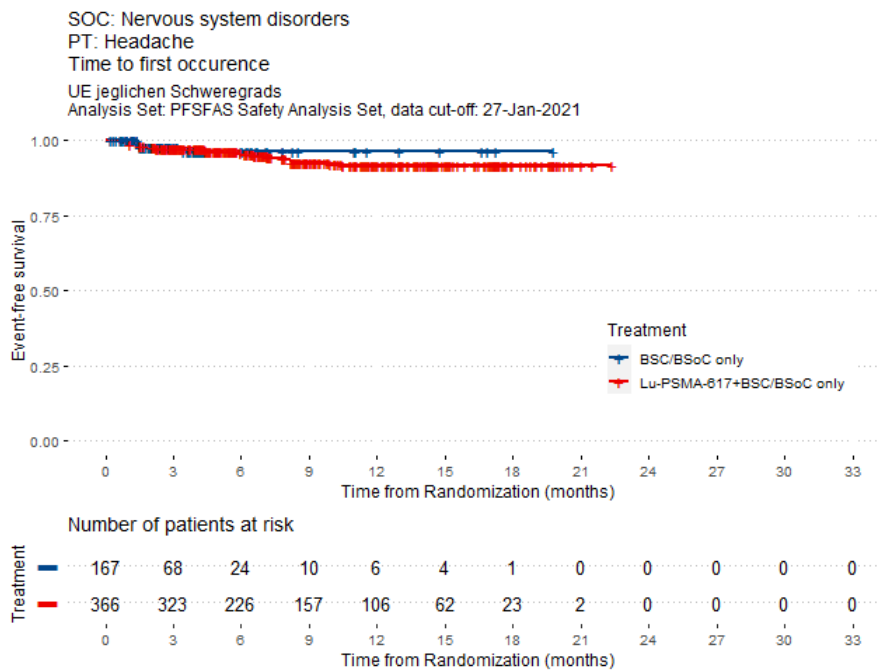


Abbildung 66: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Headache

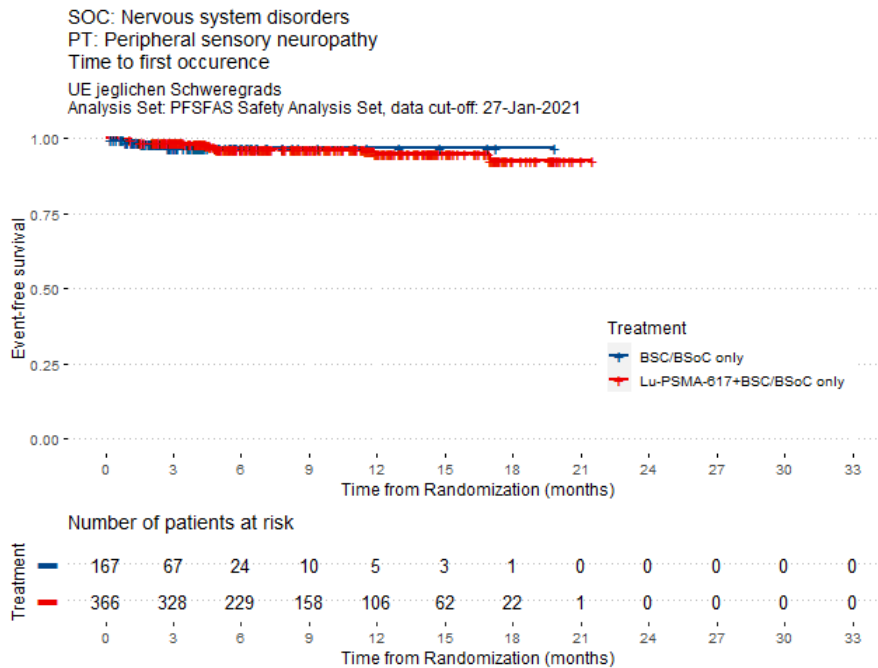


Abbildung 67: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Peripheral sensory neuropathy

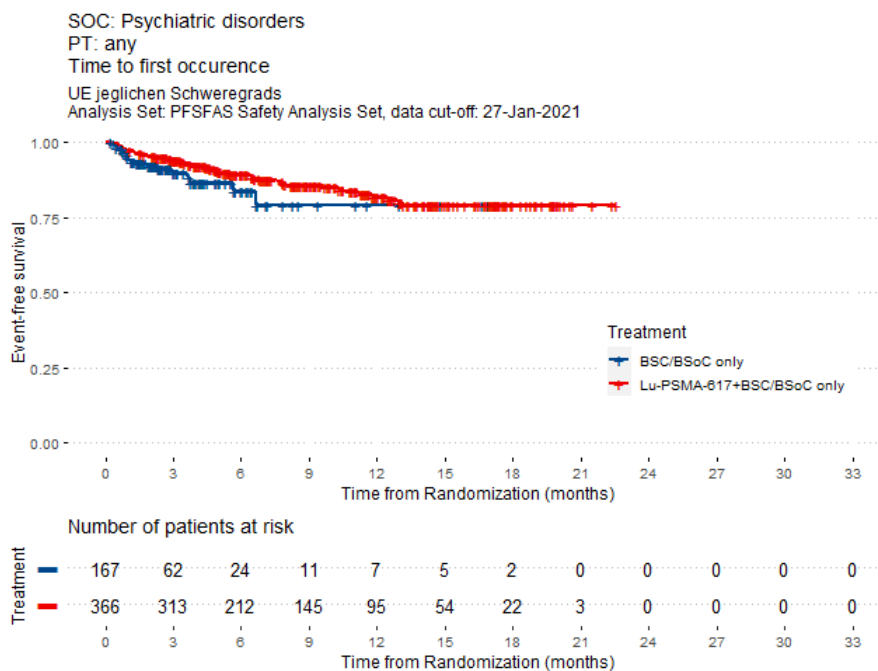


Abbildung 68: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: any

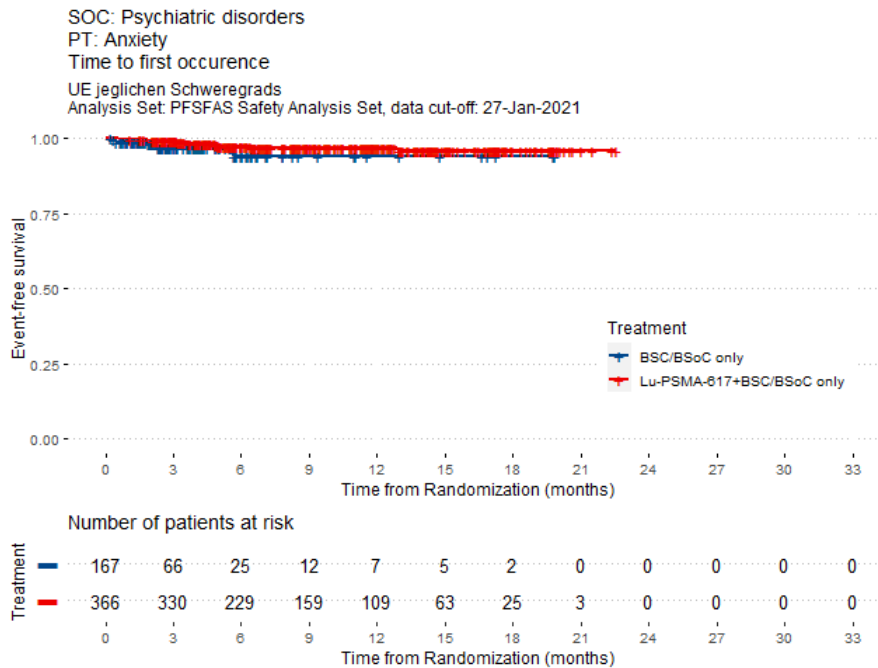


Abbildung 69: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Anxiety

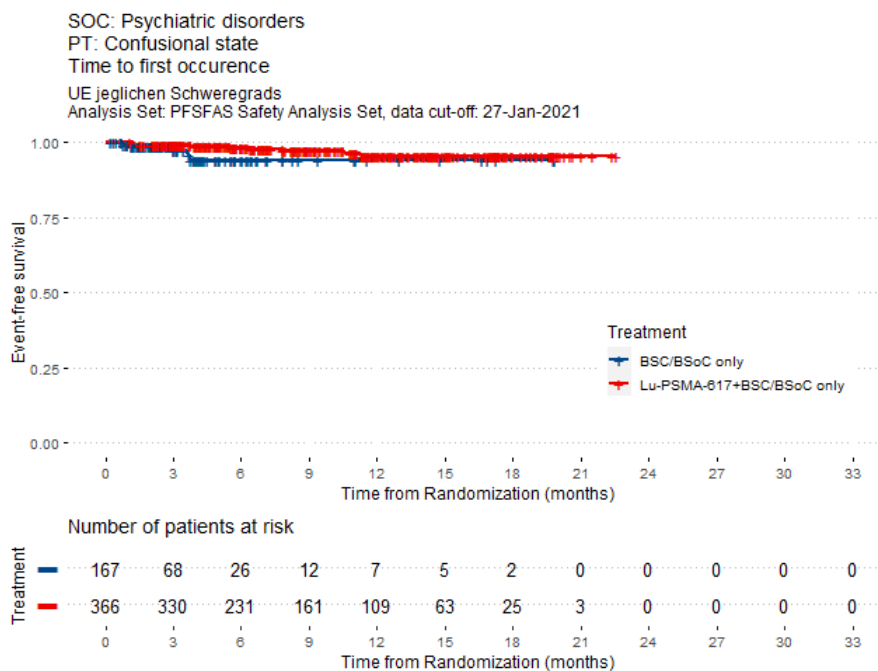


Abbildung 70: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Confusional state

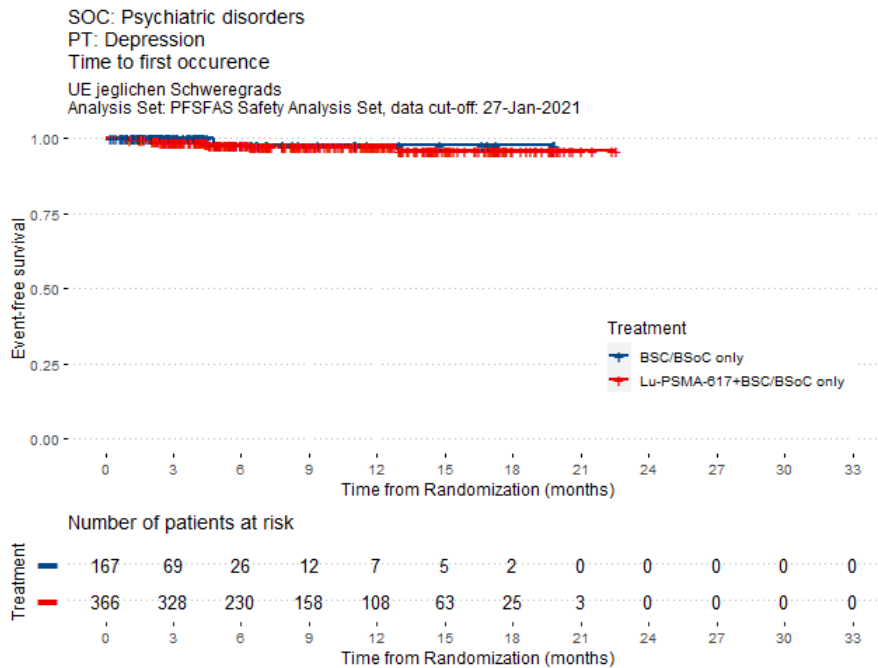


Abbildung 71: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Depression



Abbildung 72: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Insomnia

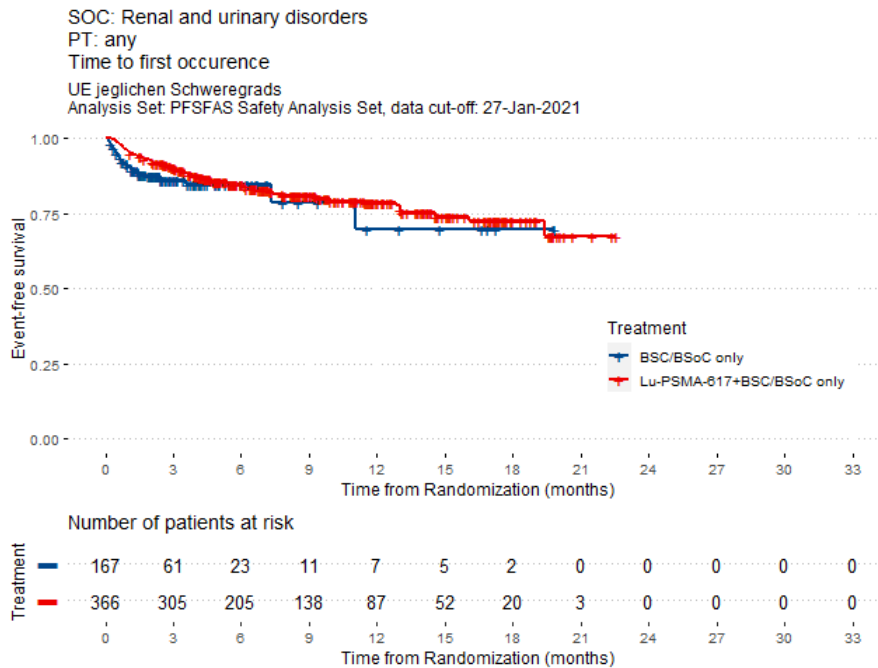


Abbildung 73: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: any

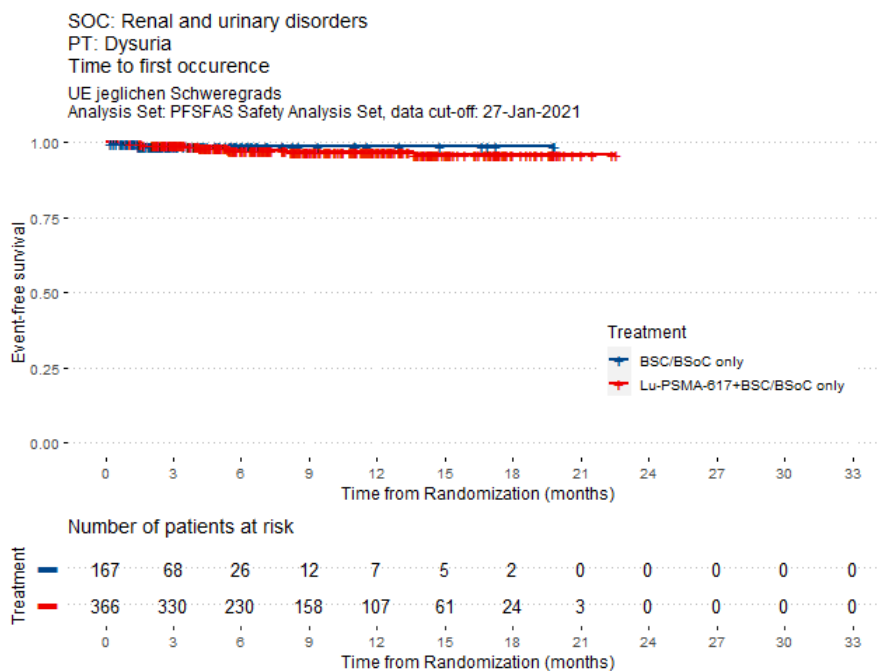


Abbildung 74: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Dysuria



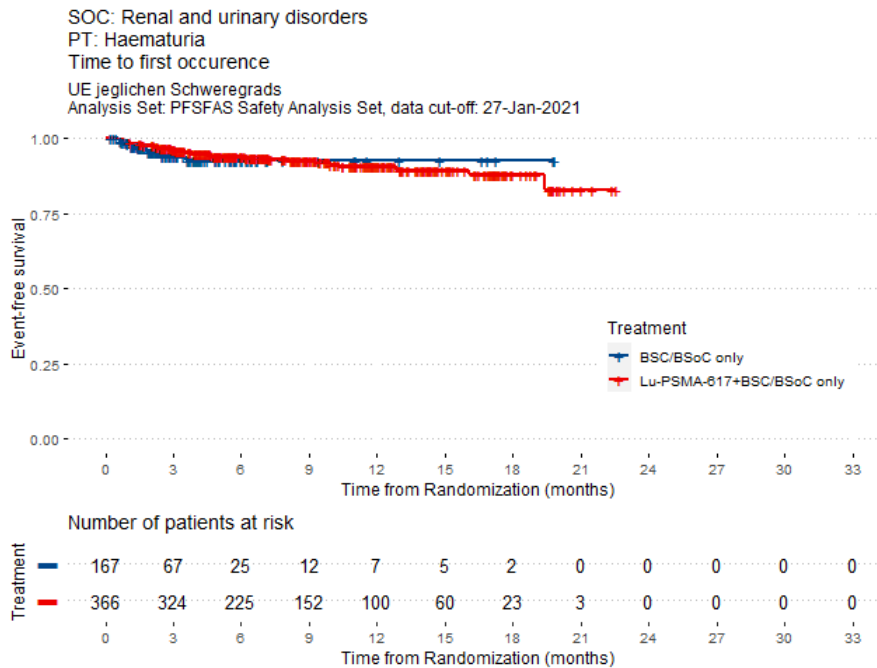


Abbildung 75: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Haematuria

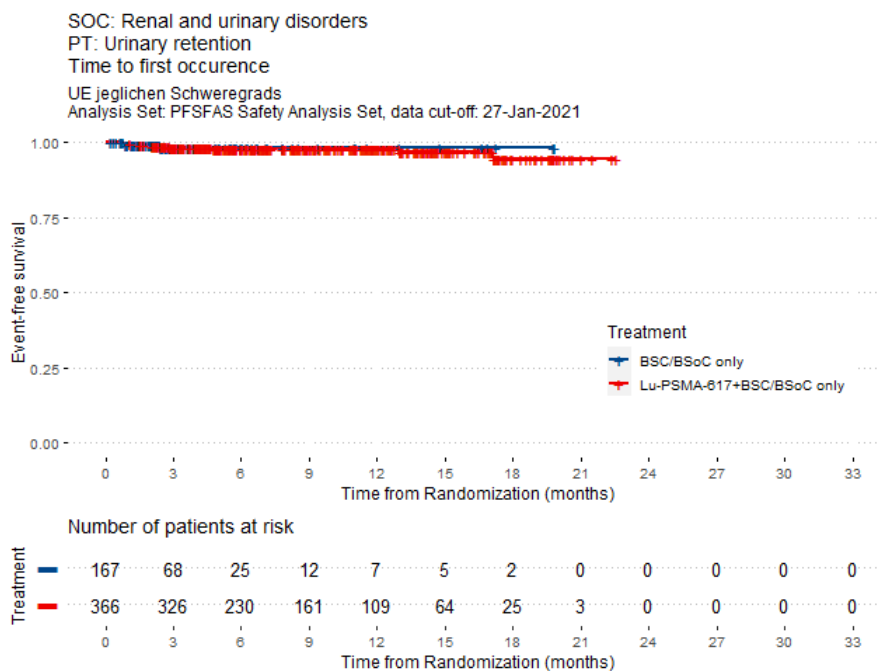


Abbildung 76: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Urinary retention

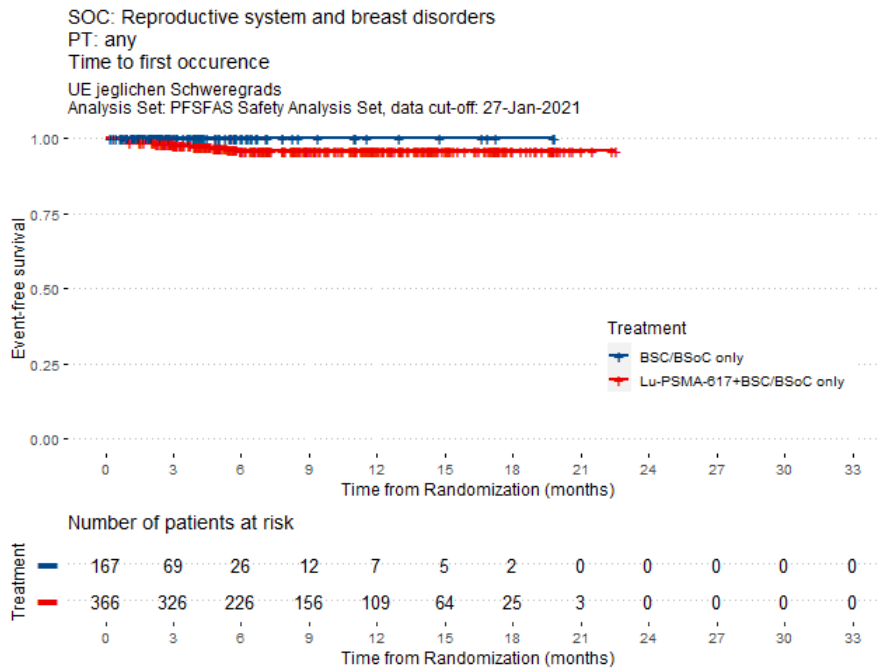


Abbildung 77: UE jeglichen Schweregrads: Time to first occurrence of SOC: Reproductive system and breast disorders; PT: any

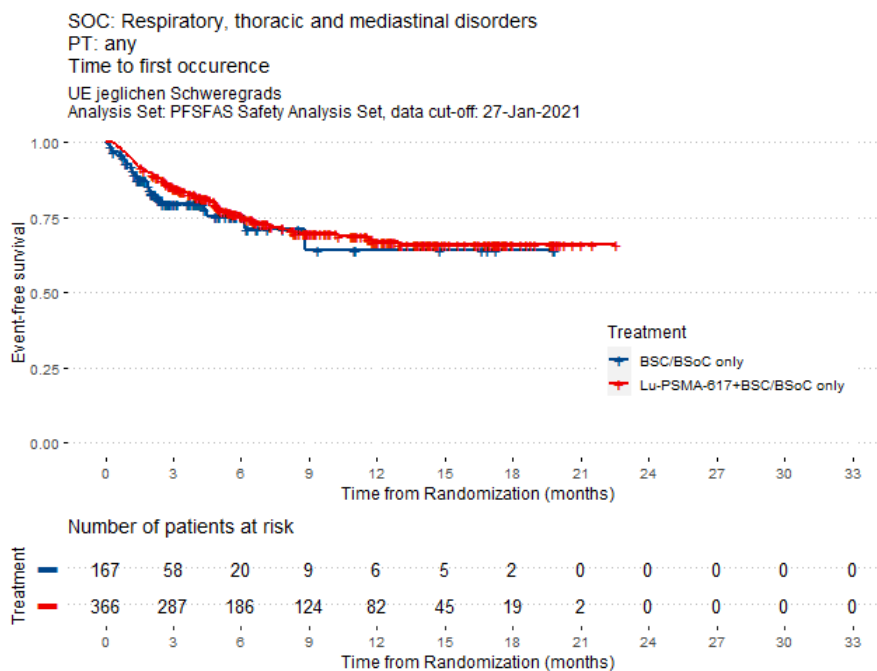


Abbildung 78: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: any

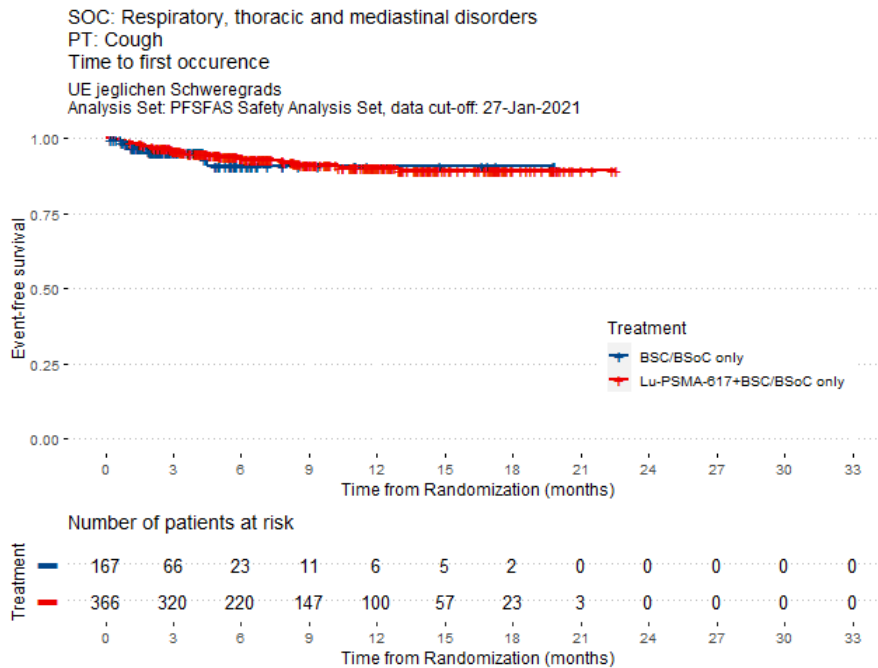


Abbildung 79: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: Cough

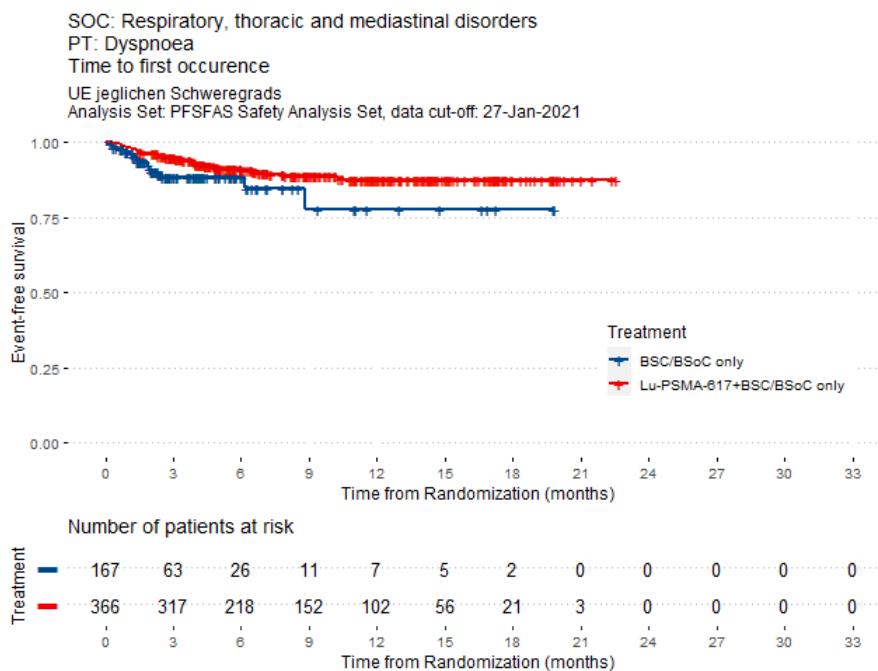


Abbildung 80: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea

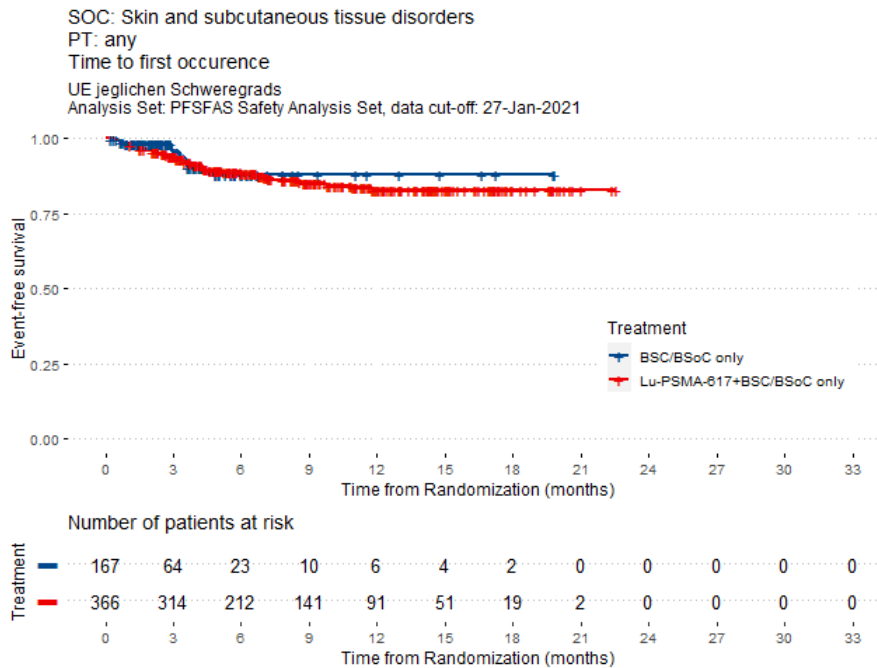


Abbildung 81: UE jeglichen Schweregrads: Time to first occurrence of SOC: Skin and subcutaneous tissue disorders; PT: any

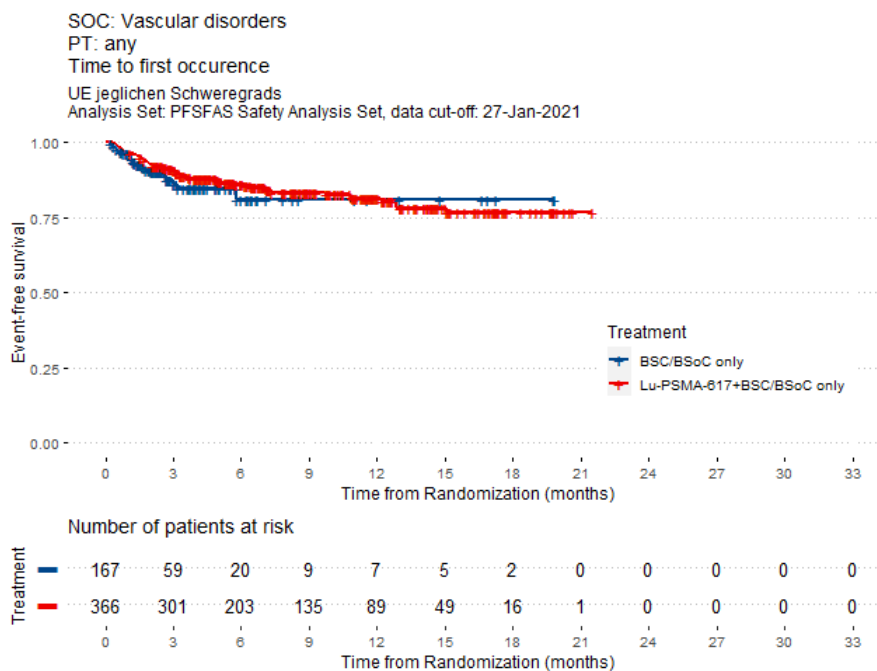


Abbildung 82: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: any

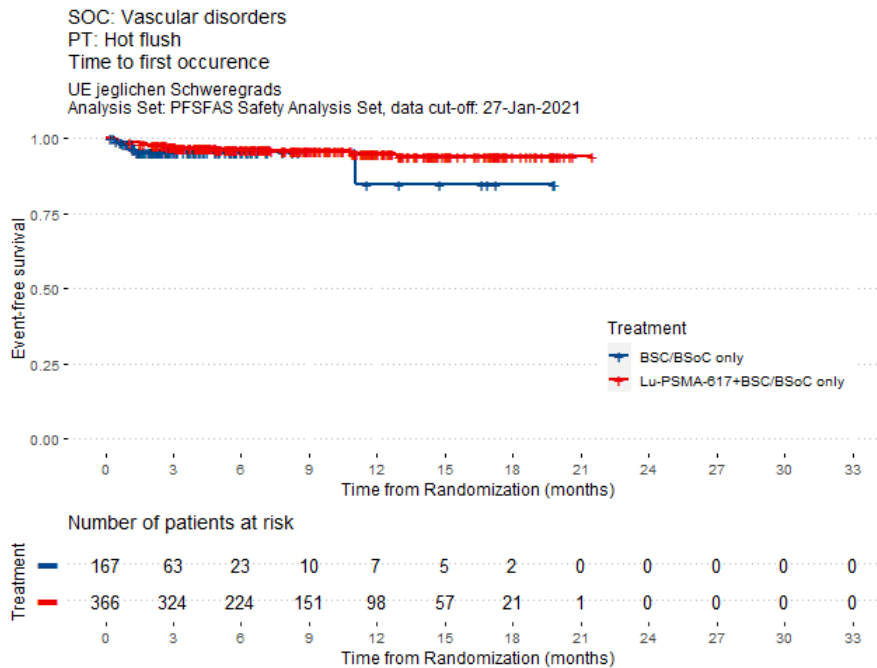


Abbildung 83: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: Hot flush

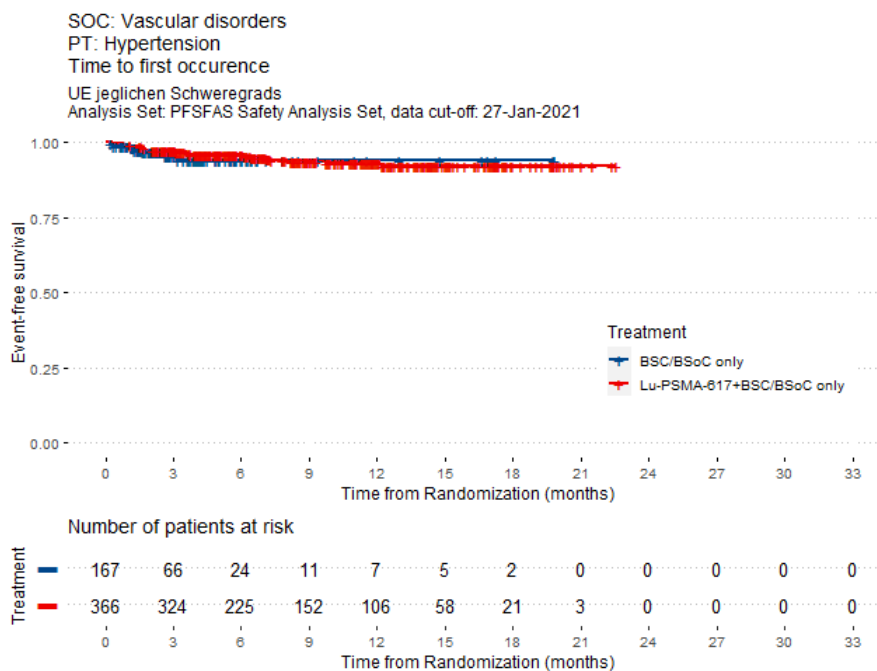


Abbildung 84: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: Hypertension

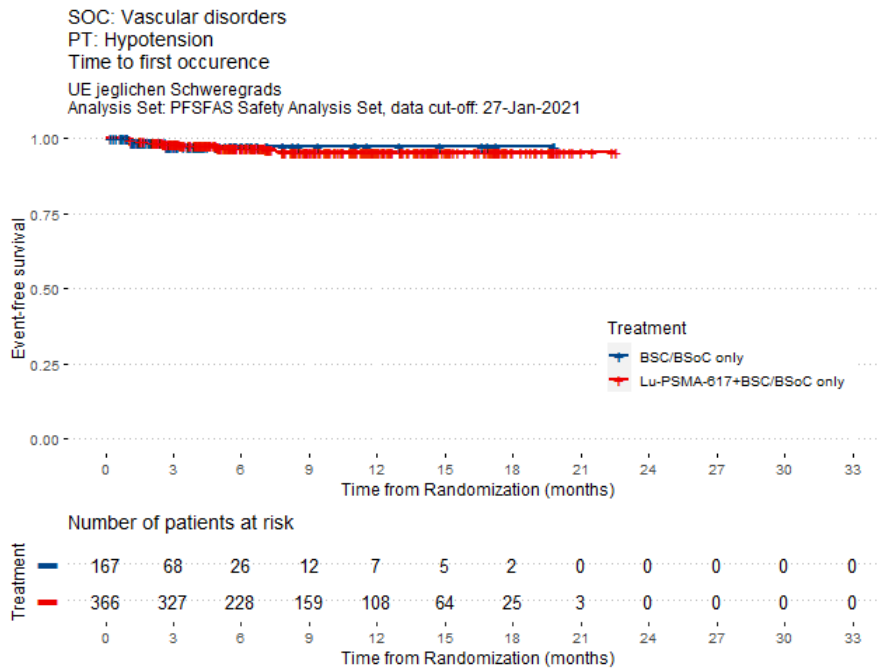


Abbildung 85: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: Hypotension

**Anhang 1.2: Schwere UE (CTCAE-Grad 3-5)**

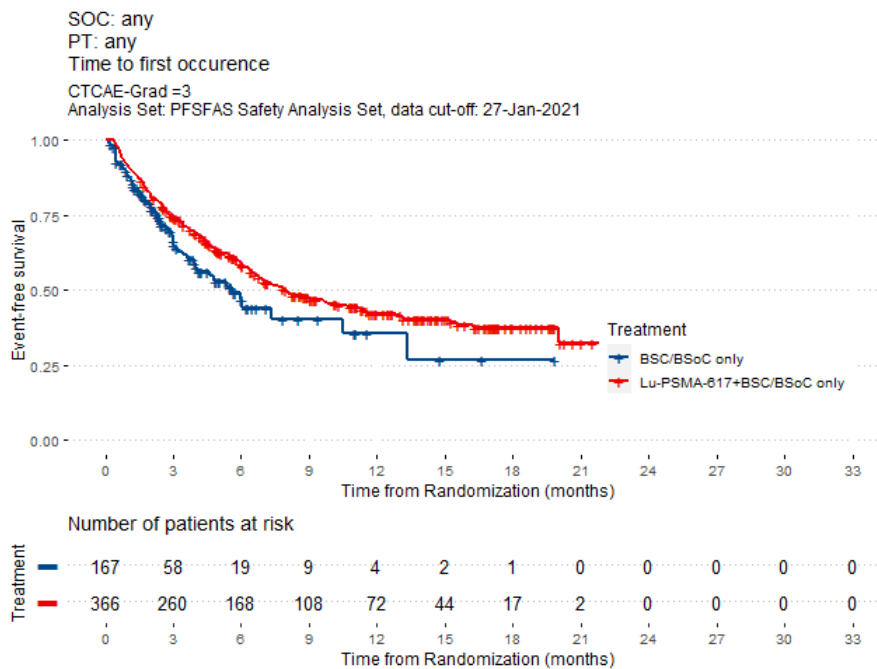


Abbildung 86: CTCAE-Grad 3-5: Time to first occurrence of SOC: any; PT: any

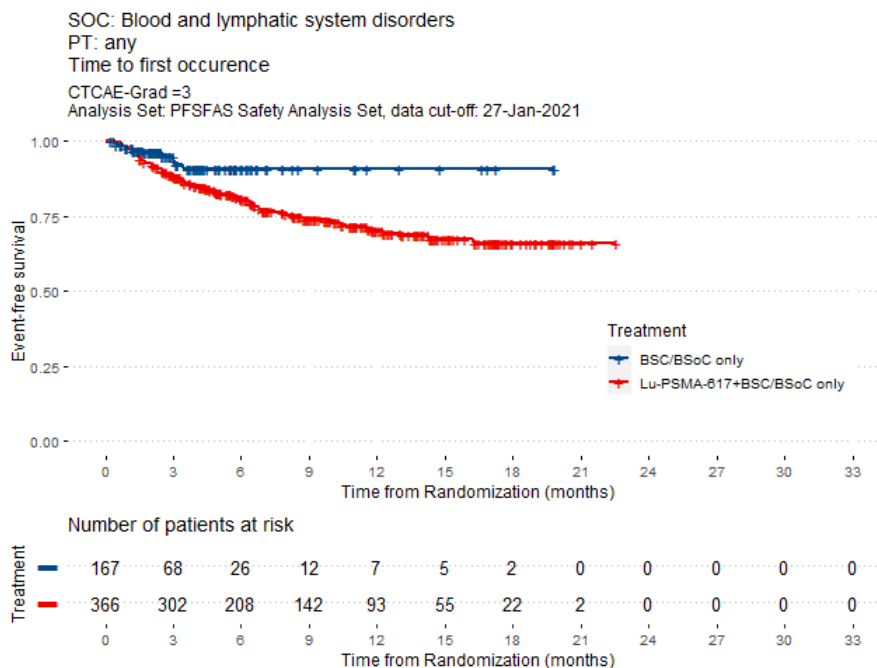


Abbildung 87: CTCAE-Grad 3-5: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: any

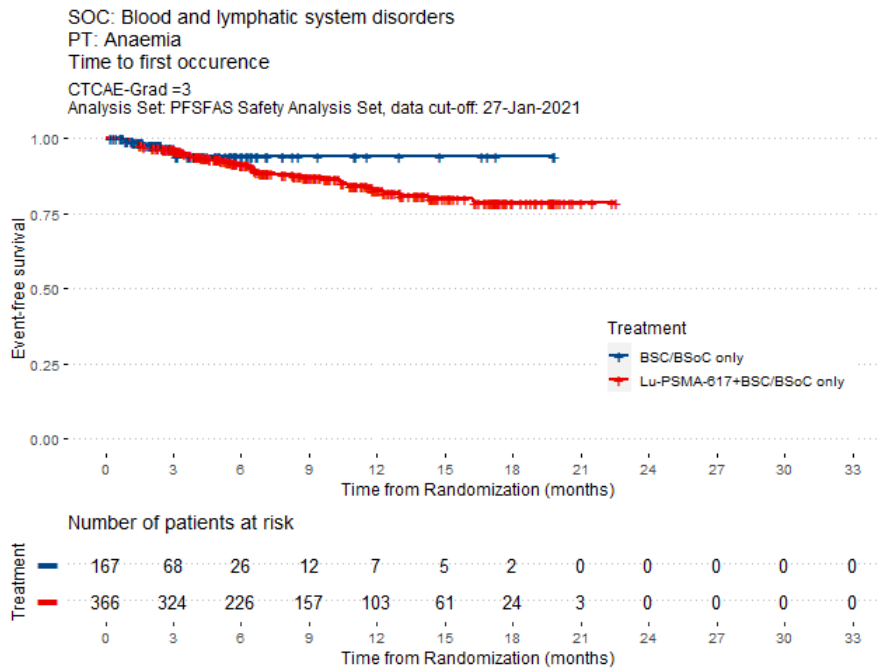


Abbildung 88: CTCAE-Grad 3-5: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Anaemia

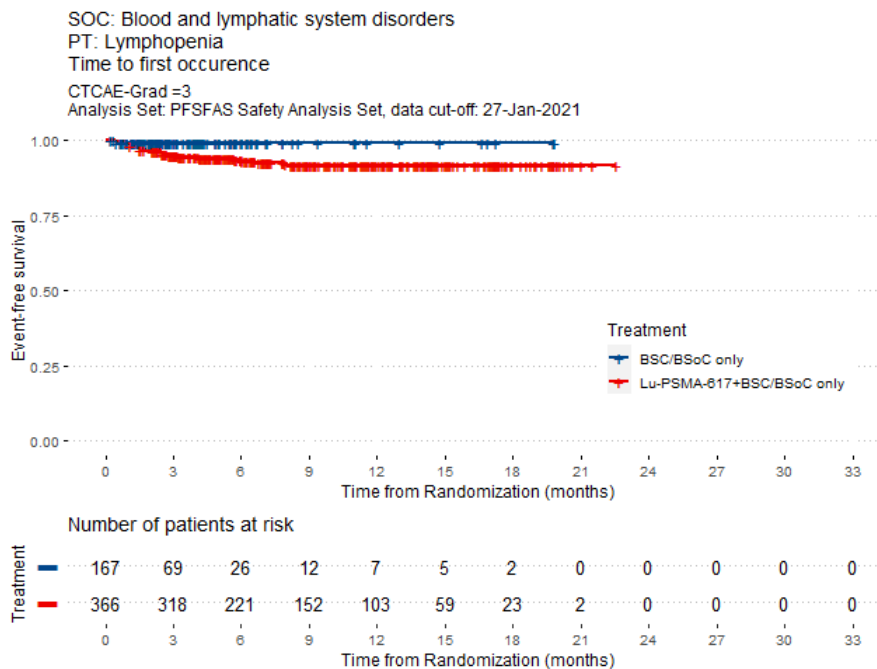


Abbildung 89: CTCAE-Grad 3-5: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Lymphopenia



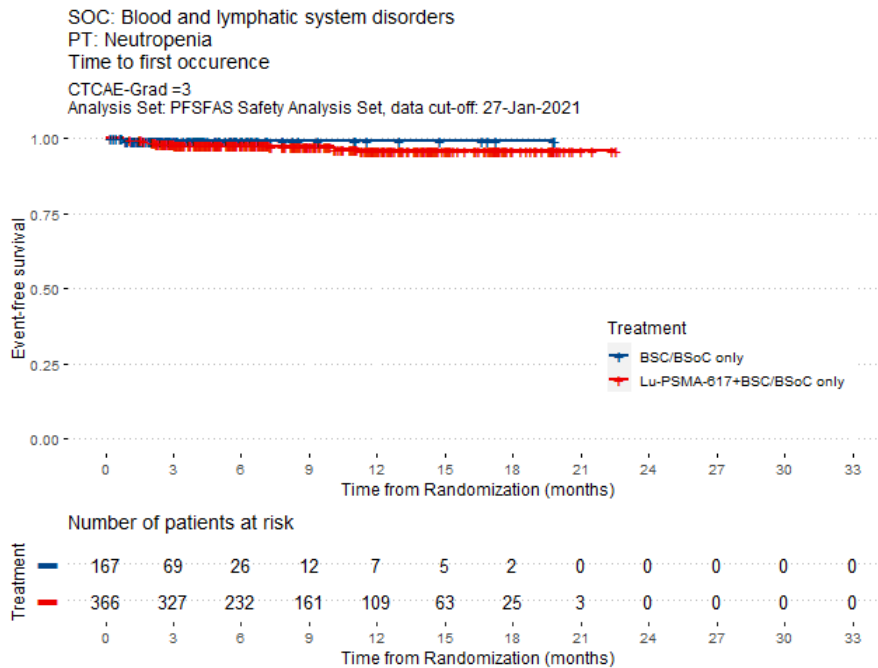


Abbildung 90: CTCAE-Grad 3-5: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Neutropenia

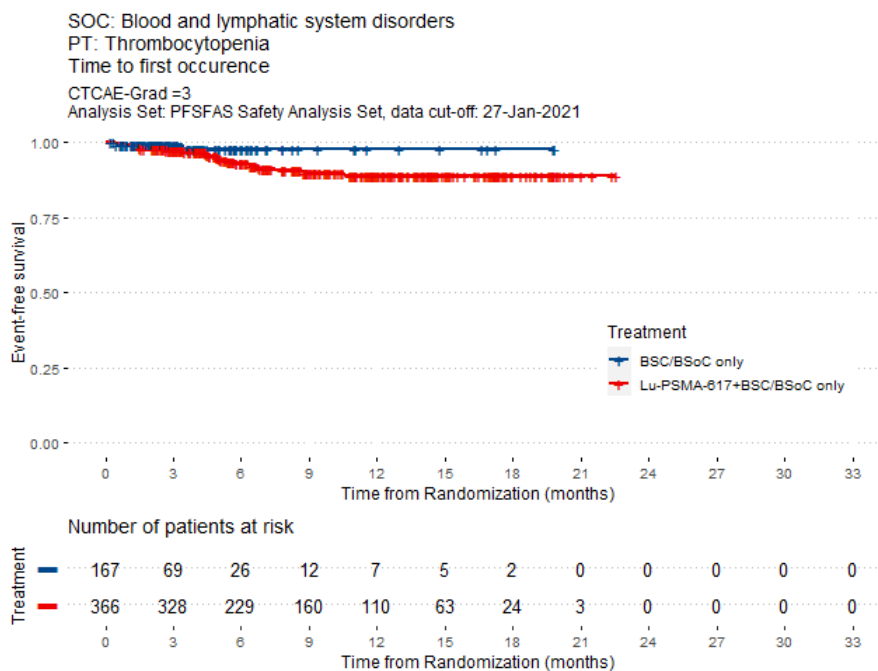


Abbildung 91: CTCAE-Grad 3-5: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Thrombocytopenia

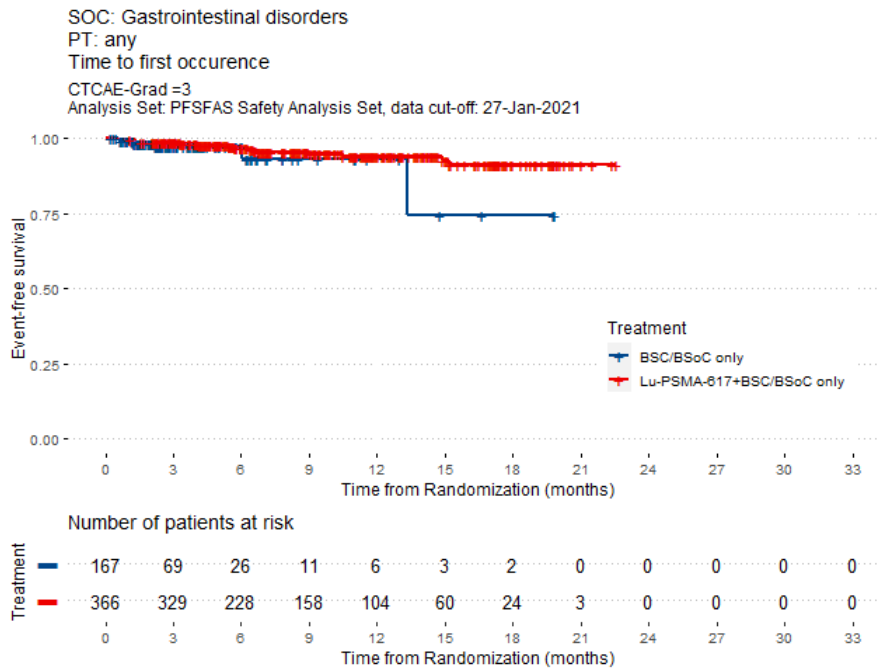


Abbildung 92: CTCAE-Grad 3-5: Time to first occurrence of SOC: Gastrointestinal disorders; PT: any

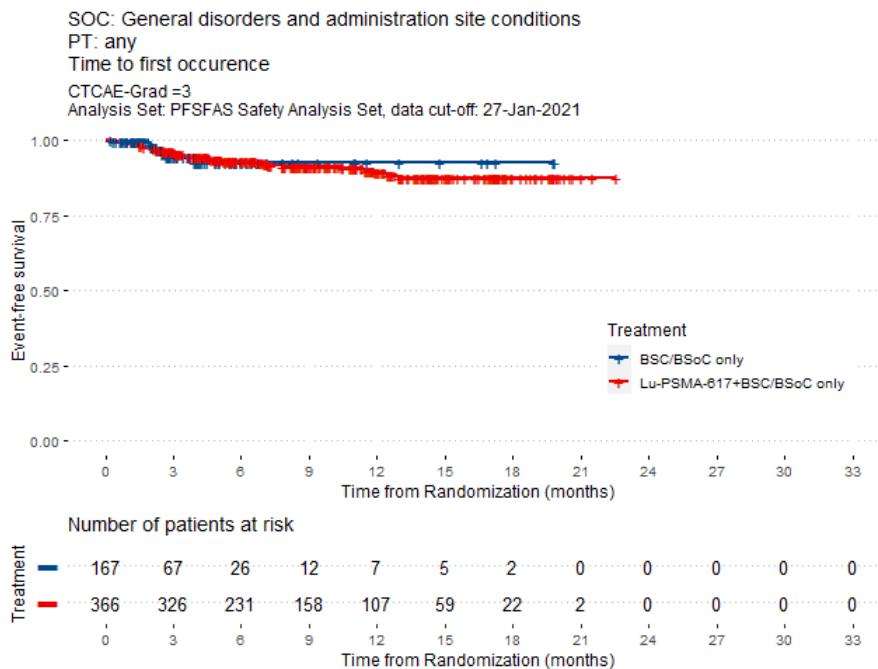


Abbildung 93: CTCAE-Grad 3-5: Time to first occurrence of SOC: General disorders and administration site conditions; PT: any

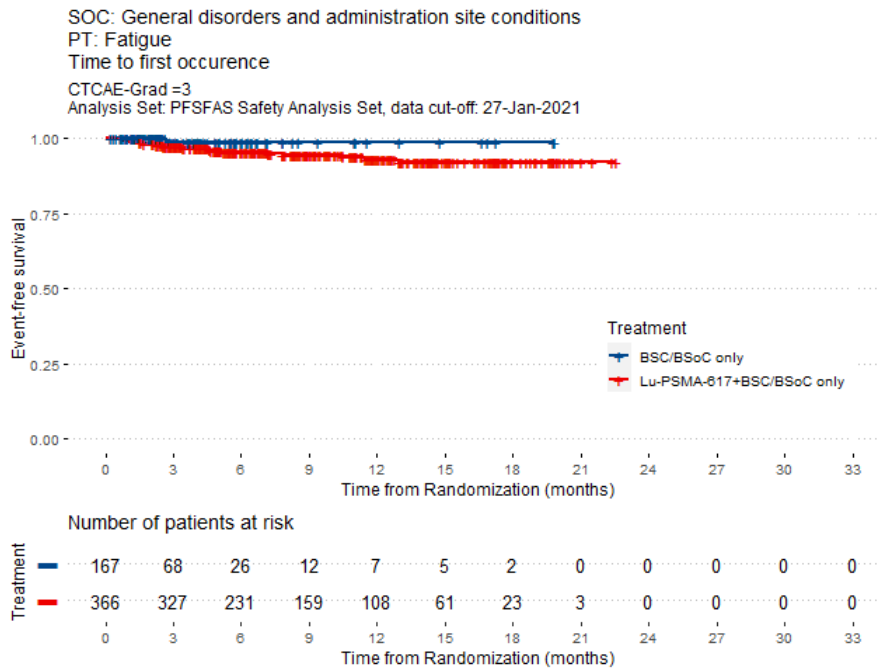


Abbildung 94: CTCAE-Grad 3-5: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Fatigue

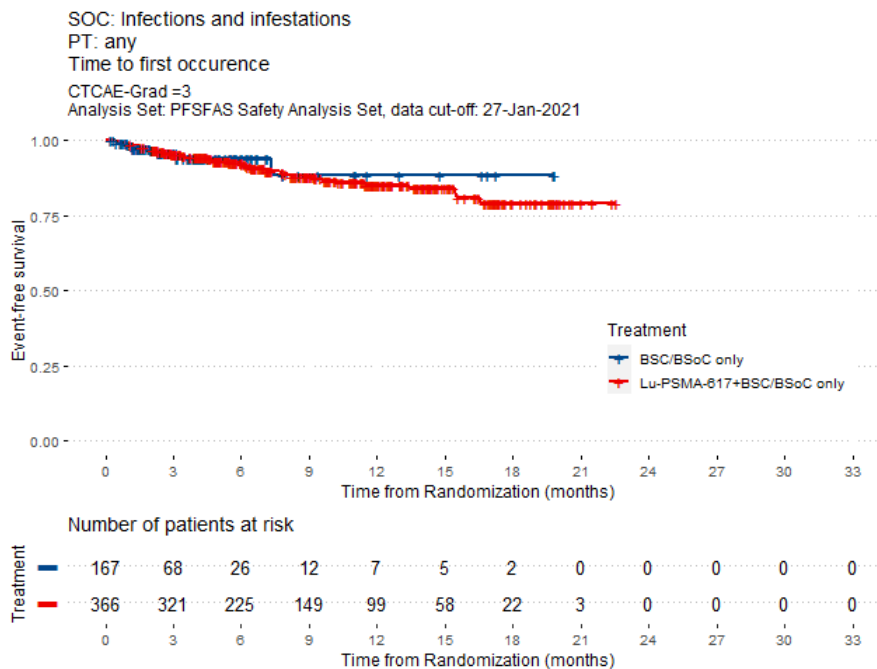


Abbildung 95: CTCAE-Grad 3-5: Time to first occurrence of SOC: Infections and infestations; PT: any

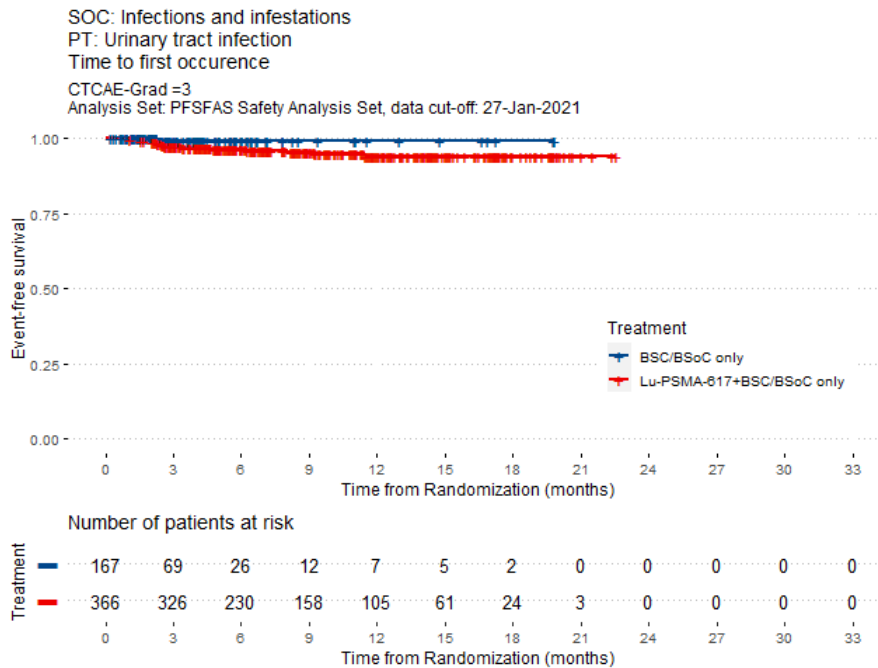


Abbildung 96: CTCAE-Grad 3-5: Time to first occurrence of SOC: Infections and infestations; PT: Urinary tract infection

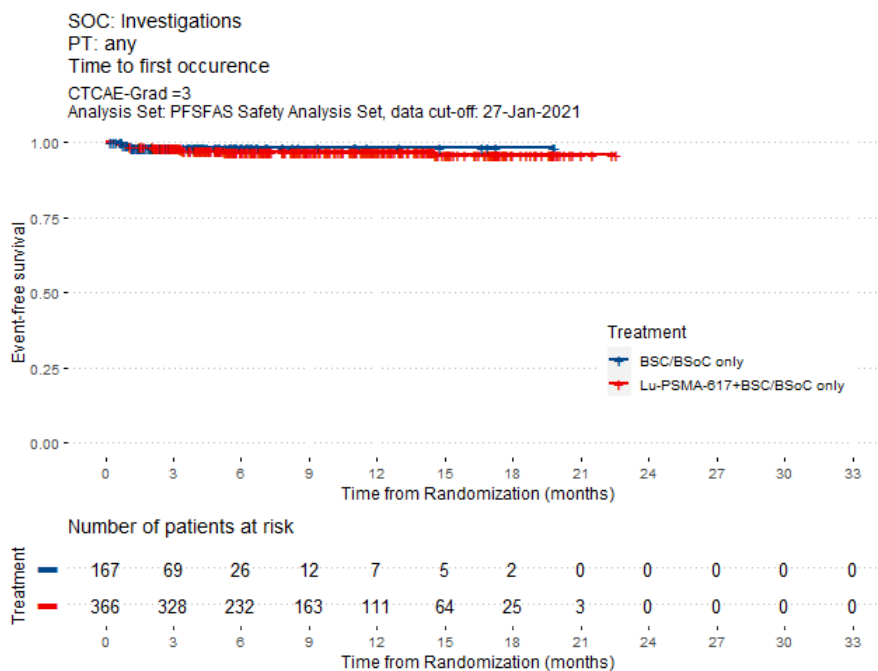


Abbildung 97: CTCAE-Grad 3-5: Time to first occurrence of SOC: Investigations; PT: any

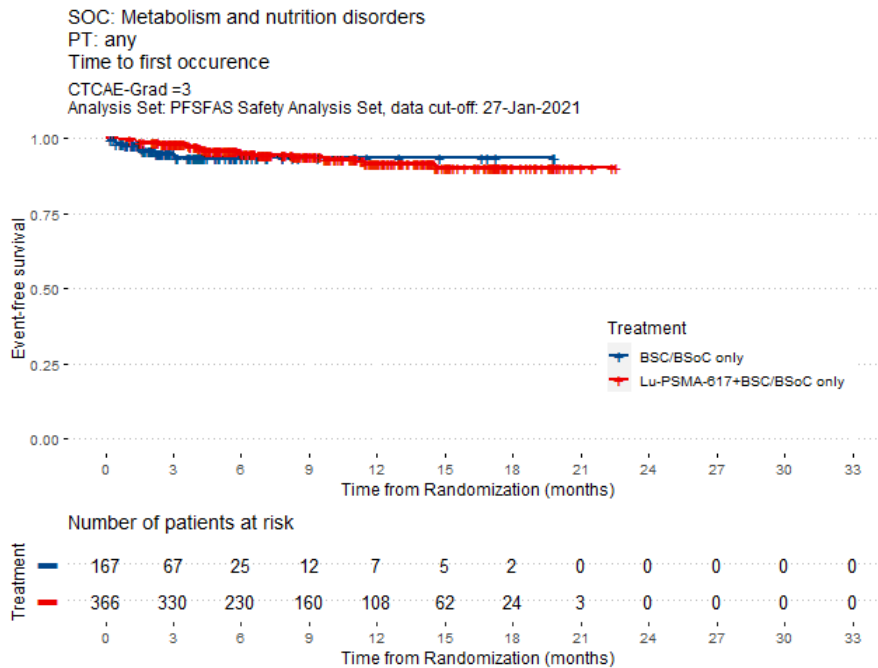


Abbildung 98: CTCAE-Grad 3-5: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: any

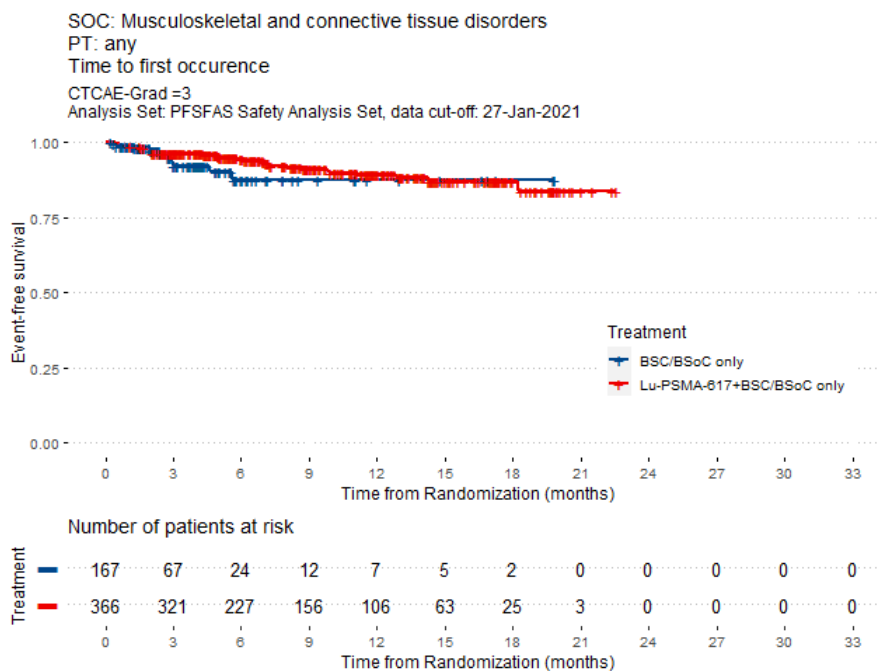


Abbildung 99: CTCAE-Grad 3-5: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: any

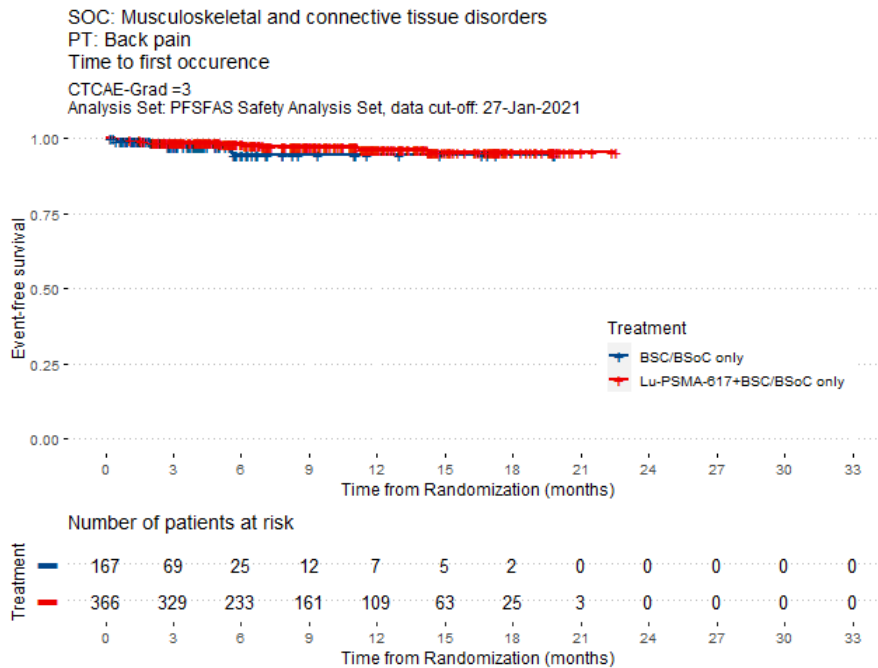


Abbildung 100: CTCAE-Grad 3-5: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Back pain

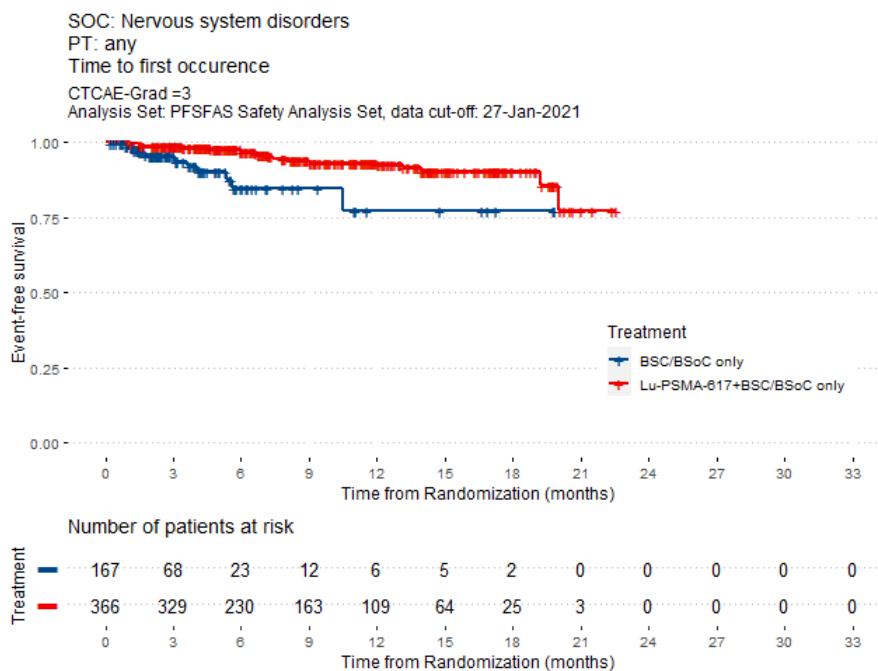


Abbildung 101: CTCAE-Grad 3-5: Time to first occurrence of SOC: Nervous system disorders; PT: any

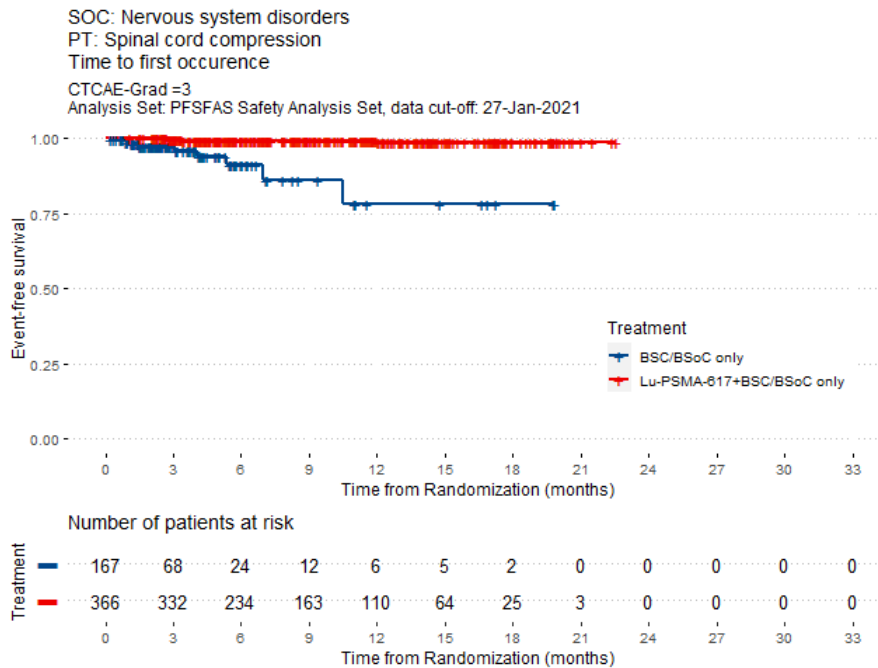


Abbildung 102: CTCAE-Grad 3-5: Time to first occurrence of SOC: Nervous system disorders; PT: Spinal cord compression

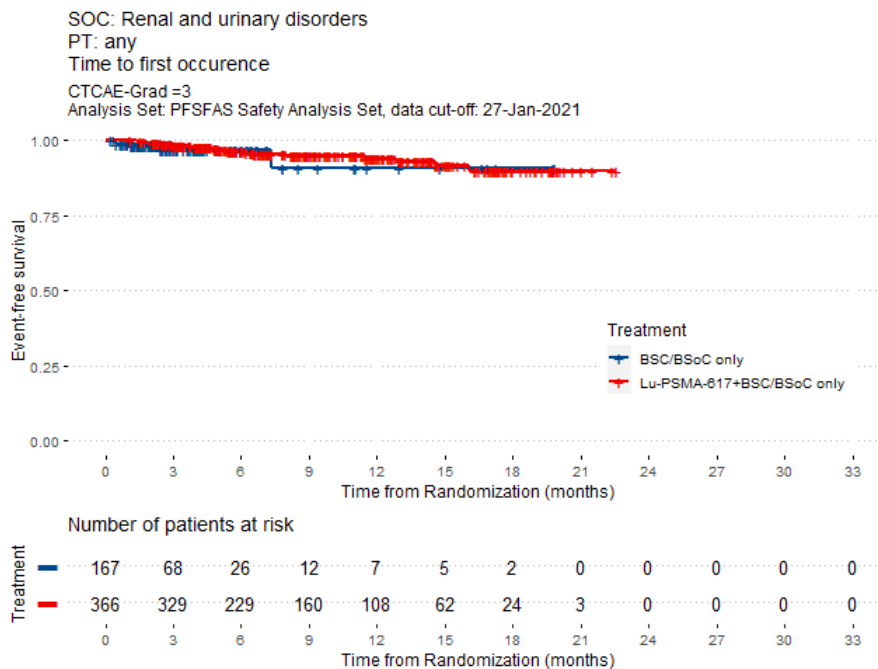


Abbildung 103: CTCAE-Grad 3-5: Time to first occurrence of SOC: Renal and urinary disorders; PT: any

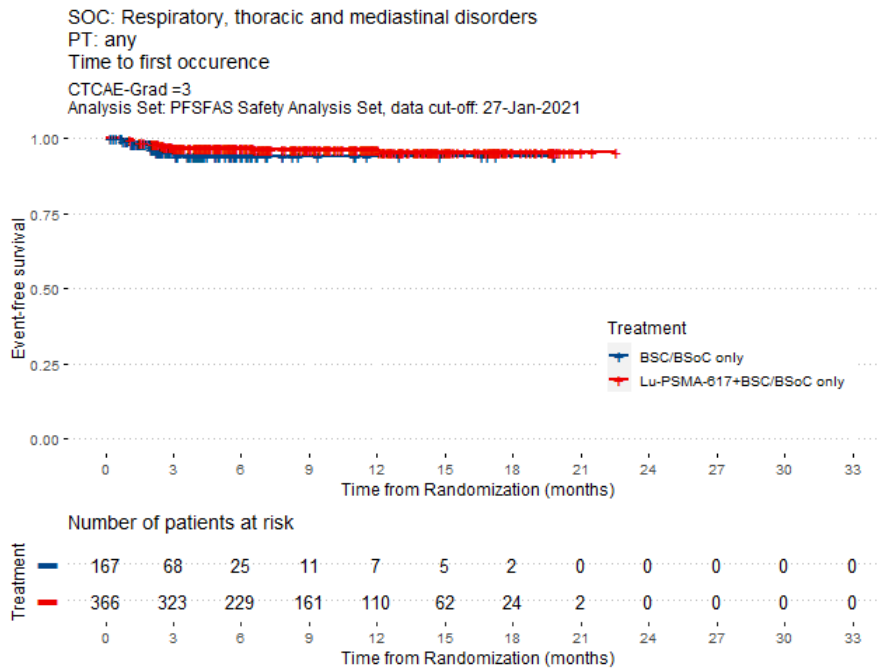


Abbildung 104: CTCAE-Grad 3-5: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: any

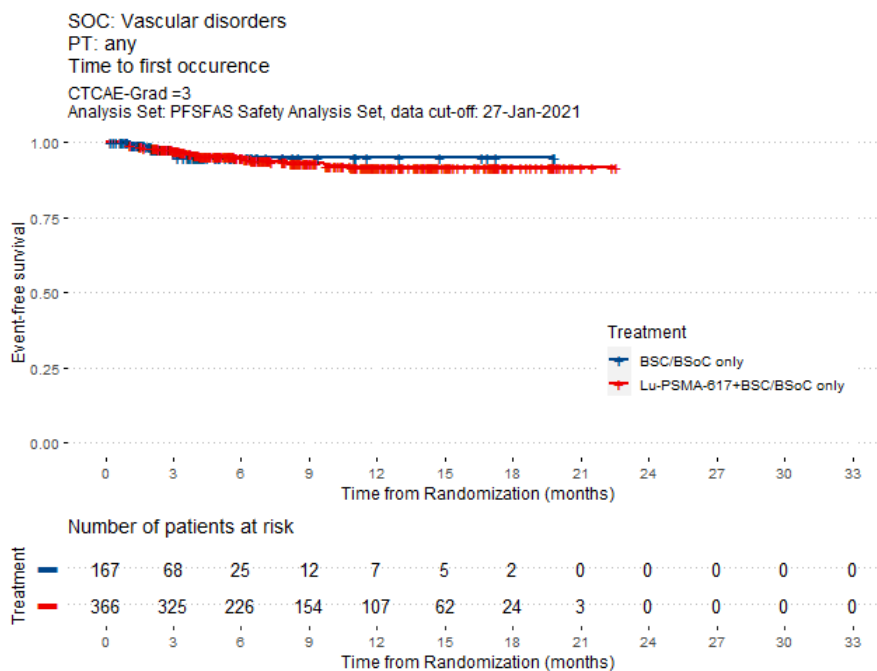


Abbildung 105: CTCAE-Grad 3-5: Time to first occurrence of SOC: Vascular disorders; PT: any



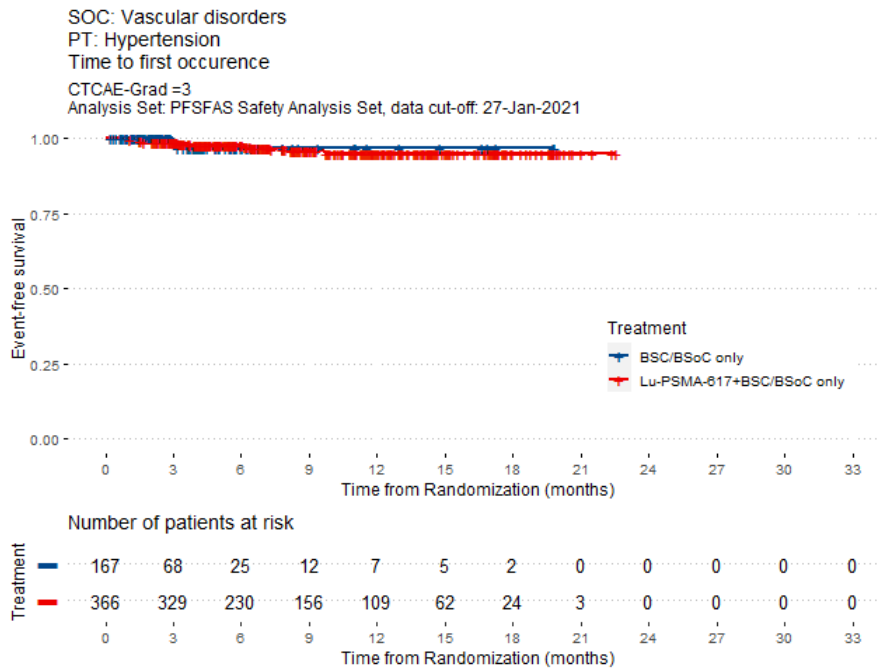


Abbildung 106: CTCAE-Grad 3-5: Time to first occurrence of SOC: Vascular disorders; PT: Hypertension

**Anhang 1.3: Schwerwiegende UE**

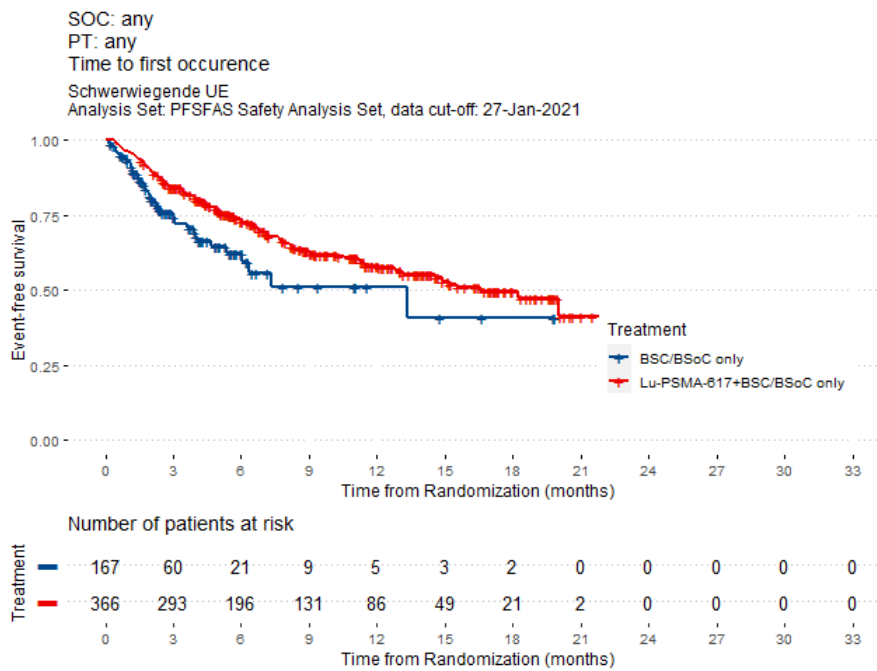


Abbildung 107: Schwerwiegende UE: Time to first occurrence of SOC: any; PT: any

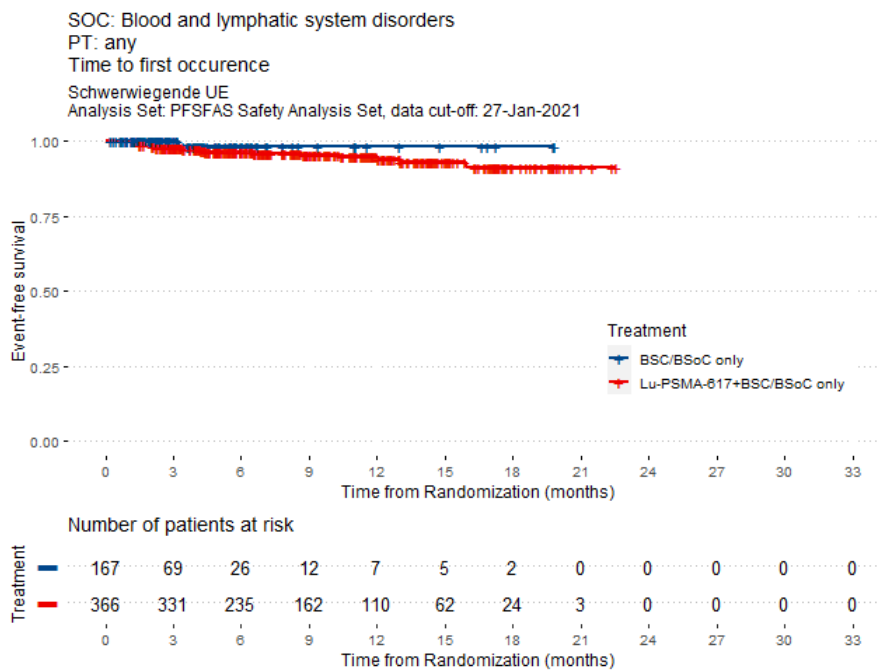


Abbildung 108: Schwerwiegende UE: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: any

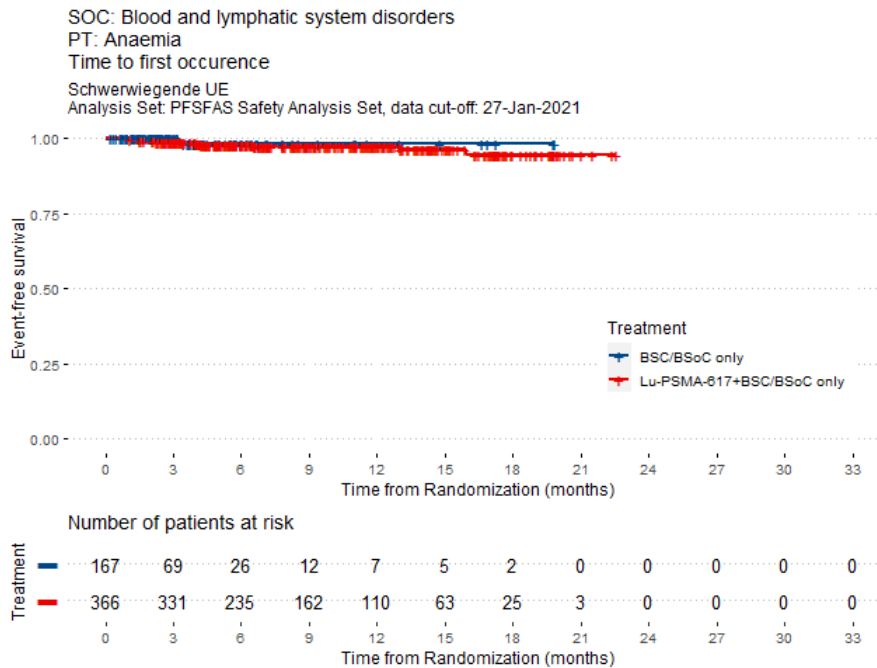


Abbildung 109: Schwerwiegende UE: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Anaemia

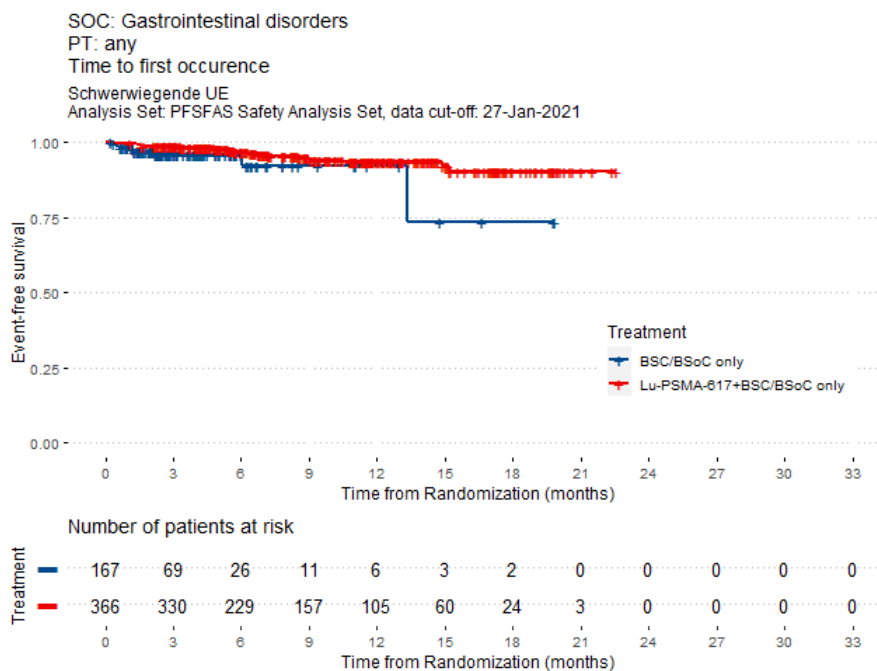


Abbildung 110: Schwerwiegende UE: Time to first occurrence of SOC: Gastrointestinal disorders; PT: any

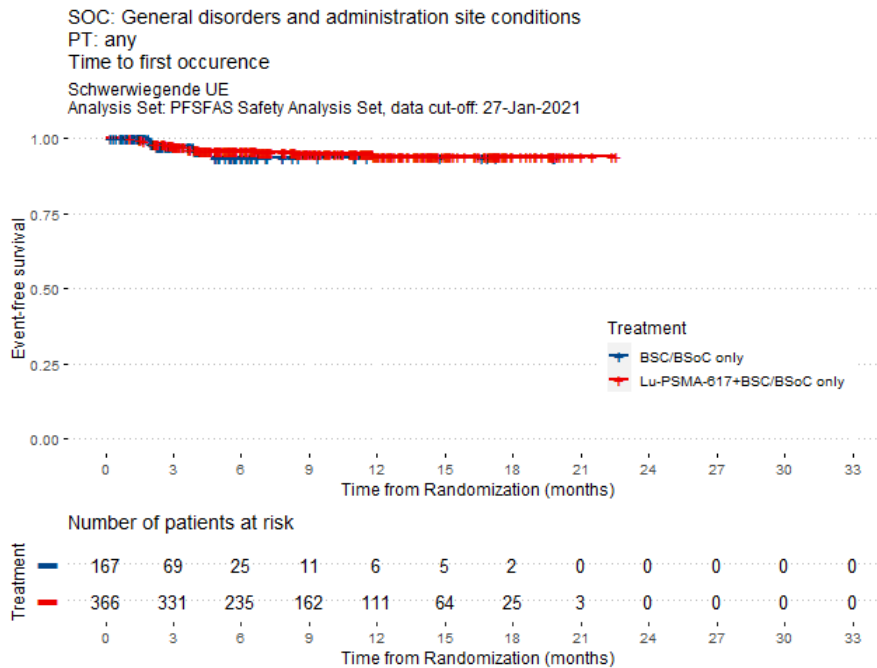


Abbildung 111: Schwerwiegende UE: Time to first occurrence of SOC: General disorders and administration site conditions; PT: any

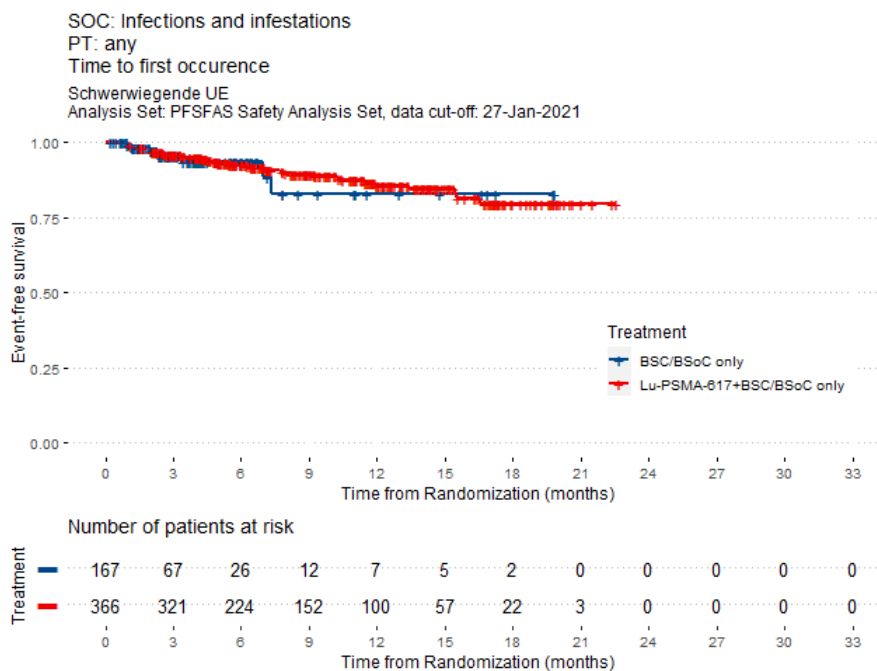


Abbildung 112: Schwerwiegende UE: Time to first occurrence of SOC: Infections and infestations; PT: any

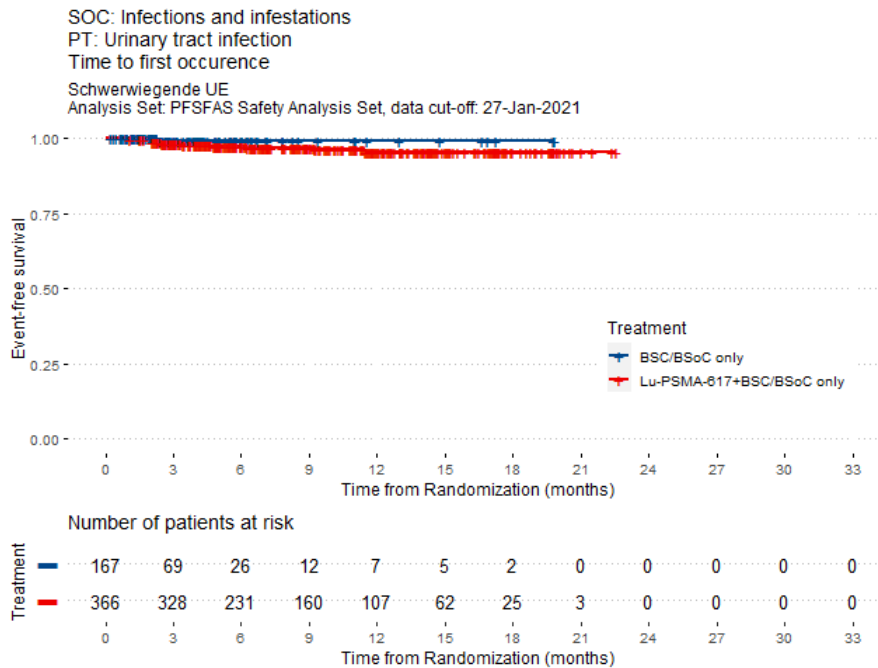


Abbildung 113: Schwerwiegende UE: Time to first occurrence of SOC: Infections and infestations; PT: Urinary tract infection

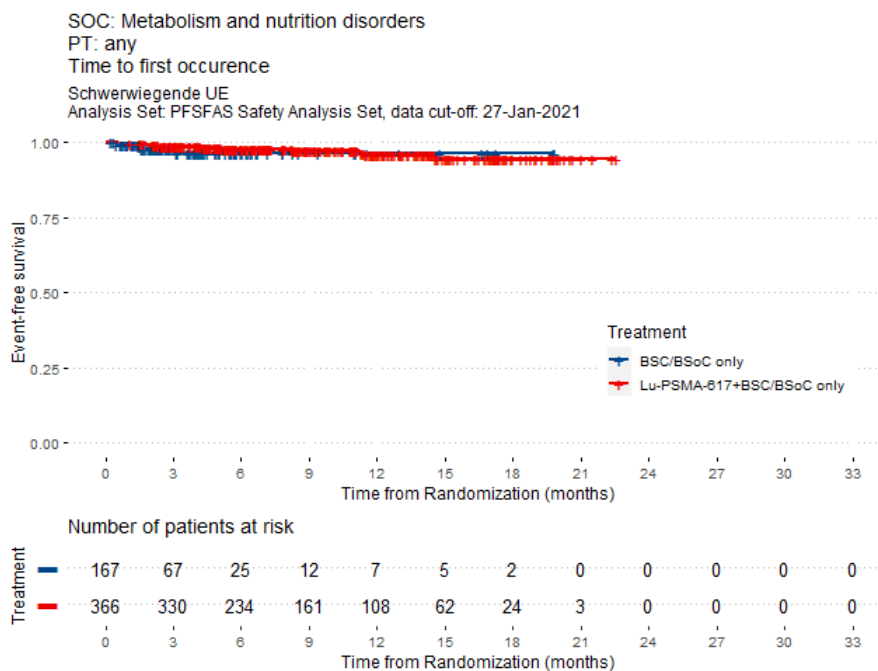


Abbildung 114: Schwerwiegende UE: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: any

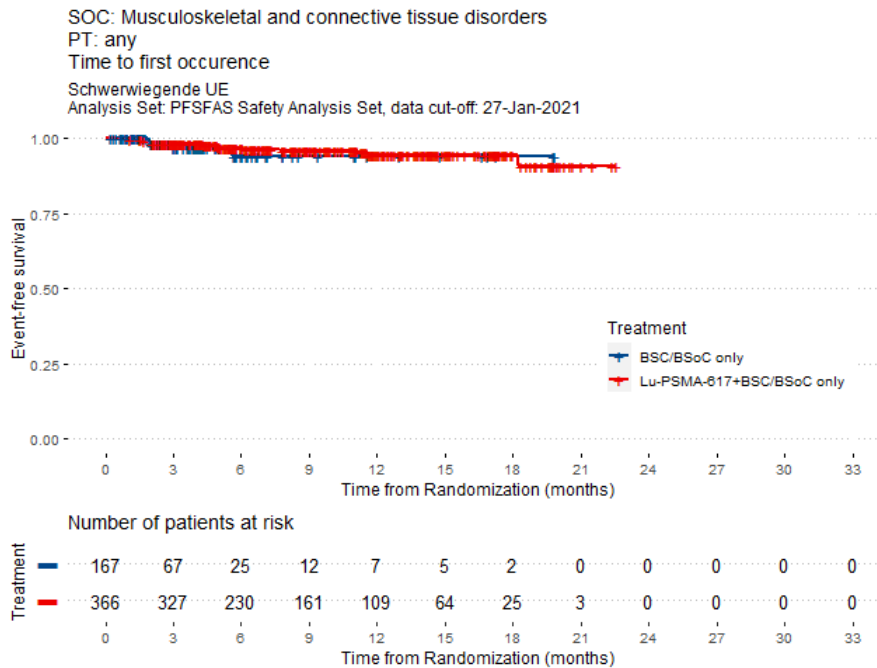


Abbildung 115: Schwerwiegende UE: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: any

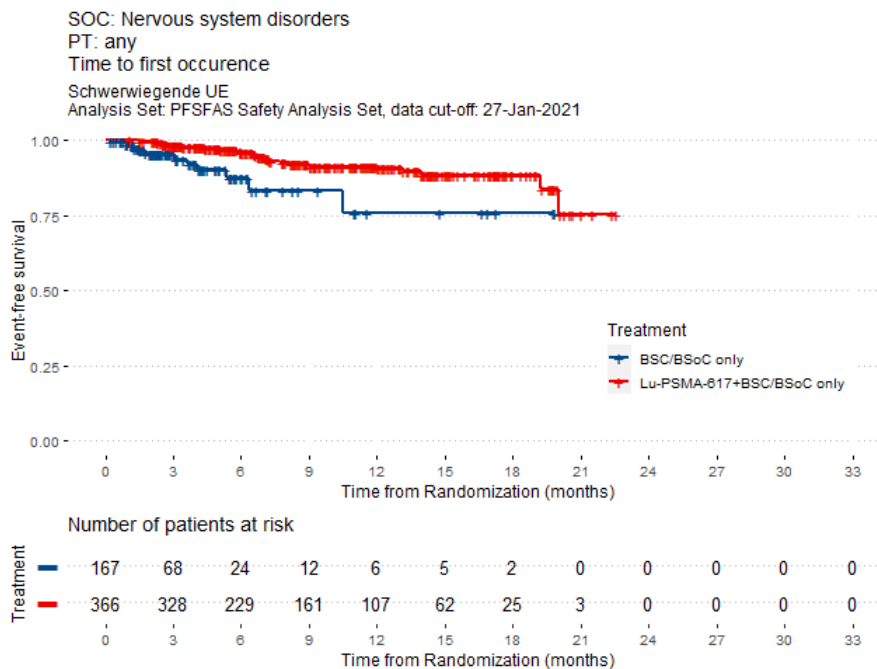


Abbildung 116: Schwerwiegende UE: Time to first occurrence of SOC: Nervous system disorders; PT: any

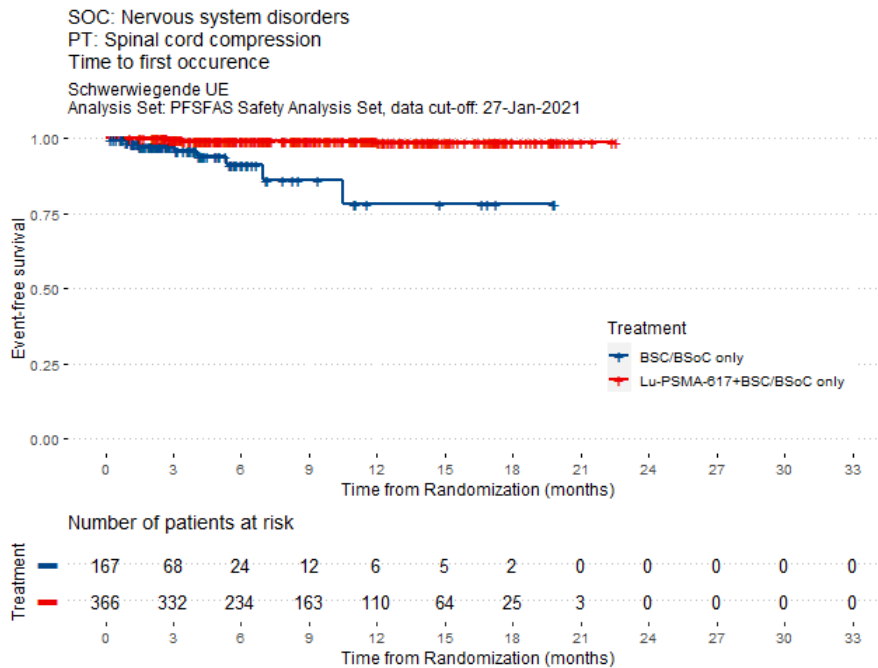


Abbildung 117: Schwerwiegende UE: Time to first occurrence of SOC: Nervous system disorders; PT: Spinal cord compression

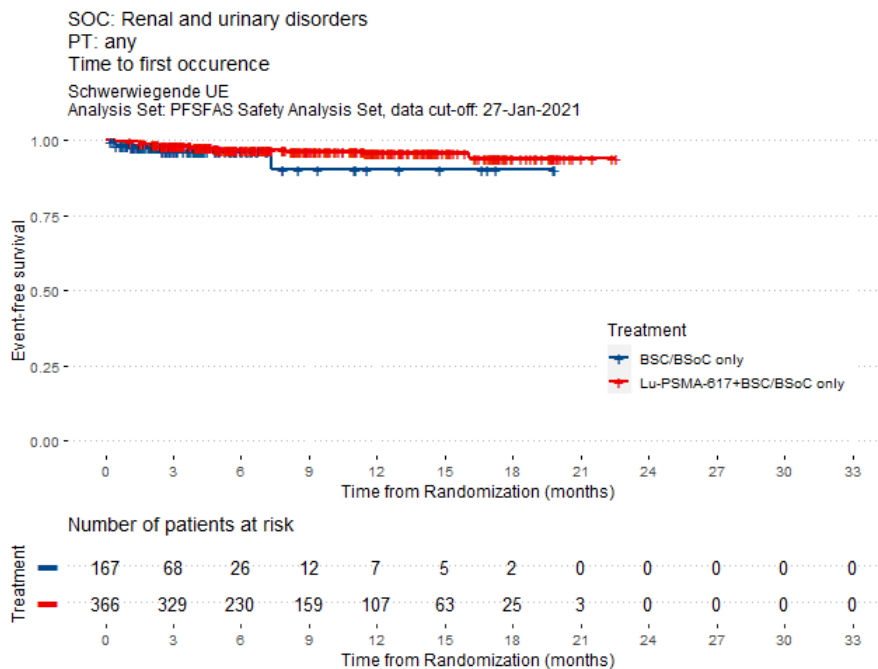


Abbildung 118: Schwerwiegende UE: Time to first occurrence of SOC: Renal and urinary disorders; PT: any

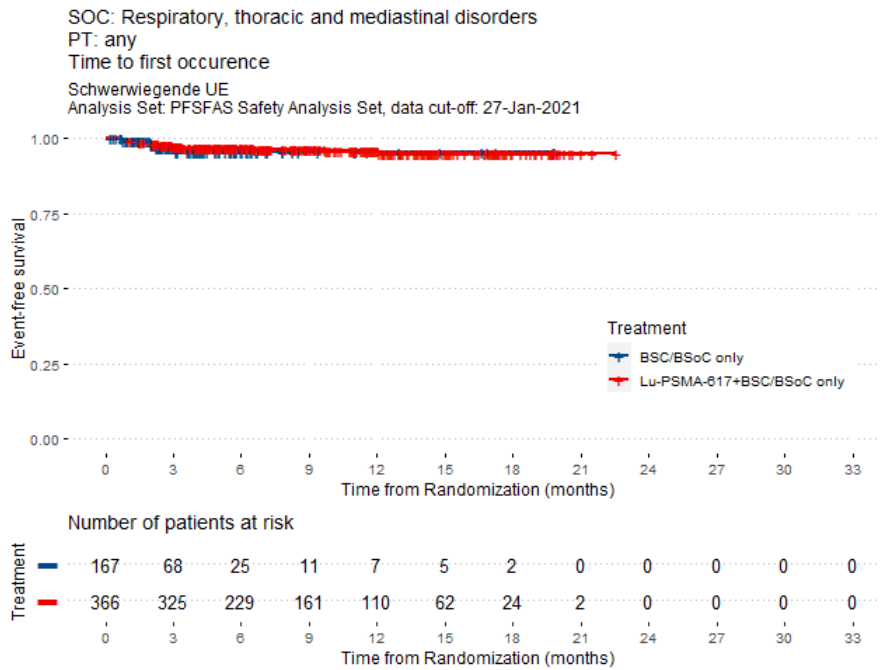


Abbildung 119: Schwerwiegende UE: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: any



## Anhang 2: Unerwünschte Ereignisse von besonderem Interesse

### Anhang 2.1: UE jeglichen Schweregrads

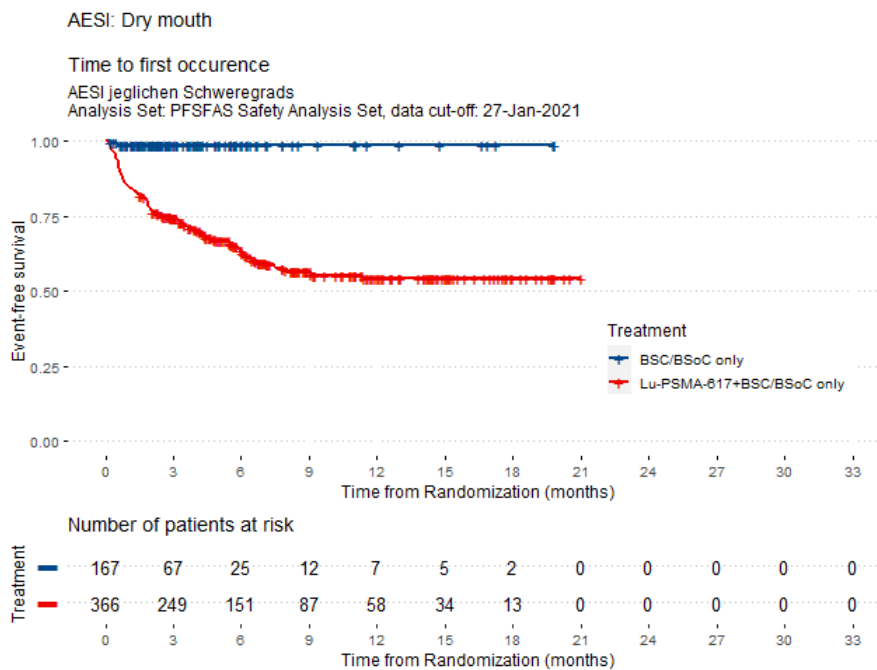


Abbildung 120: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Dry mouth

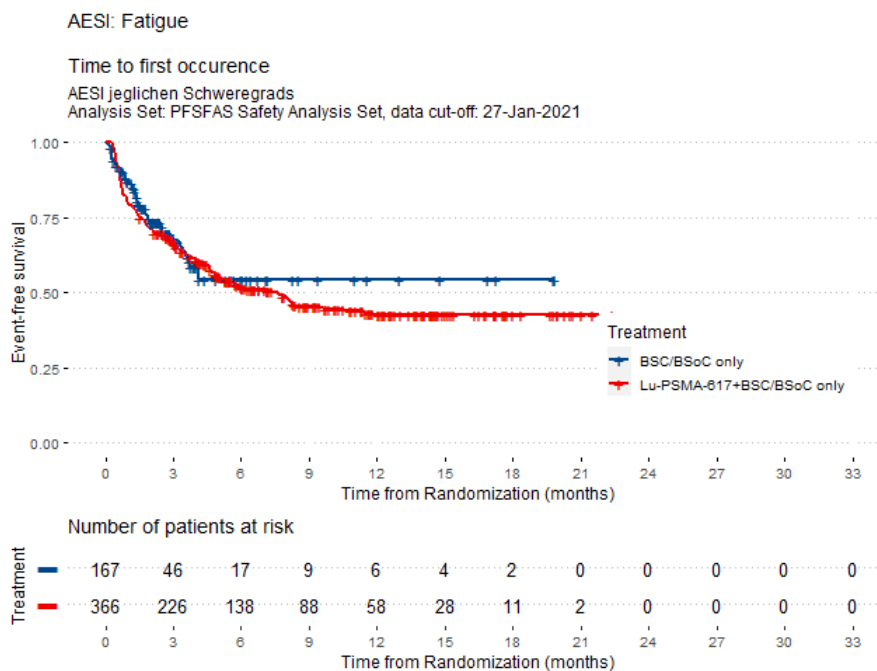


Abbildung 121: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Fatigue

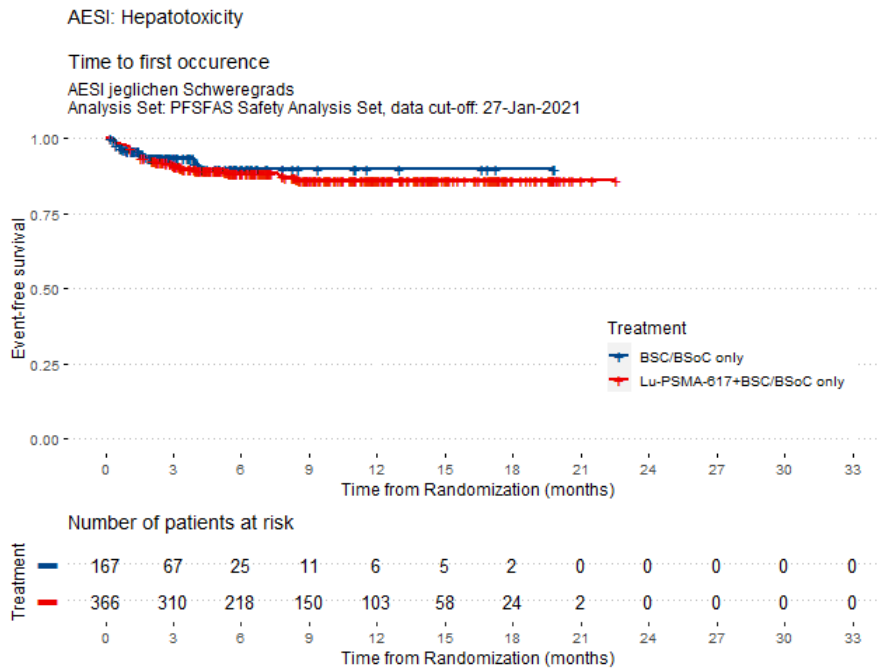


Abbildung 122: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Hepatotoxicity

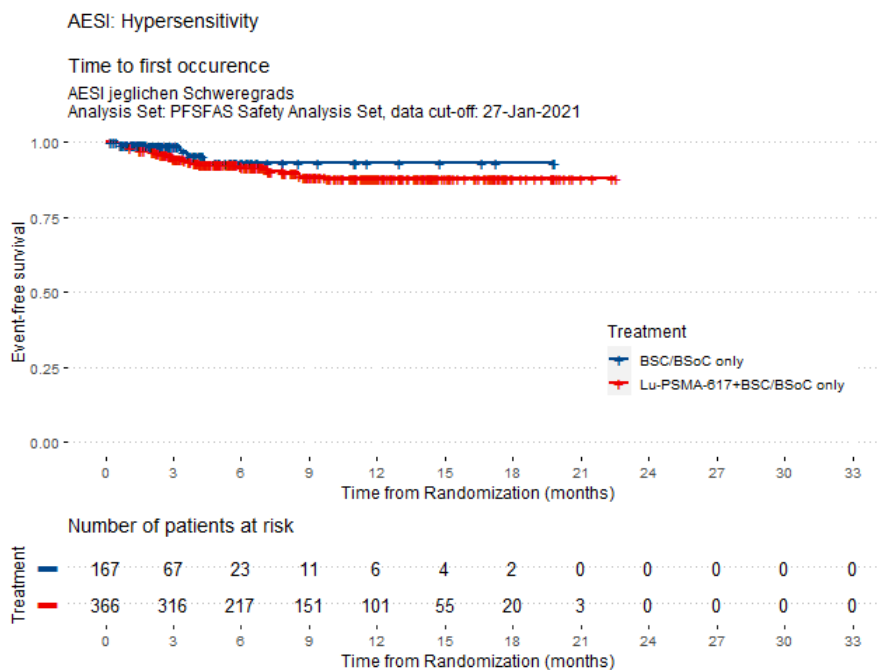


Abbildung 123: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Hypersensitivity

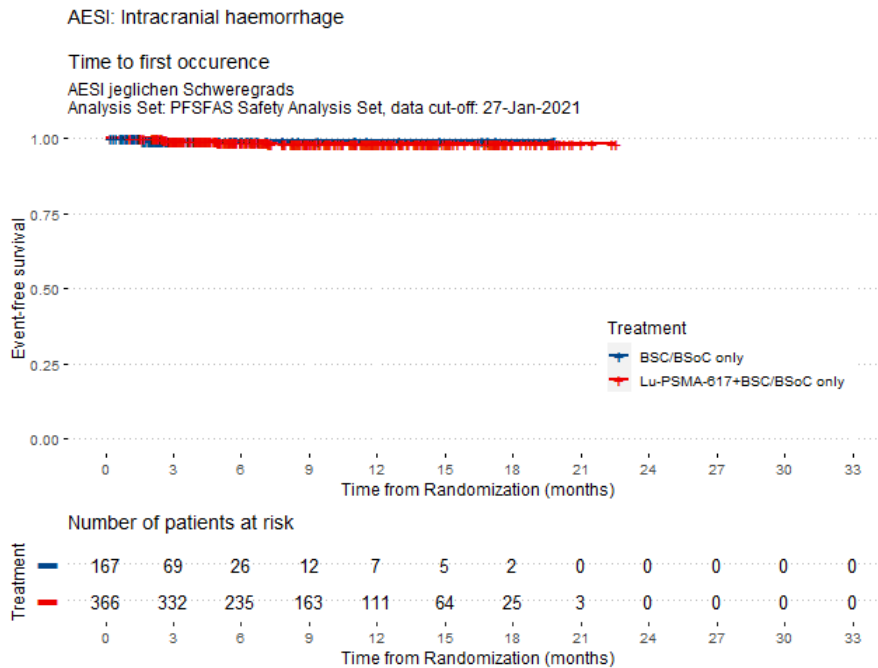


Abbildung 124: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Intracranial haemorrhage

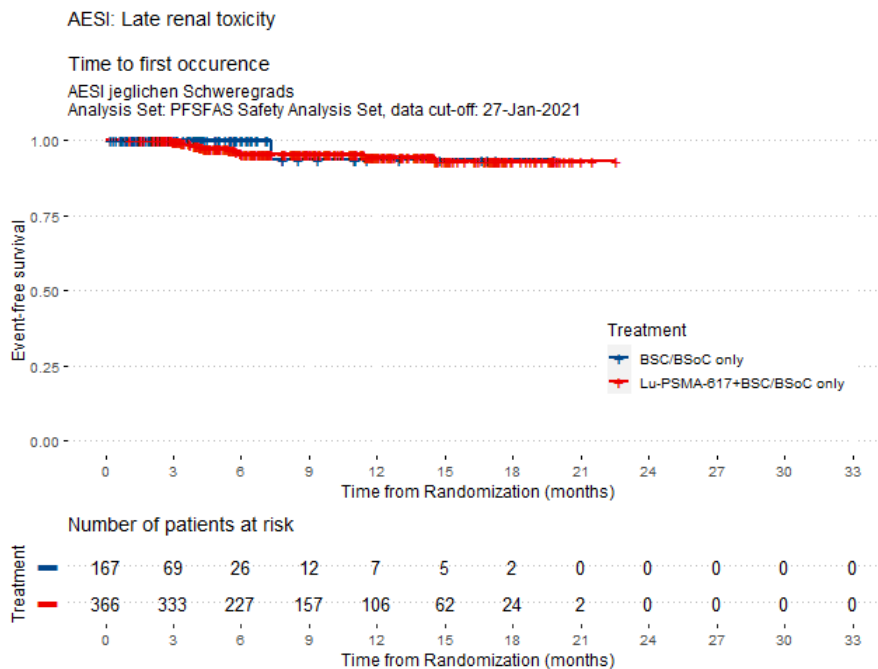


Abbildung 125: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Late renal toxicity

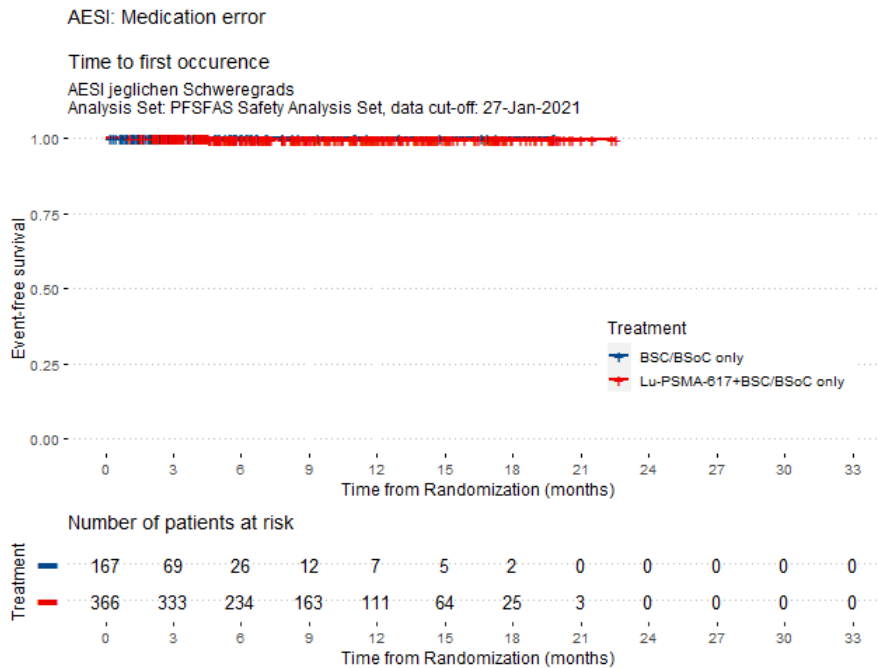


Abbildung 126: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Medication error

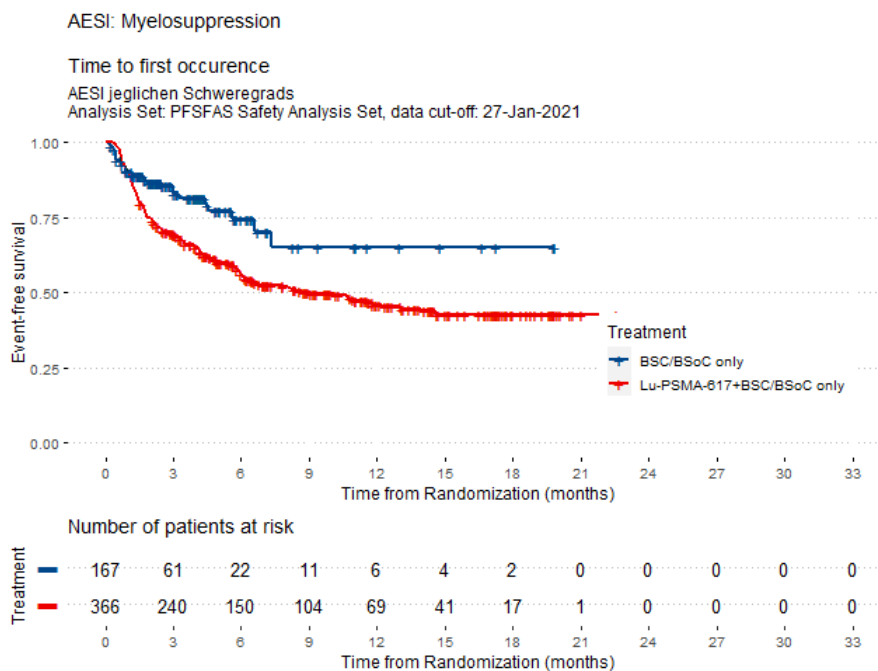


Abbildung 127: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Myelosuppression

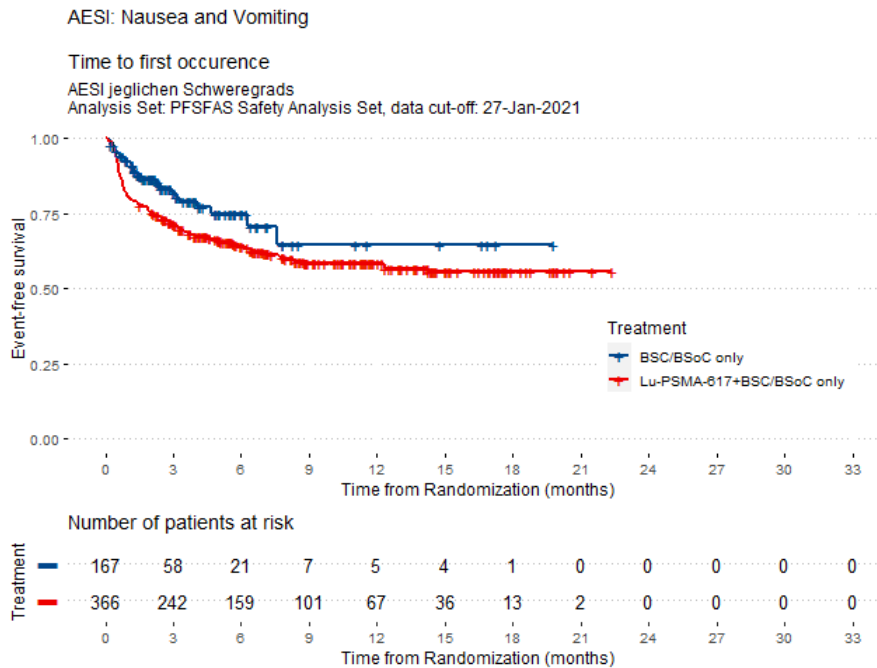


Abbildung 128: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Nausea and Vomiting

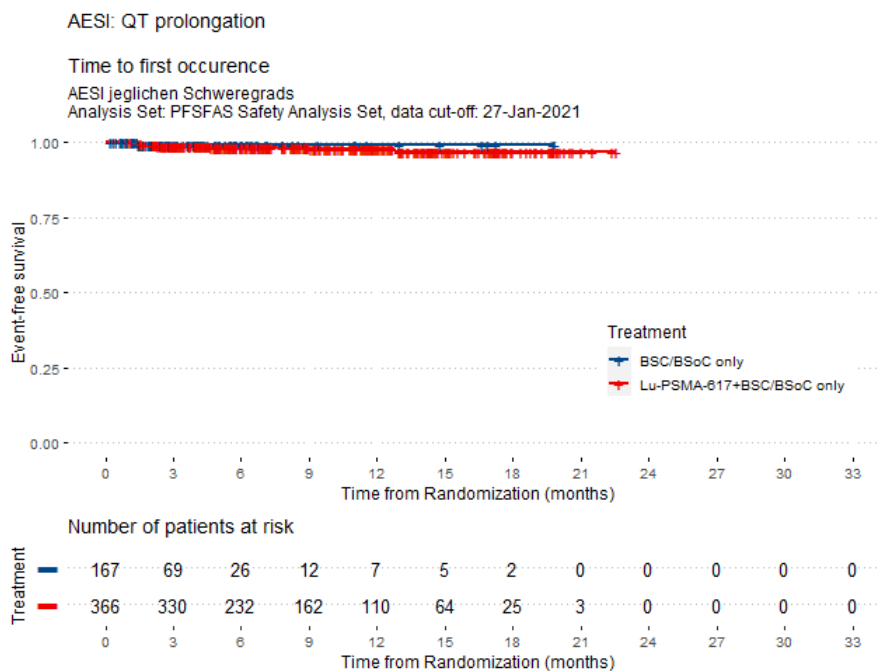


Abbildung 129: AESI jeglichen Schweregrads: Time to first occurrence of AESI: QT prolongation

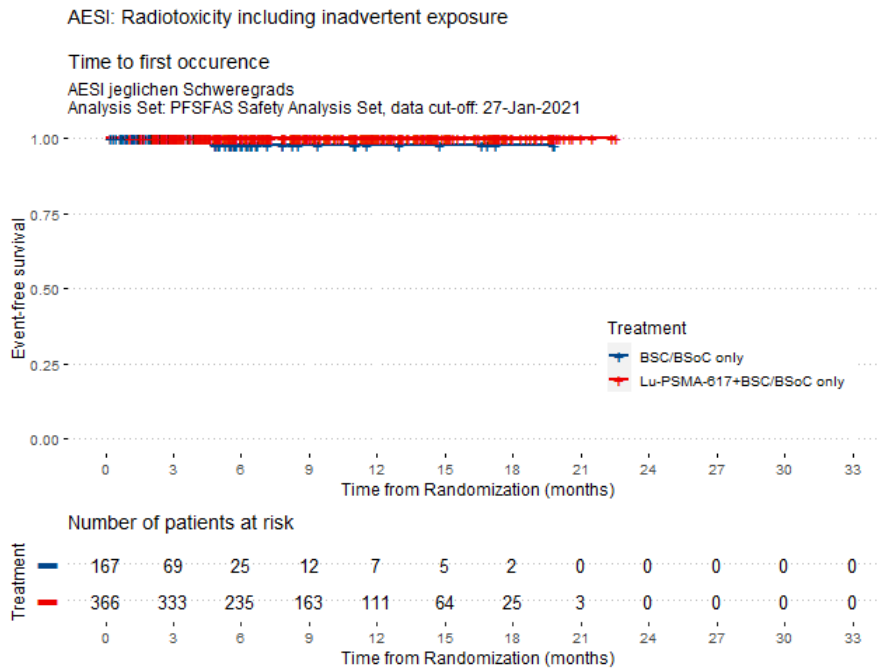


Abbildung 130: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Radiotoxicity including inadvertent exposure

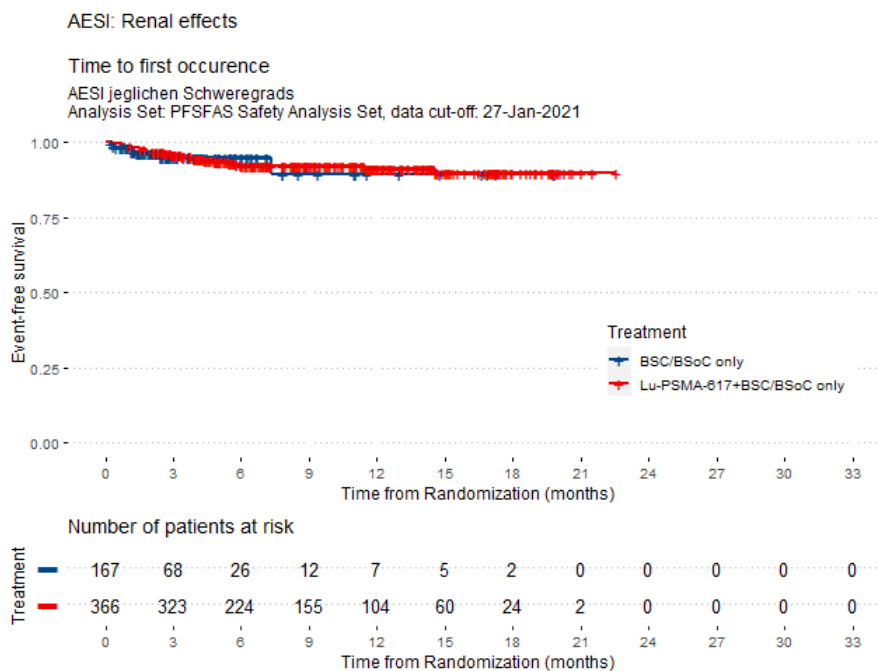


Abbildung 131: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Renal effects

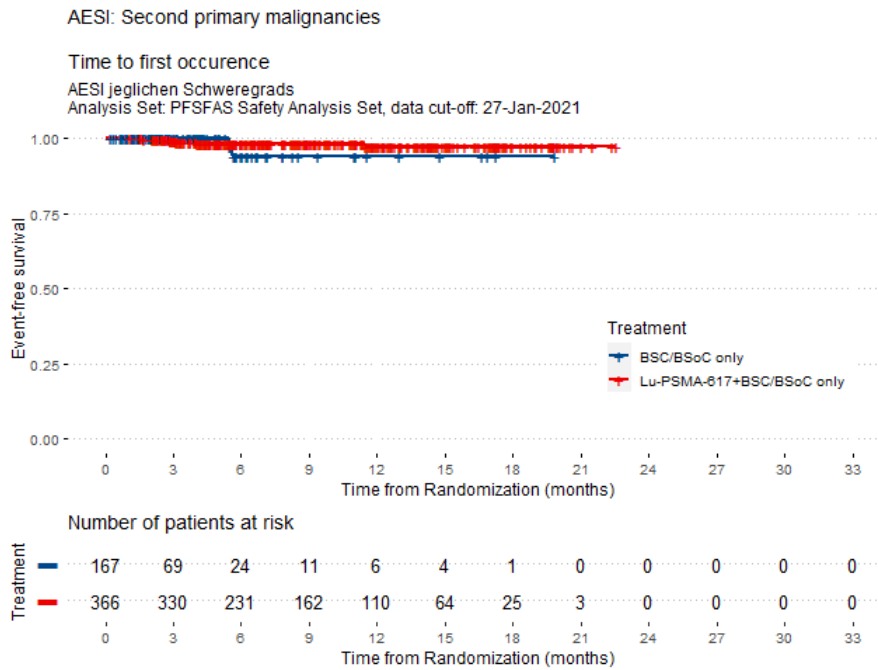


Abbildung 132: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Second primary malignancies

**Anhang 2.2: Nicht-schwere UE (CTCAE-Grad 1-2)**

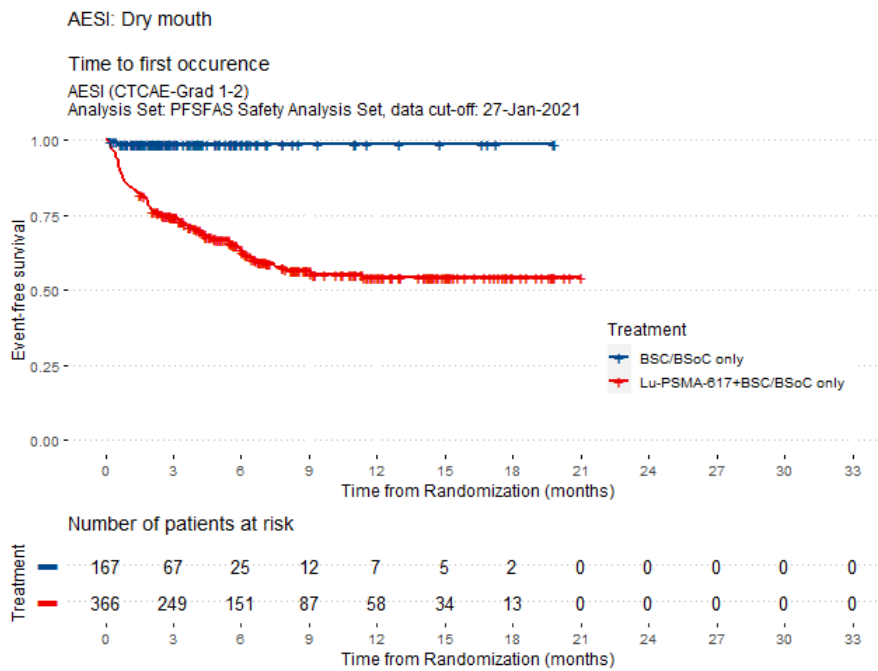


Abbildung 133: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Dry mouth

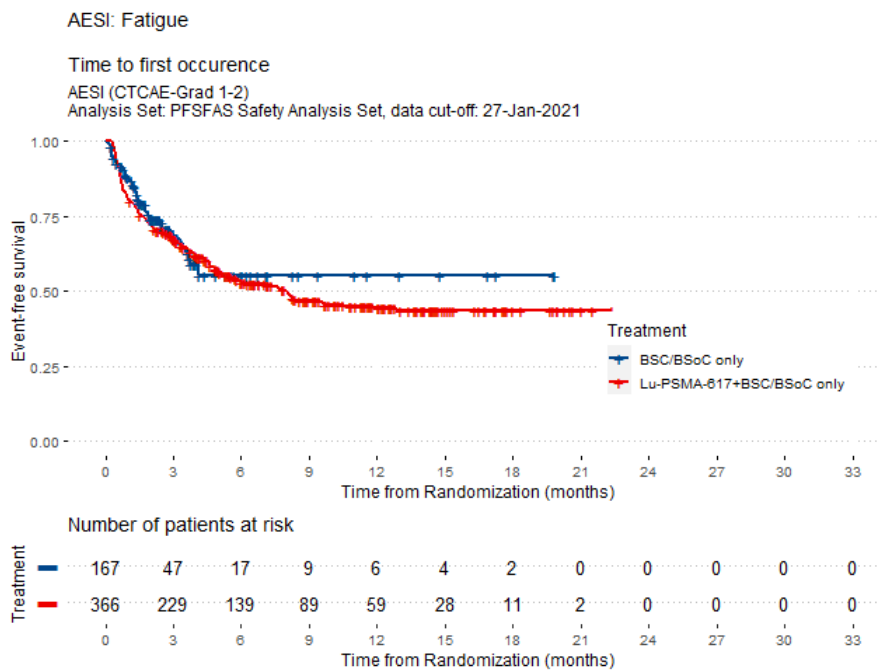


Abbildung 134: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Fatigue



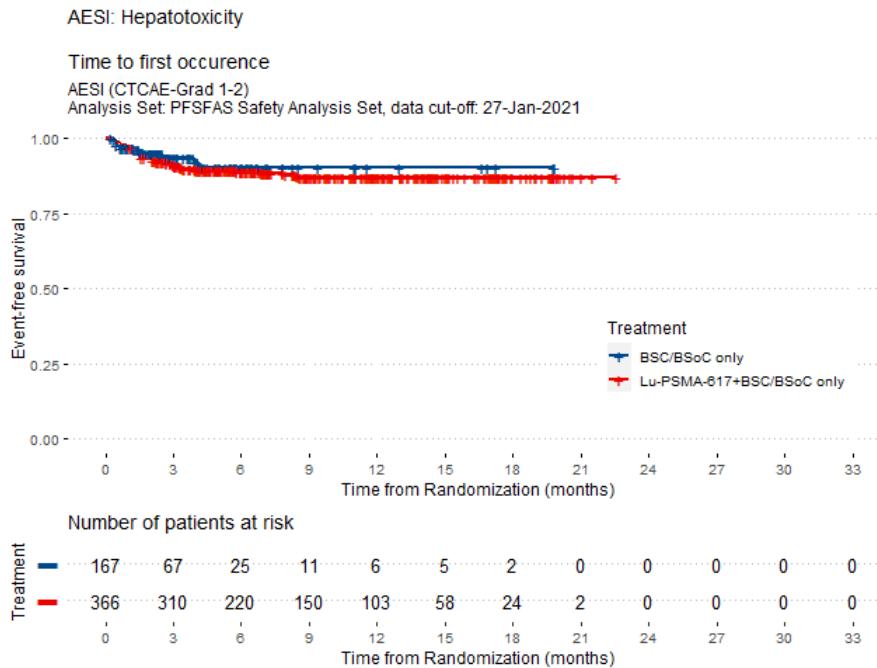


Abbildung 135: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Hepatotoxicity

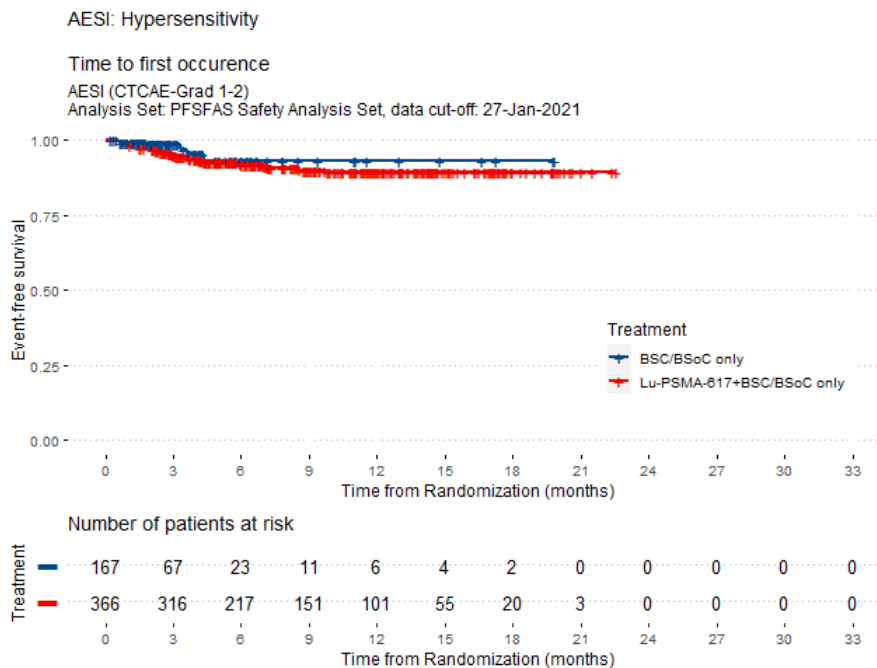


Abbildung 136: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Hypersensitivity

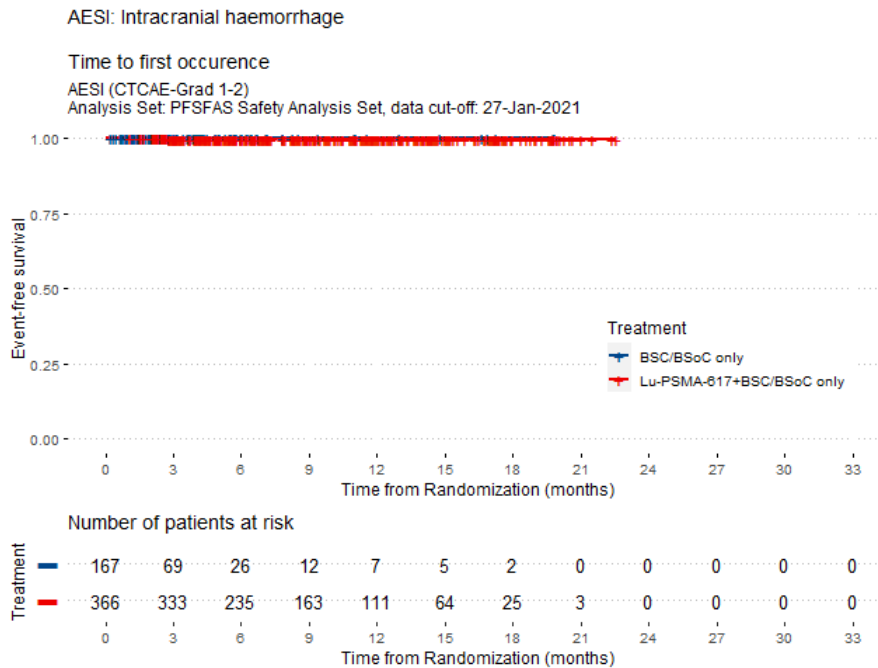


Abbildung 137: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Intracranial haemorrhage

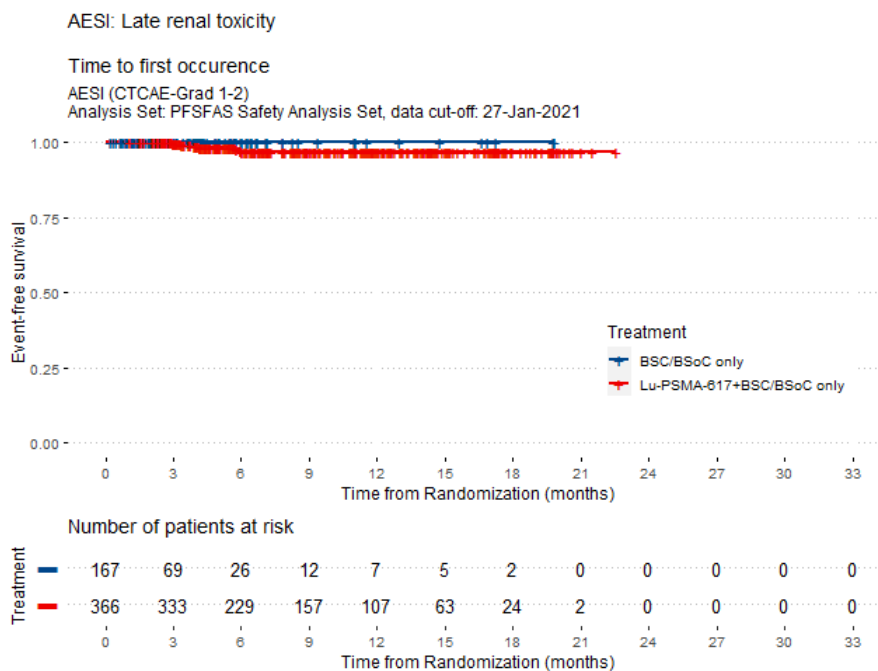


Abbildung 138: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Late renal toxicity

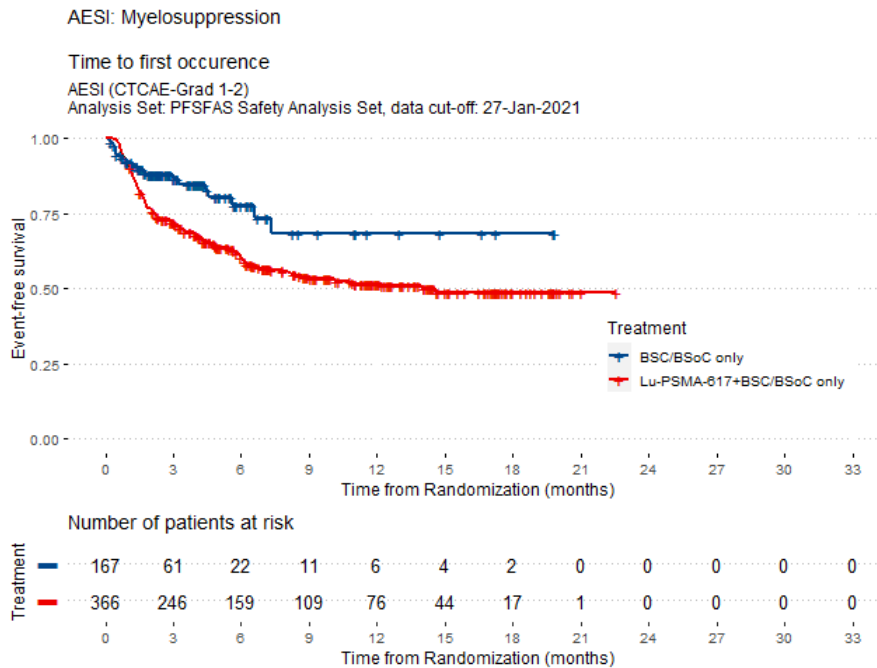


Abbildung 139: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Myelosuppression

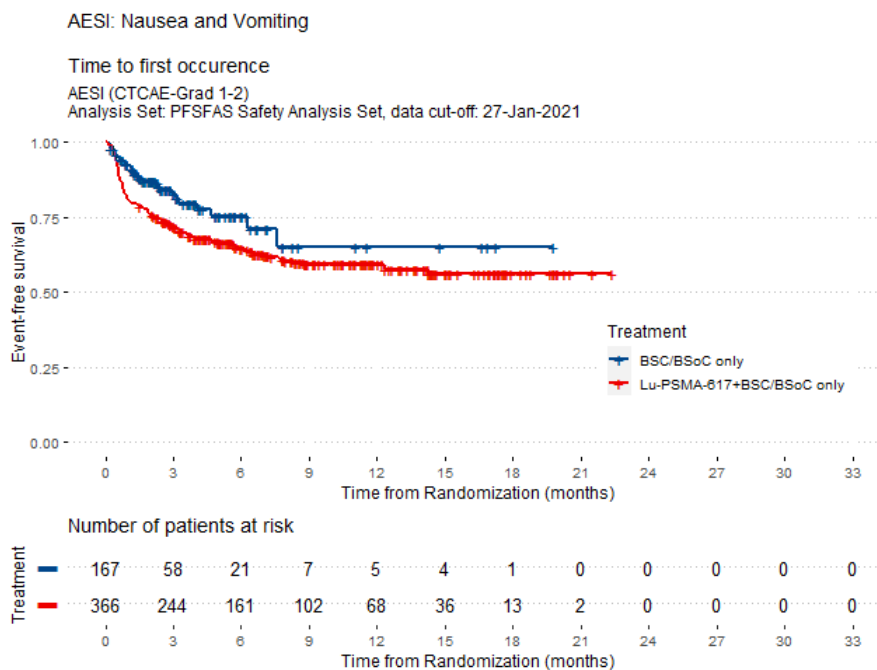


Abbildung 140: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Nausea and Vomiting

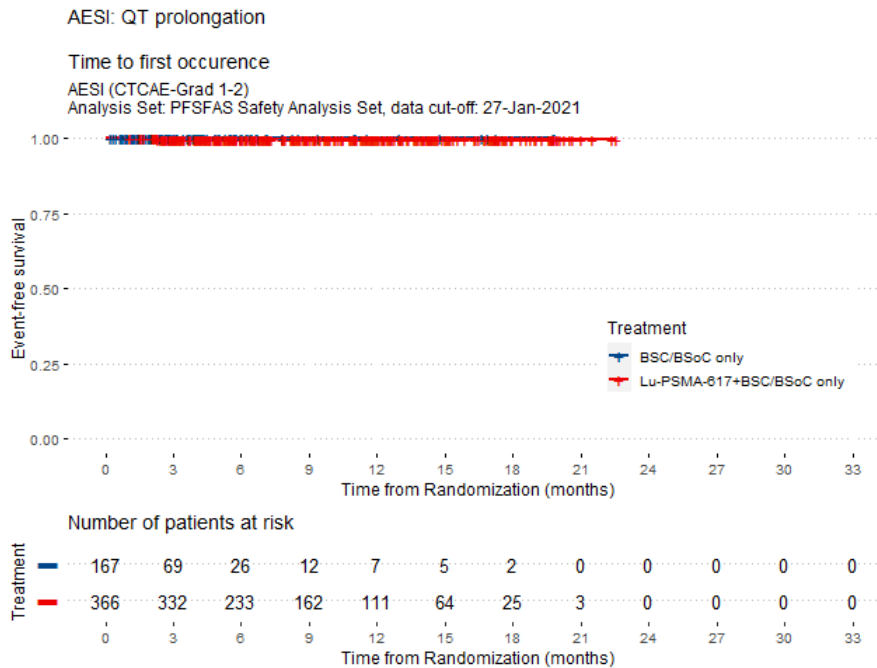


Abbildung 141: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: QT prolongation

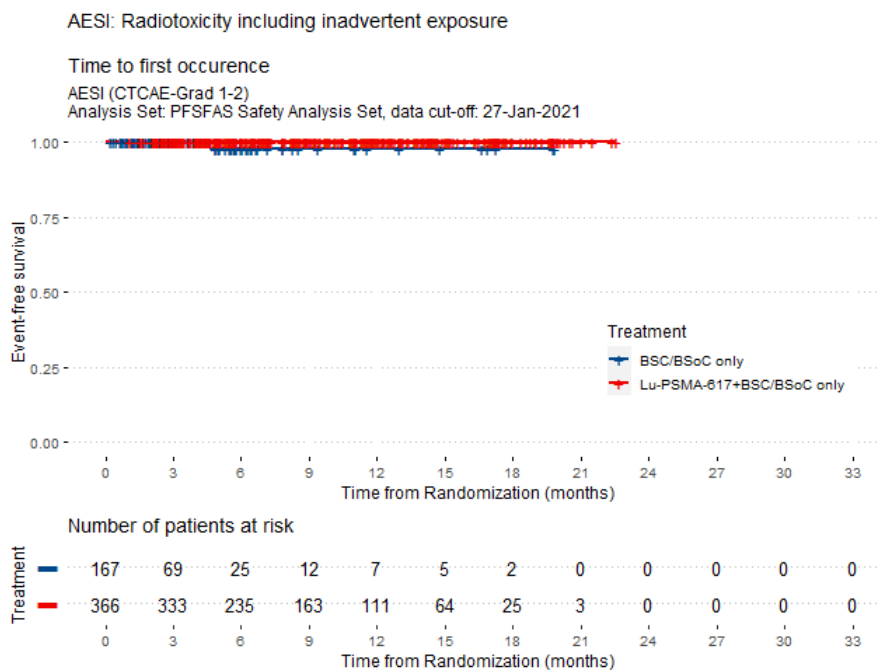


Abbildung 142: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Radiotoxicity including inadvertent exposure

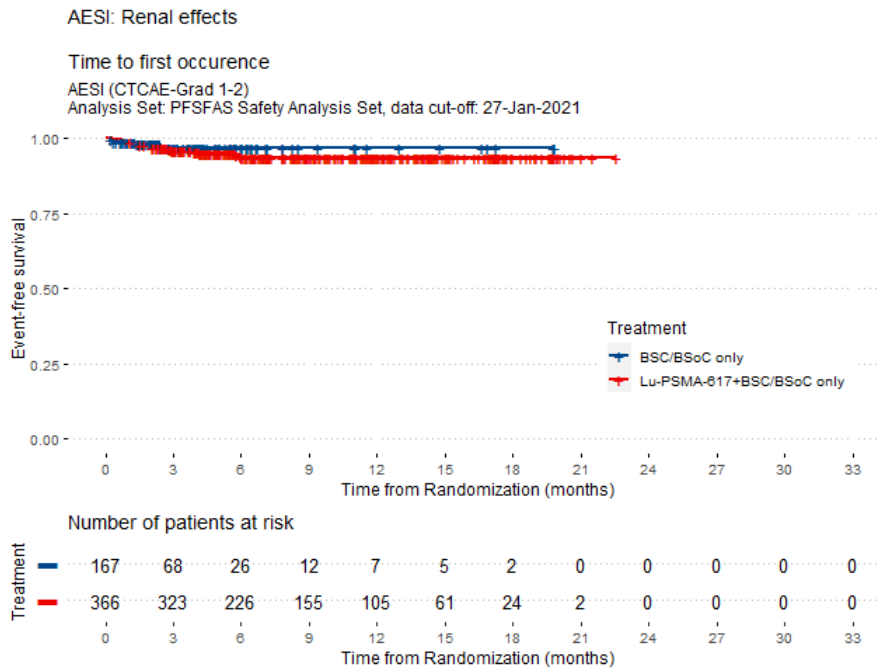


Abbildung 143: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Renal effects

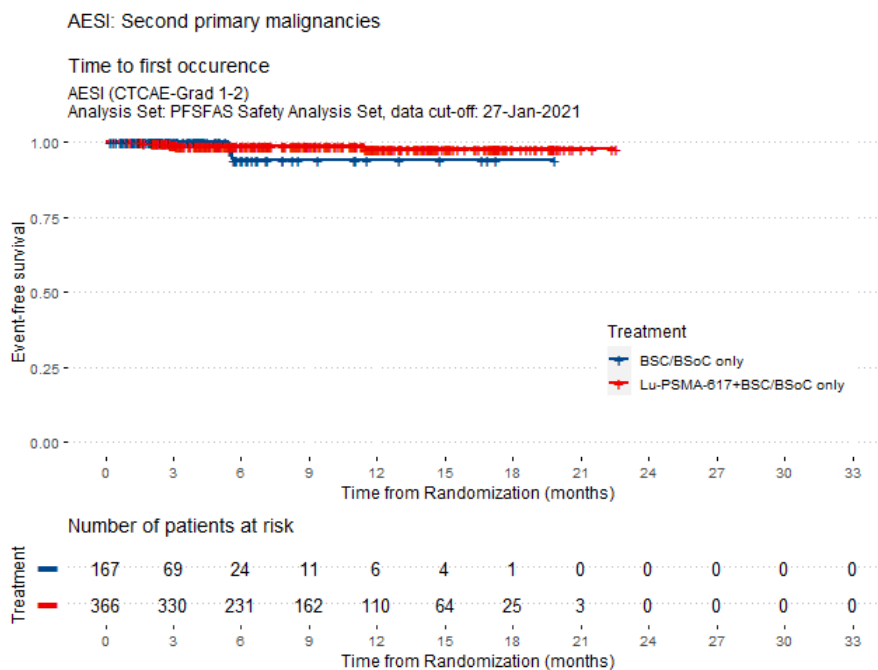


Abbildung 144: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Second primary malignancies

### Anhang 2.3: Schwere UE (CTCAE-Grad 3-5)

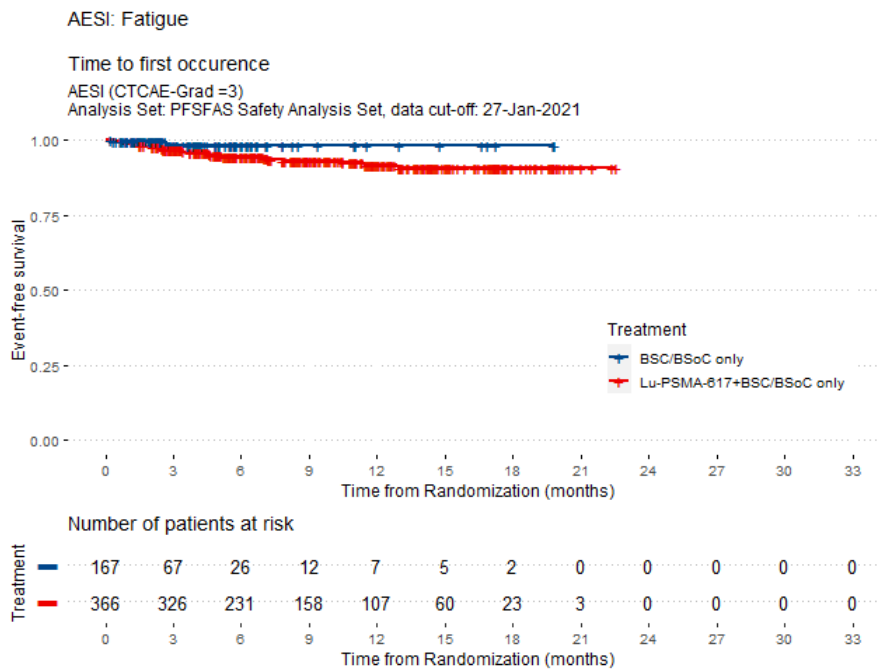


Abbildung 145: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Fatigue

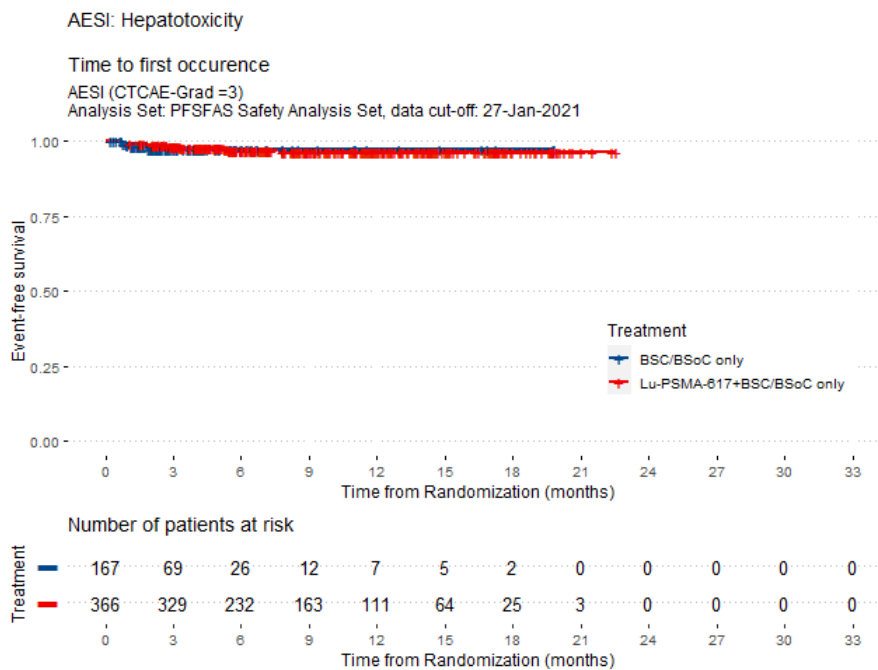


Abbildung 146: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Hepatotoxicity

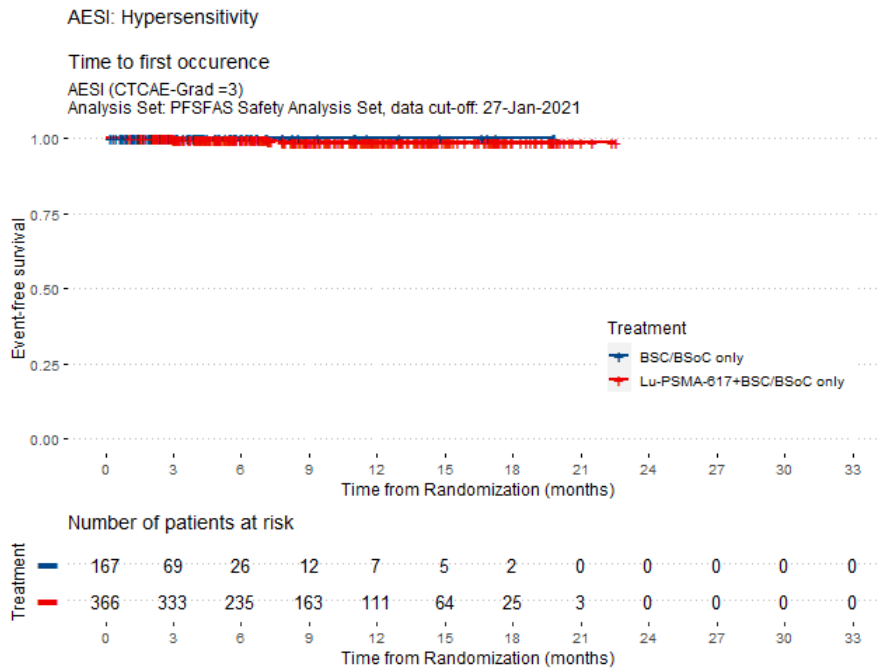


Abbildung 147: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Hypersensitivity

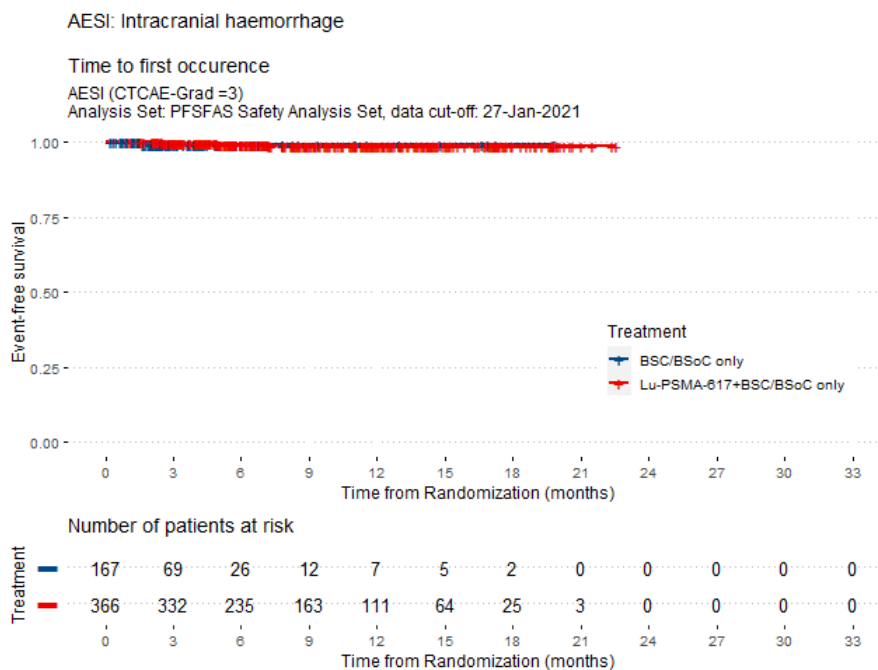


Abbildung 148: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Intracranial haemorrhage

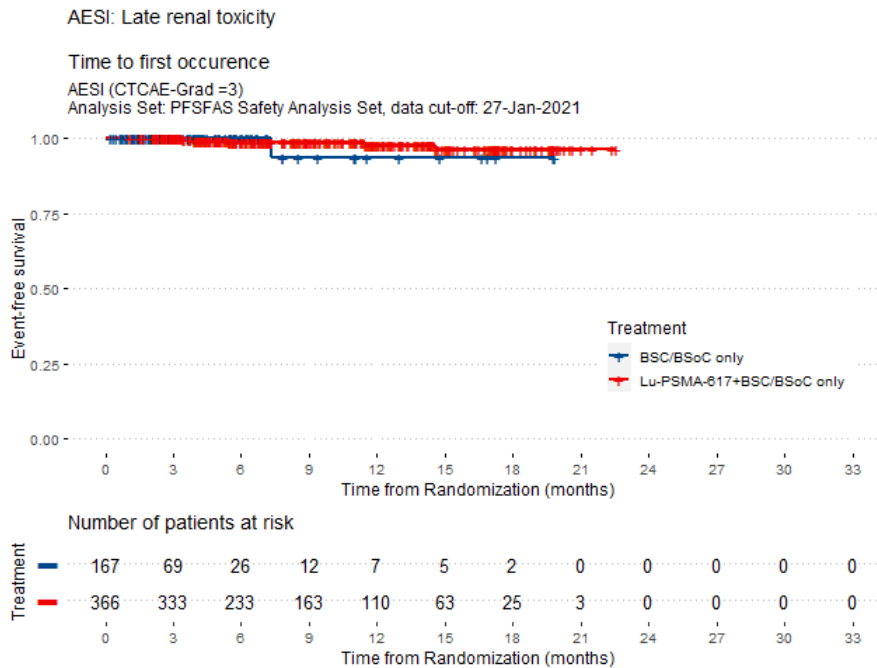


Abbildung 149: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Late renal toxicity

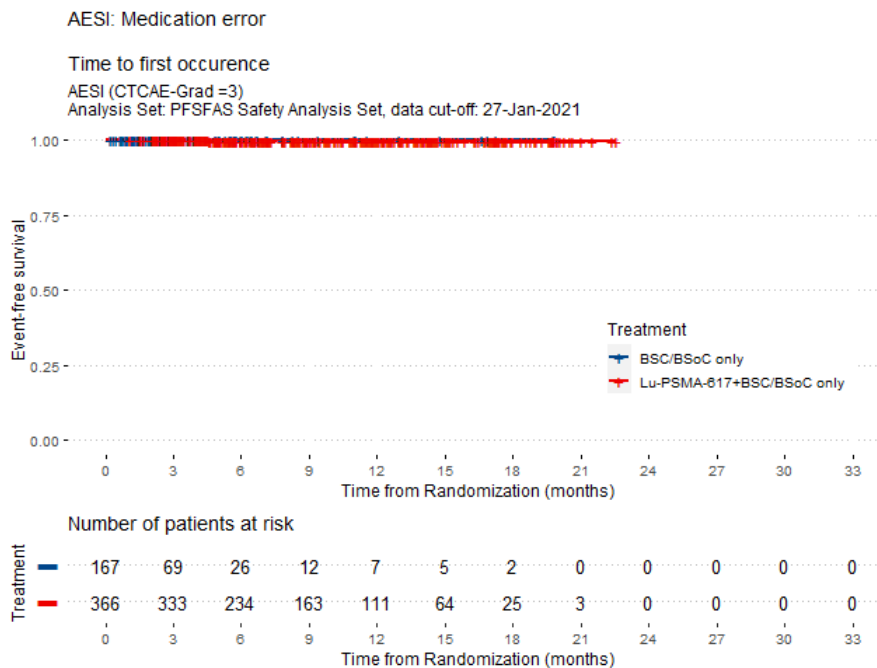


Abbildung 150: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Medication error



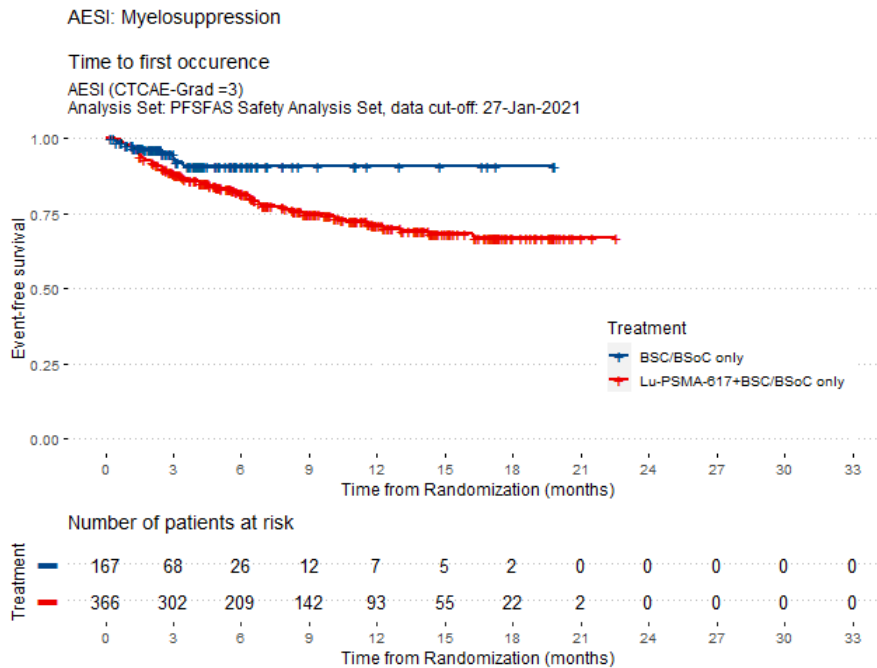


Abbildung 151: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Myelosuppression

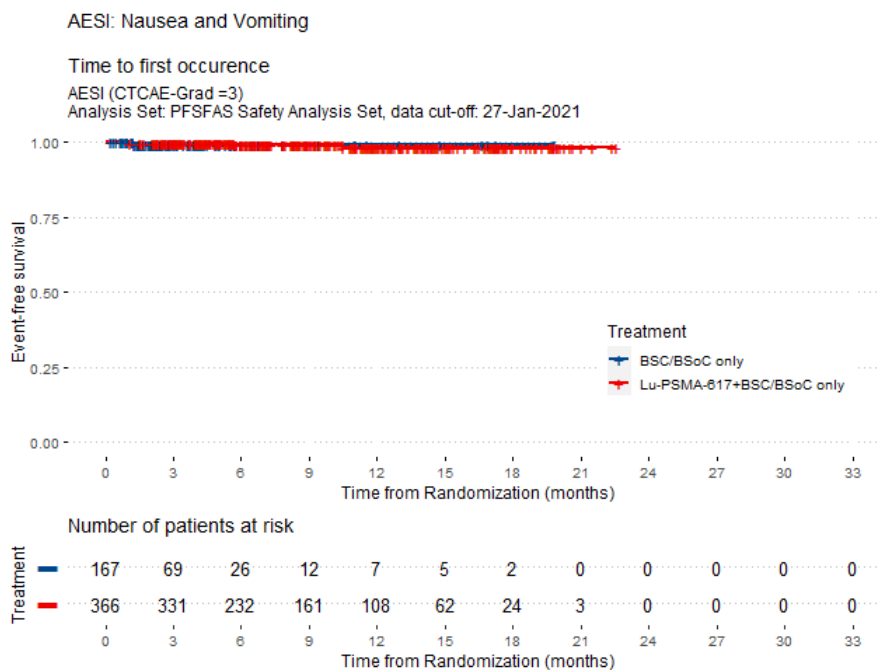


Abbildung 152: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Nausea and Vomiting

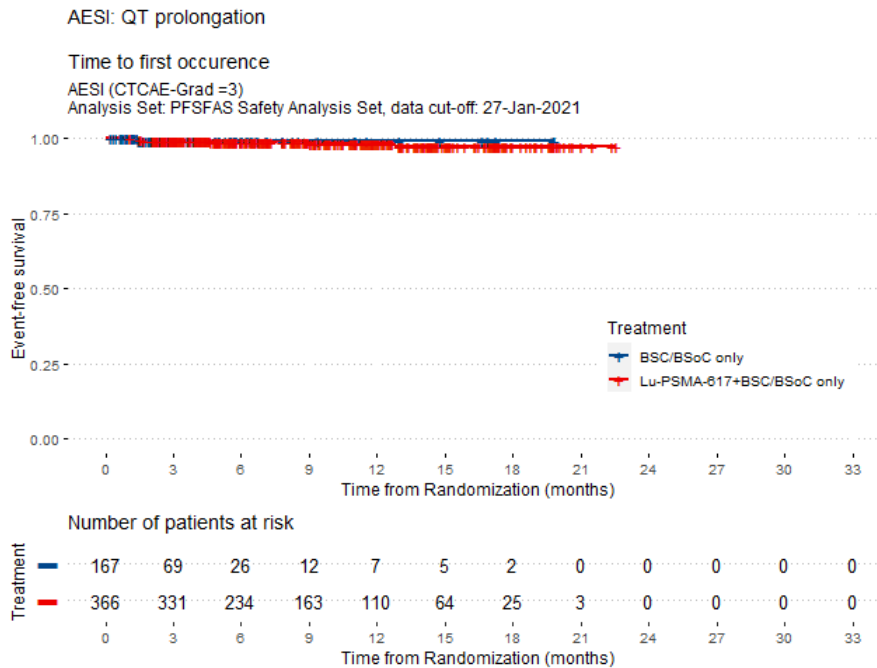


Abbildung 153: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: QT prolongation

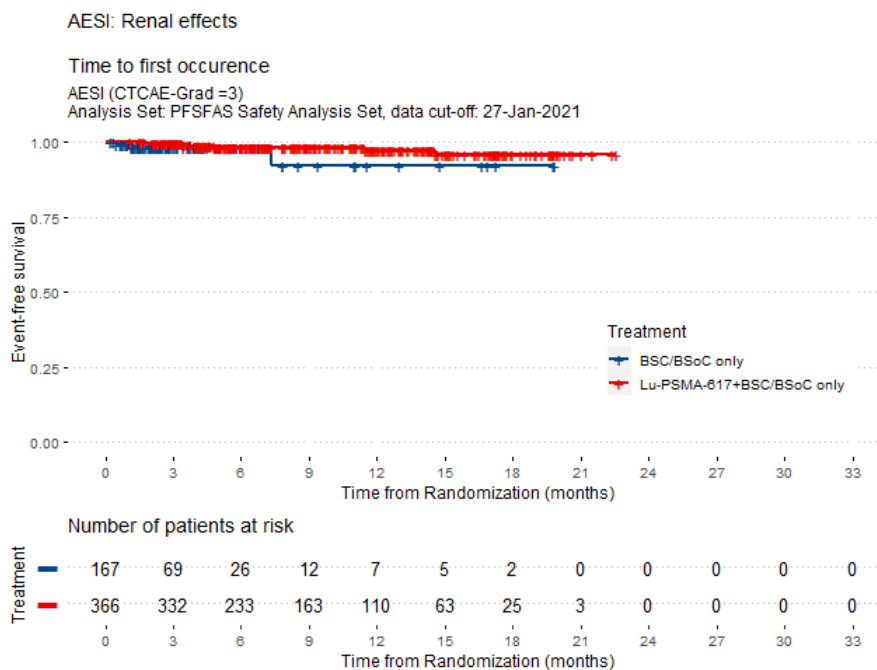


Abbildung 154: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Renal effects

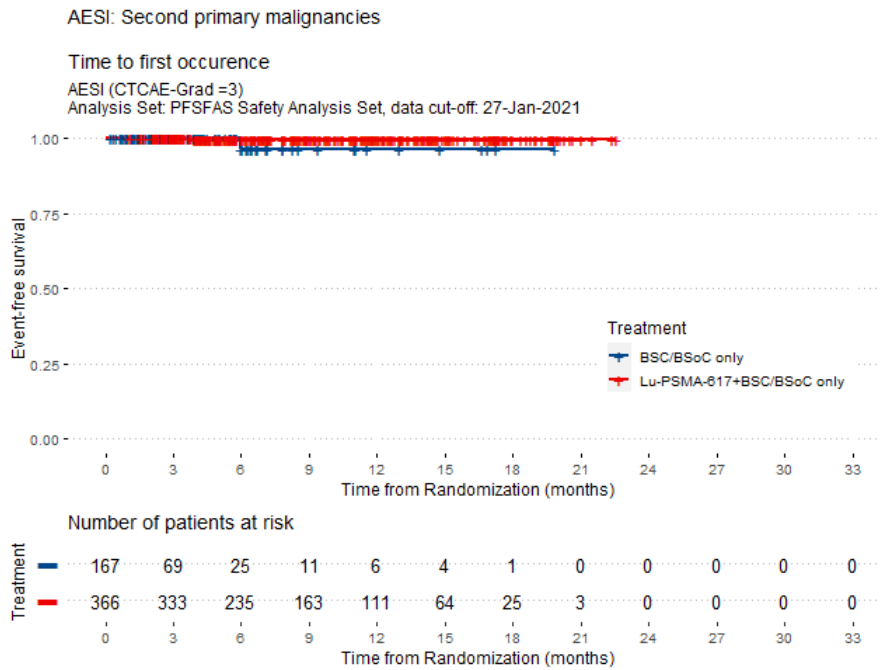


Abbildung 155: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Second primary malignancies

### Anhang 2.4: Schwerwiegende UE

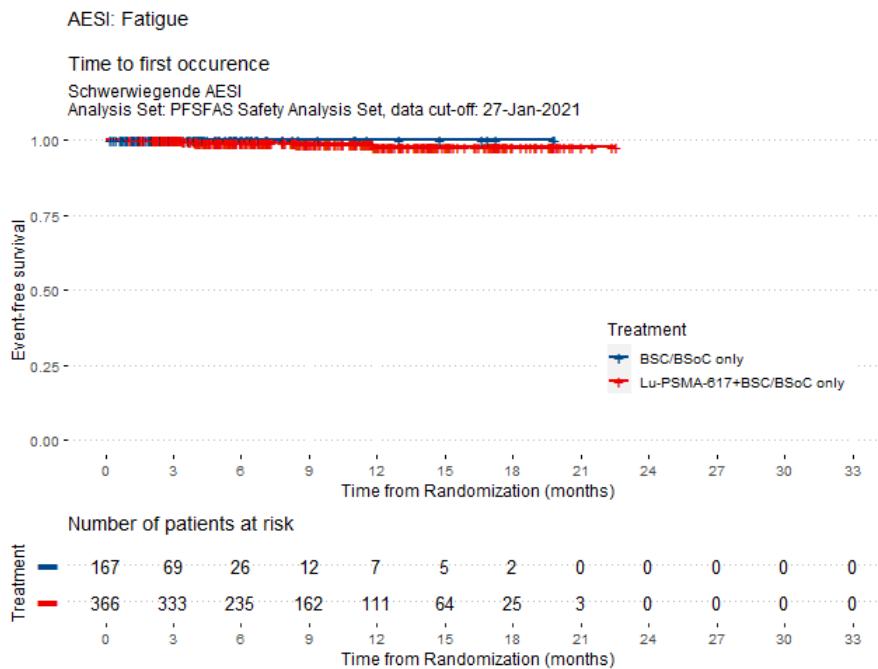


Abbildung 156: Schwerwiegende AESI: Time to first occurrence of AESI: Fatigue

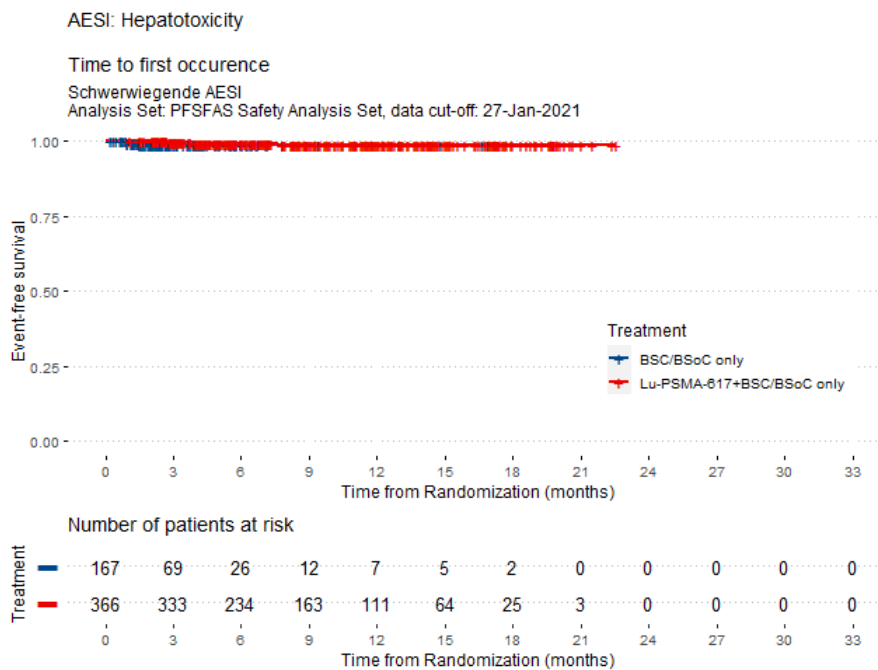


Abbildung 157: Schwerwiegende AESI: Time to first occurrence of AESI: Hepatotoxicity

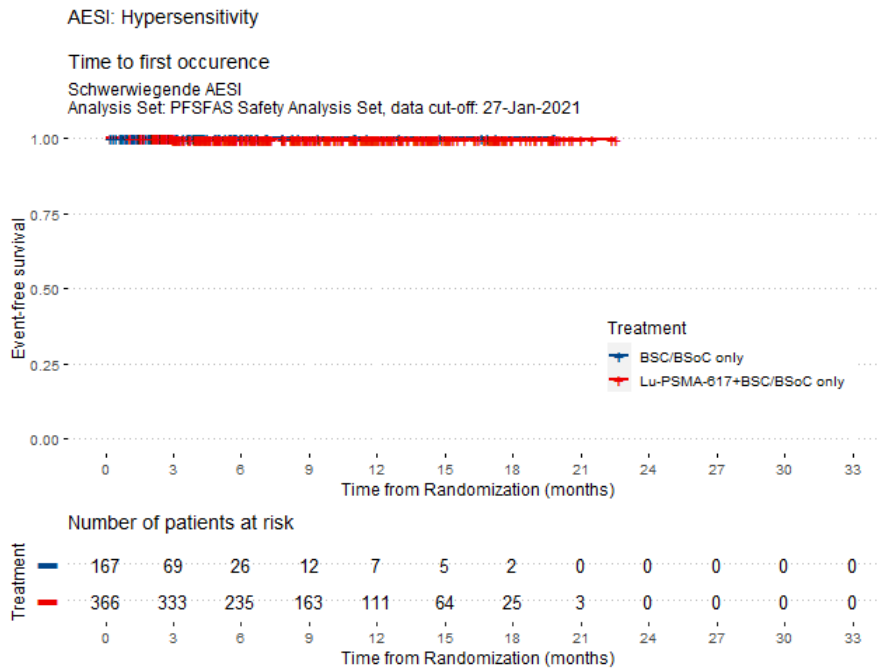


Abbildung 158: Schwerwiegende AESI: Time to first occurrence of AESI: Hypersensitivity

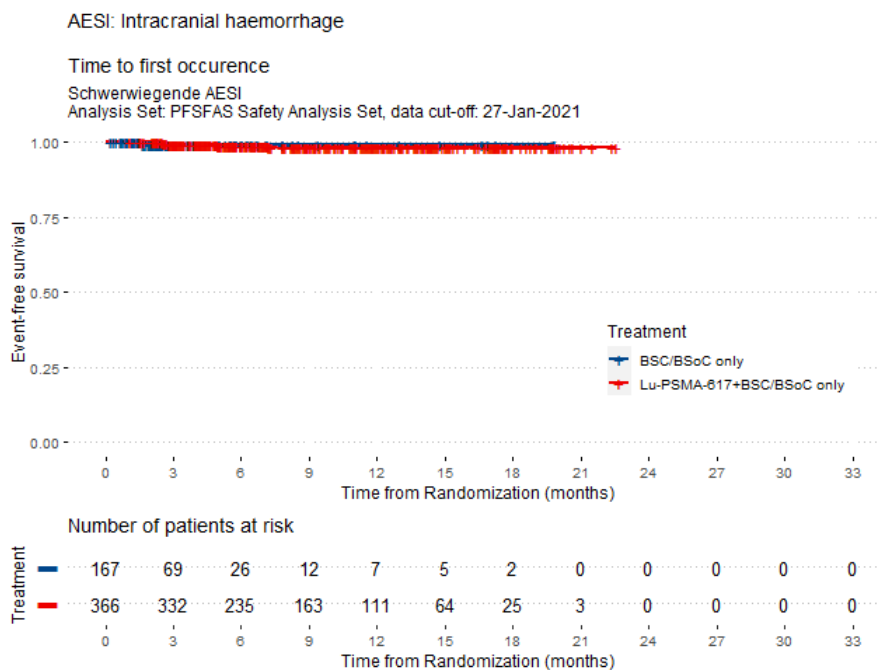


Abbildung 159: Schwerwiegende AESI: Time to first occurrence of AESI: Intracranial haemorrhage

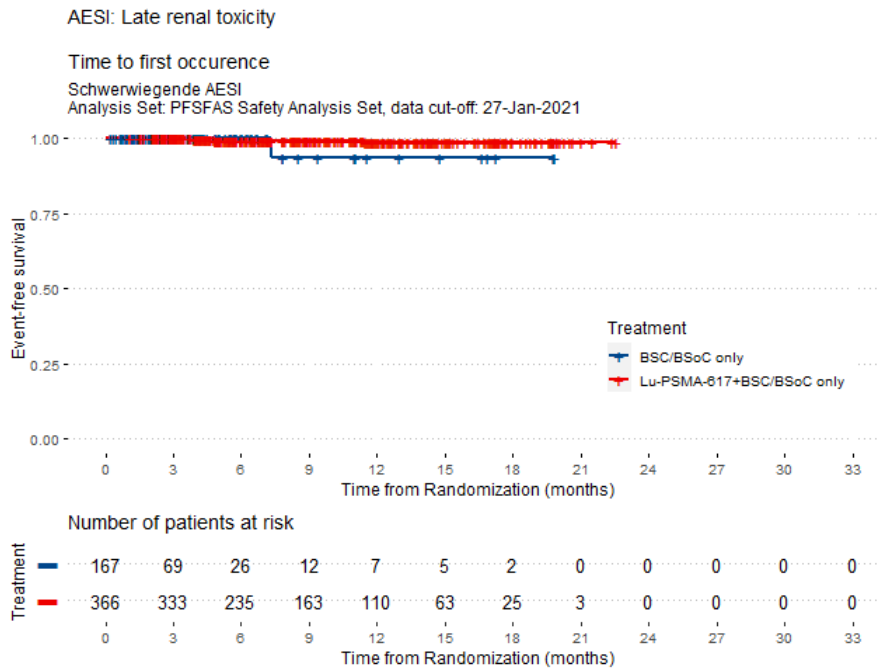


Abbildung 160: Schwerwiegende AESI: Time to first occurrence of AESI: Late renal toxicity

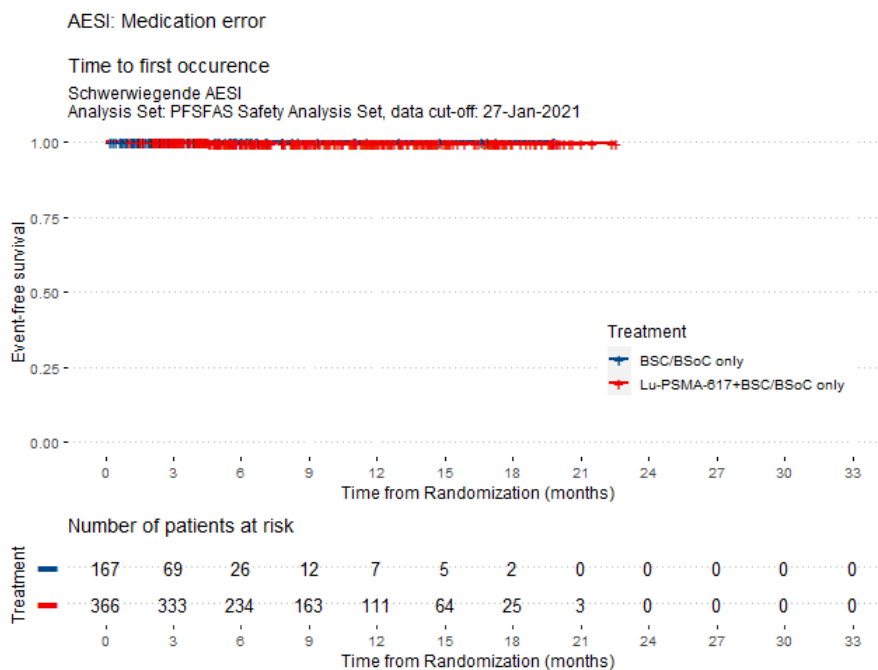


Abbildung 161: Schwerwiegende AESI: Time to first occurrence of AESI: Medication error

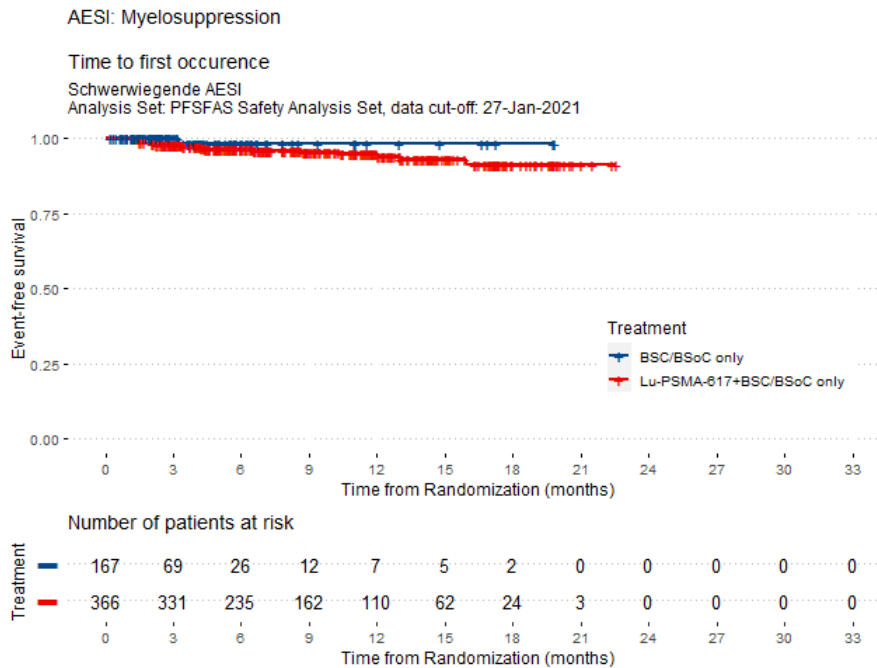


Abbildung 162: Schwerwiegende AESI: Time to first occurrence of AESI: Myelosuppression

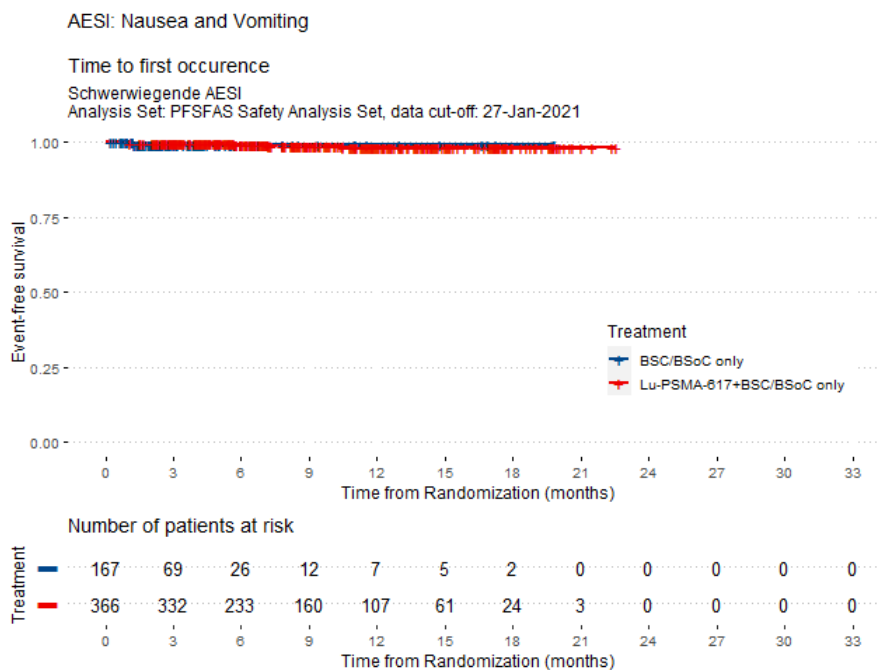


Abbildung 163: Schwerwiegende AESI: Time to first occurrence of AESI: Nausea and Vomiting

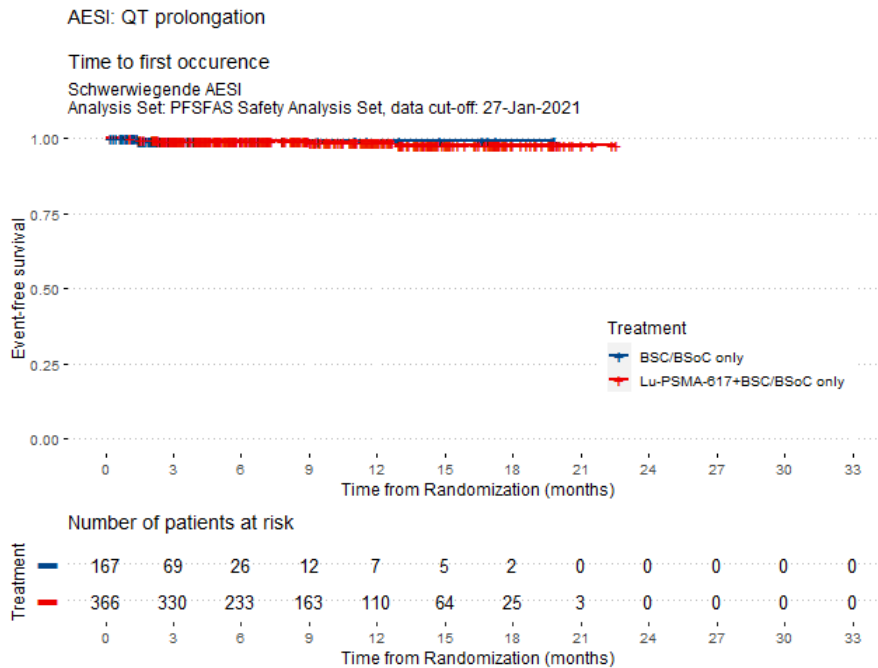


Abbildung 164: Schwerwiegende AESI: Time to first occurrence of AESI: QT prolongation

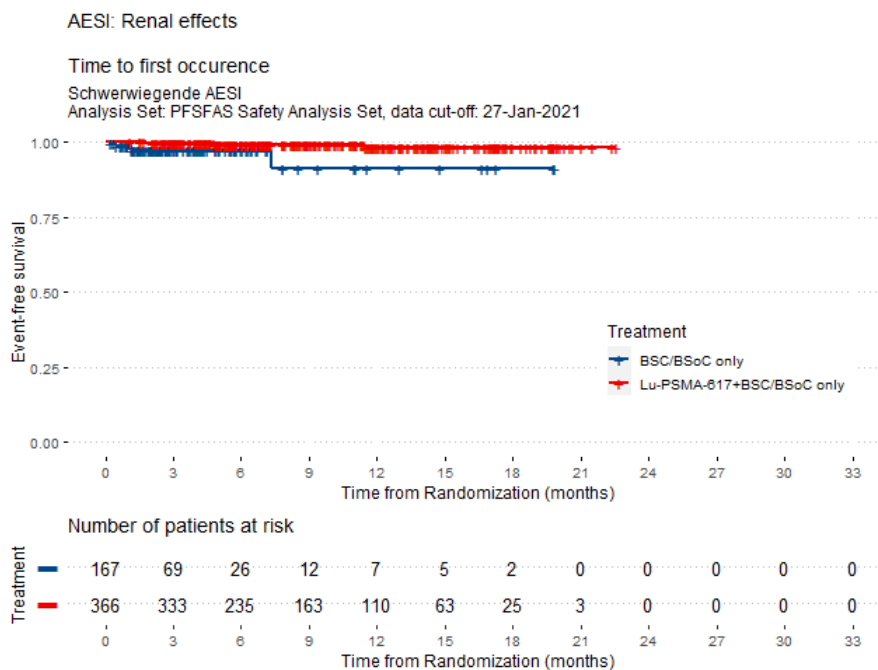


Abbildung 165: Schwerwiegende AESI: Time to first occurrence of AESI: Renal effects



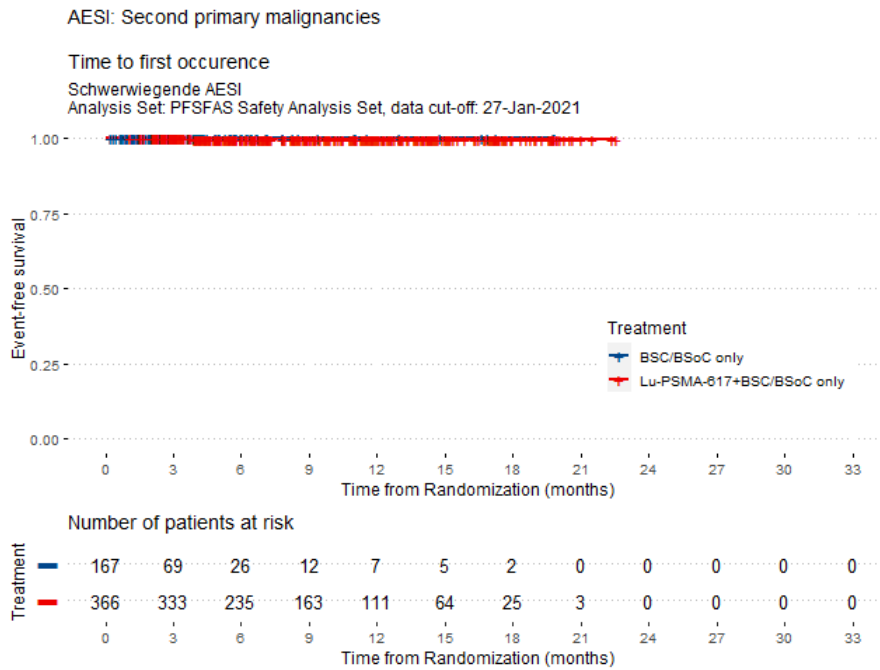


Abbildung 166: Schwerwiegende AESI: Time to first occurrence of AESI: Second primary malignancies

**Anhang 3: Ergebnisse zum Datenschnitt vom 28. Juni 2021**

**Anhang 3.1: Gesamtraten UE**

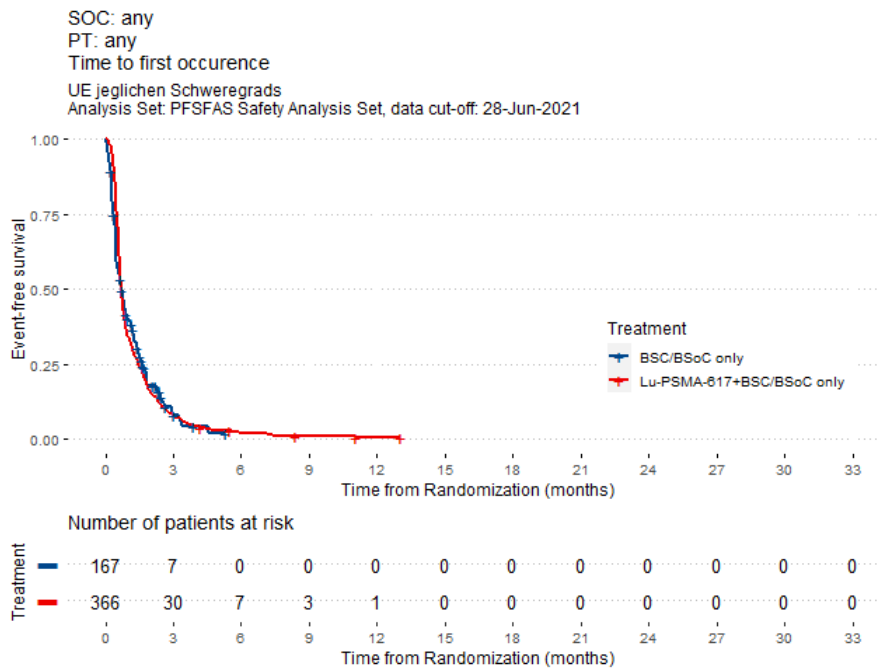


Abbildung 167: UE jeglichen Schweregrads: Time to first occurrence of SOC: any; PT: any

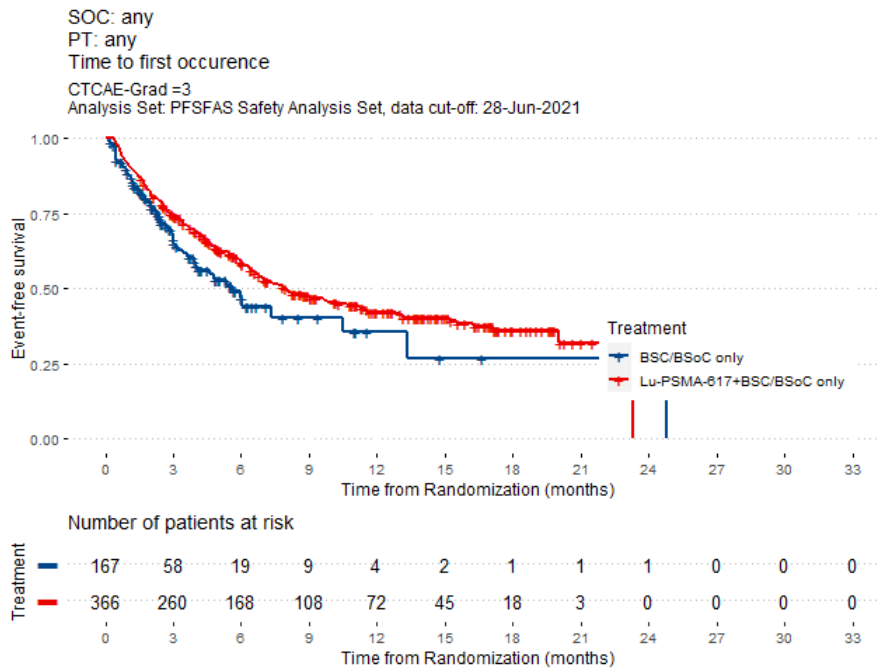


Abbildung 168: CTCAE-Grad 3-5: Time to first occurrence of SOC: any; PT: any

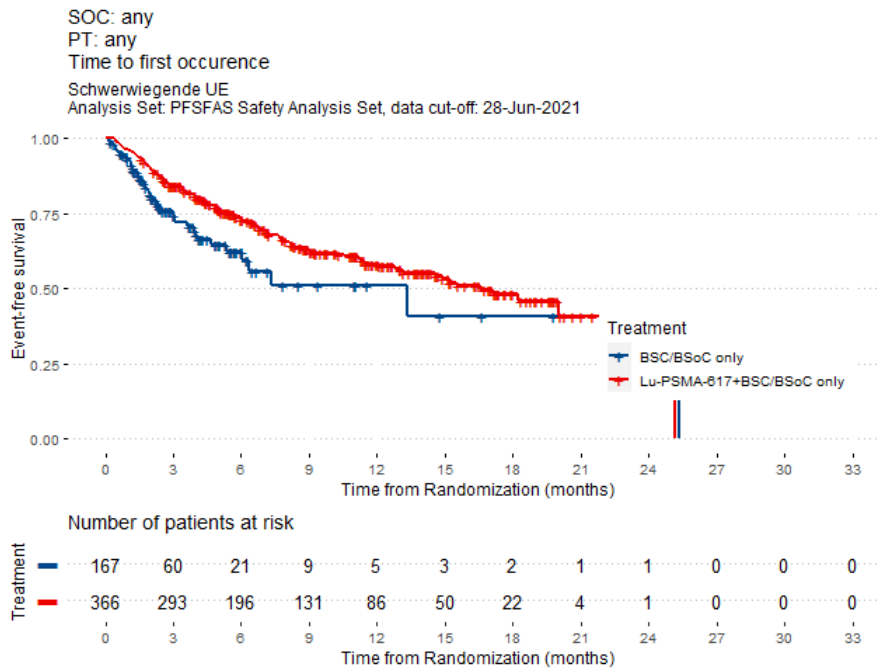


Abbildung 169: Schwerwiegende UE: Time to first occurrence of SOC: any; PT: any

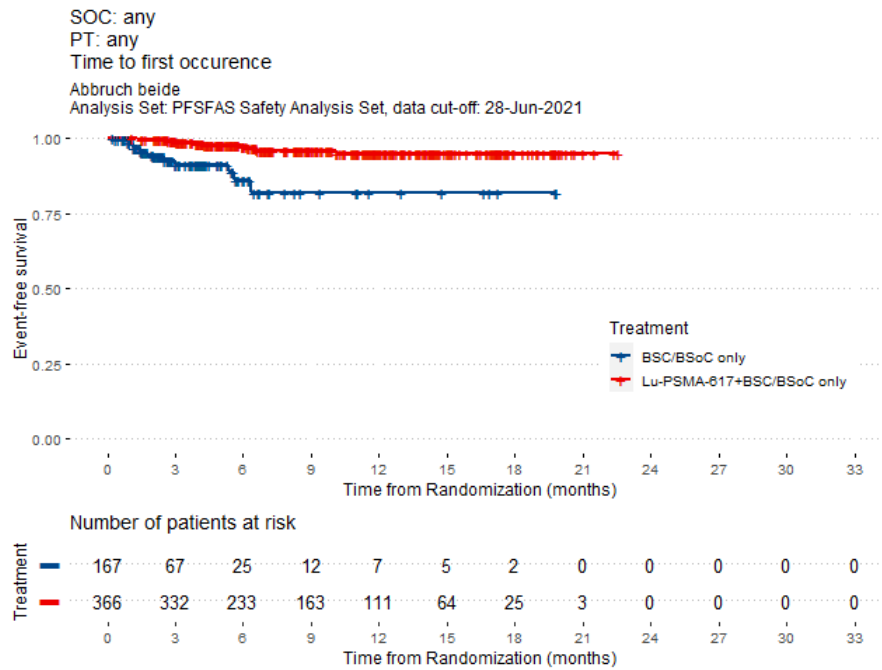


Abbildung 170: Abbruch beide: Time to first occurrence of SOC: any; PT: any

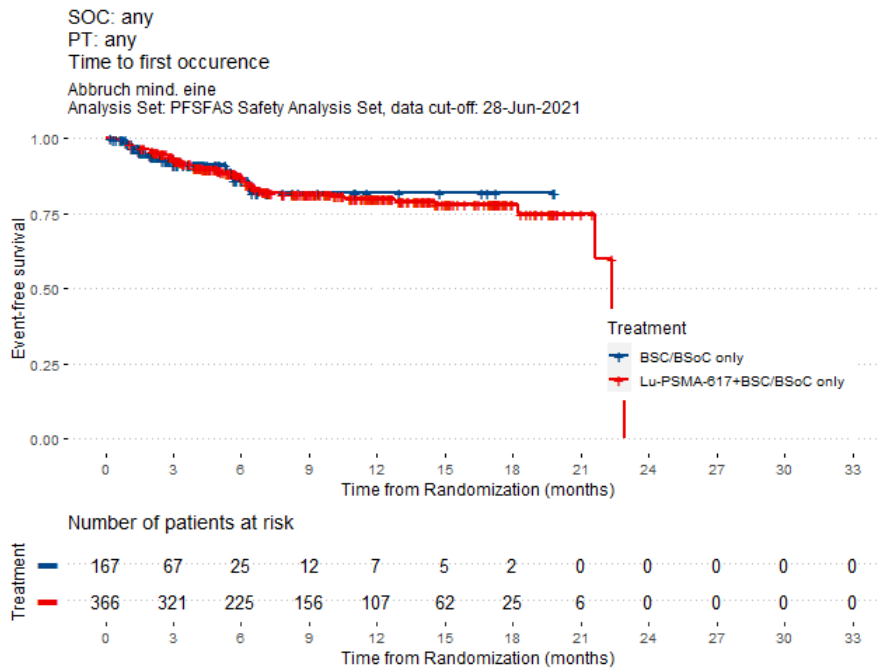


Abbildung 171: Abbruch mind. eine: Time to first occurrence of SOC: any; PT: any

**Anhang 3.2: Gesamtraten UE ohne Berücksichtigung der UE, die im Rahmen eines symptomatischen skelettbezogenen Ereignisses auftraten**

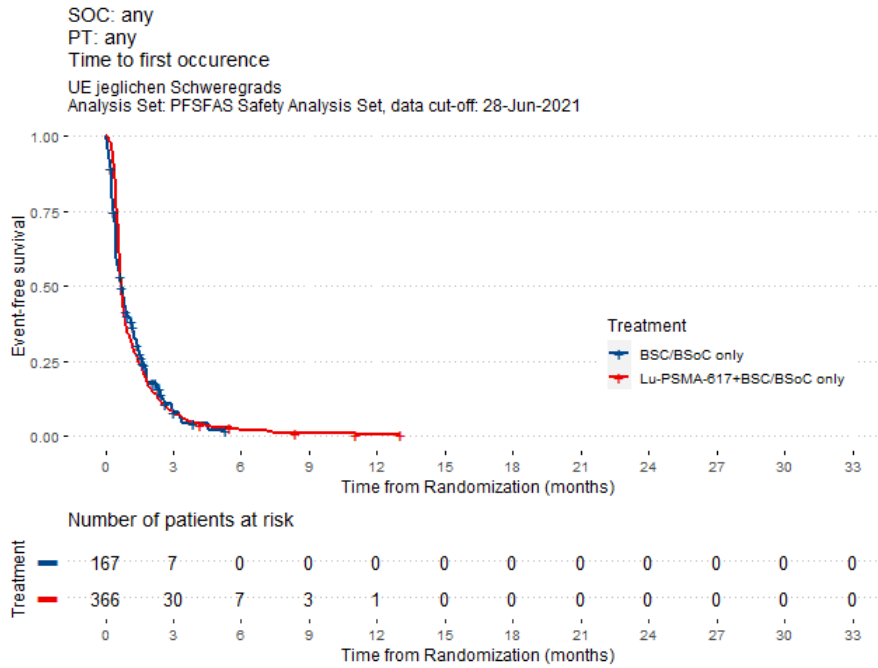


Abbildung 172: UE jeglichen Schweregrads: Time to first occurrence of SOC: any; PT: any

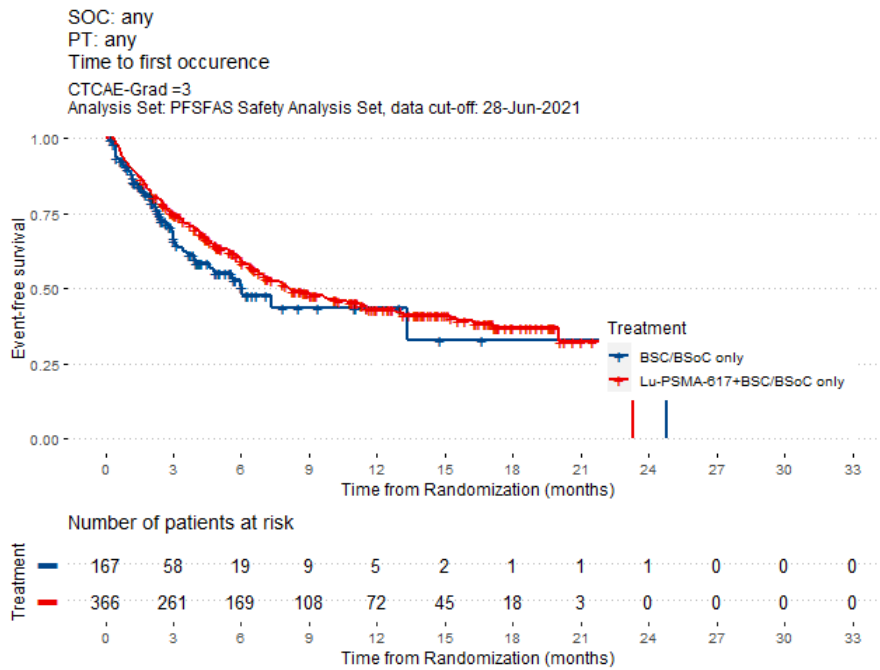


Abbildung 173: CTCAE-Grad 3-5: Time to first occurrence of SOC: any; PT: any



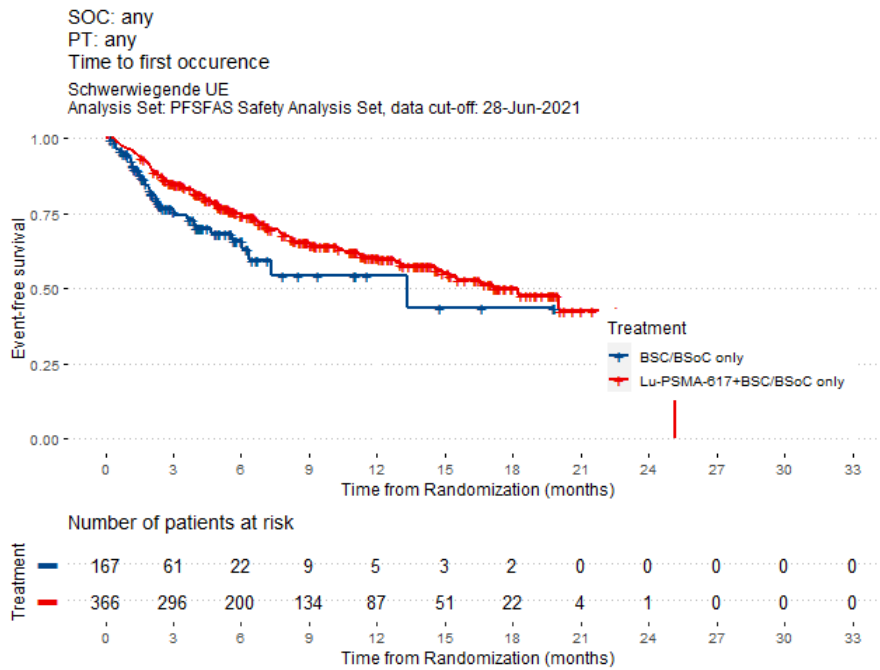


Abbildung 174: Schwerwiegende UE: Time to first occurrence of SOC: any; PT: any

**Anhang 3.3: Unerwünschte Ereignisse von besonderem Interesse**

**Anhang 3.3.1: UE jeglichen Schweregrads**

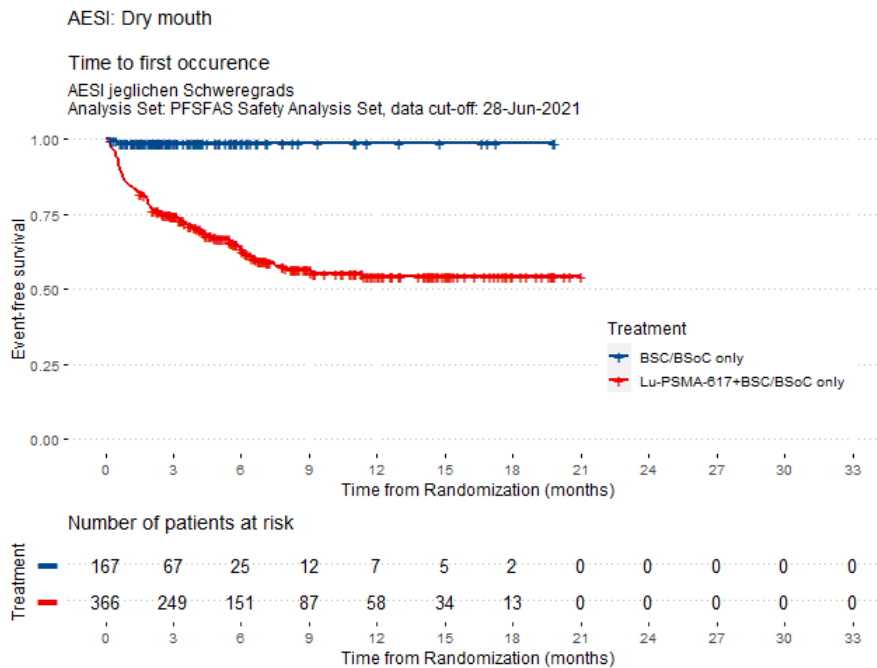


Abbildung 175: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Dry mouth

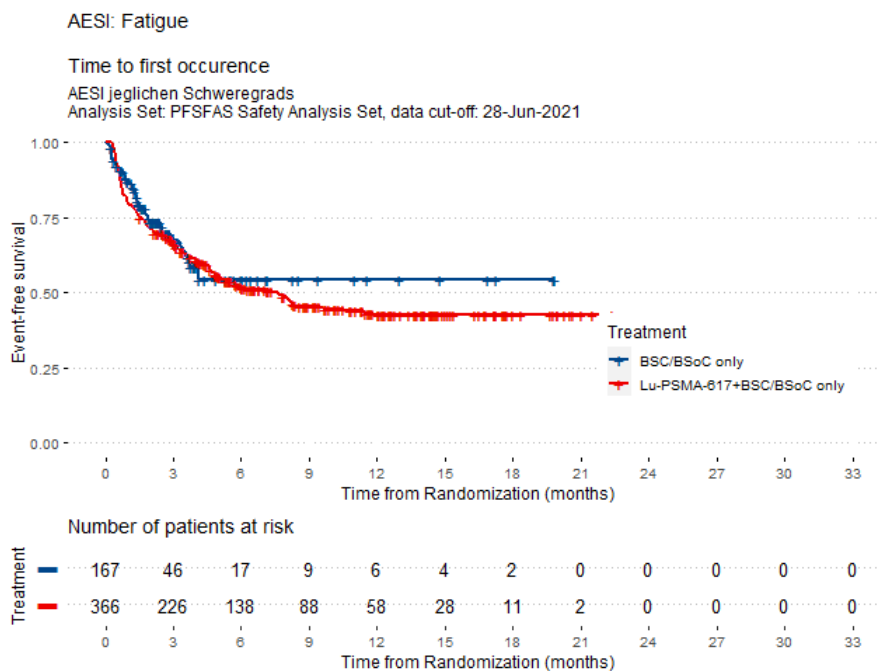


Abbildung 176: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Fatigue

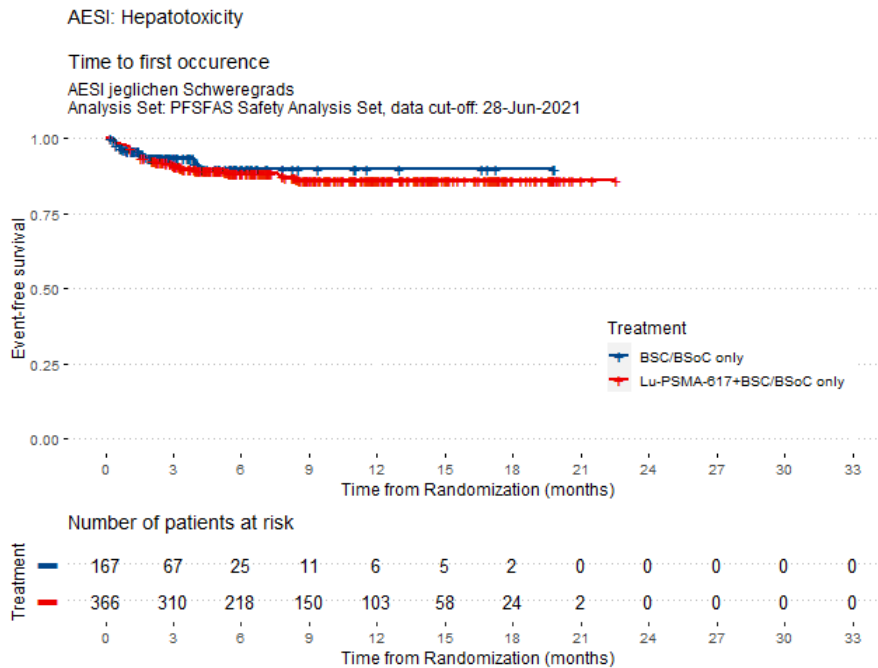


Abbildung 177: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Hepatotoxicity

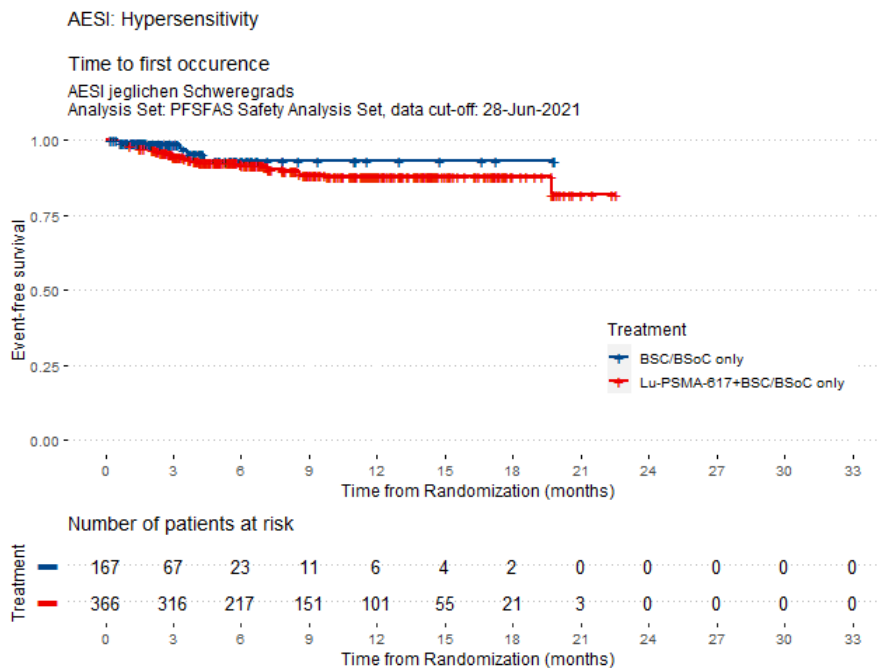


Abbildung 178: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Hypersensitivity

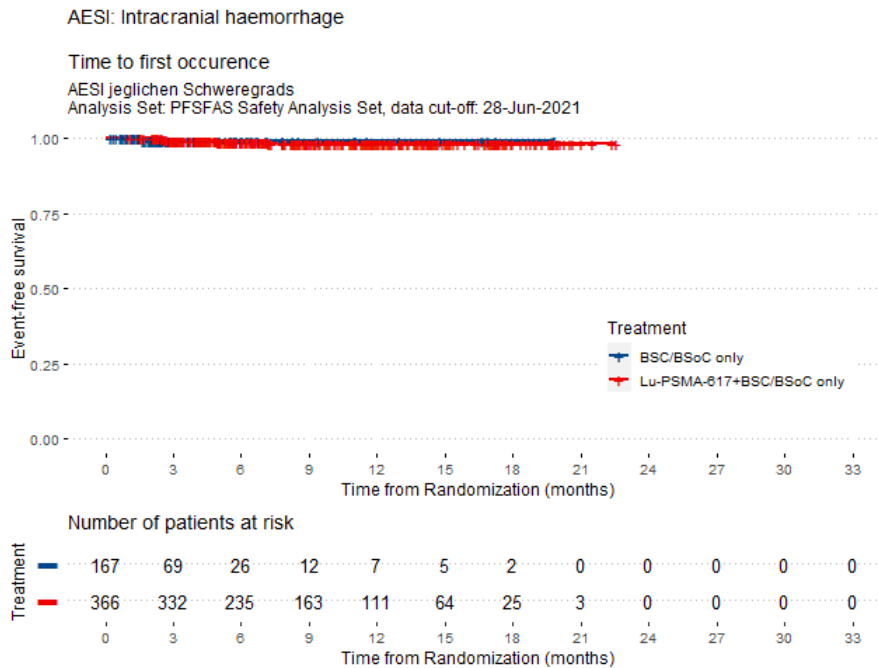


Abbildung 179: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Intracranial haemorrhage

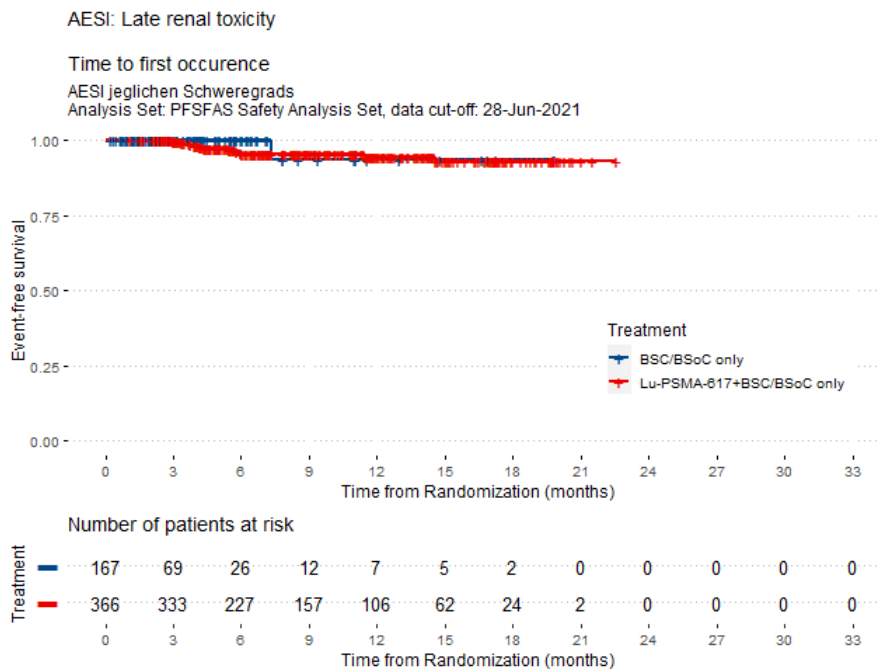


Abbildung 180: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Late renal toxicity

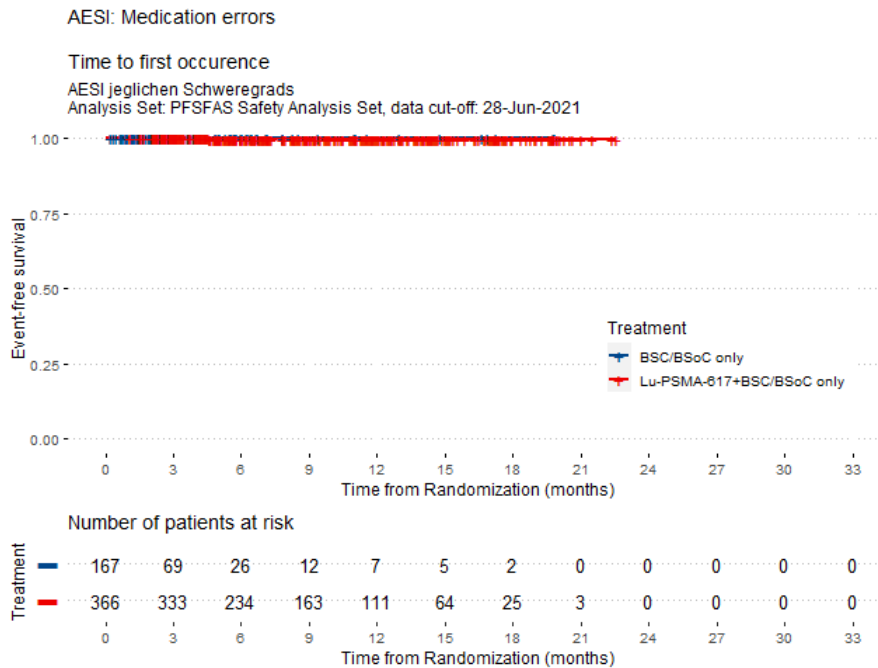


Abbildung 181: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Medication errors

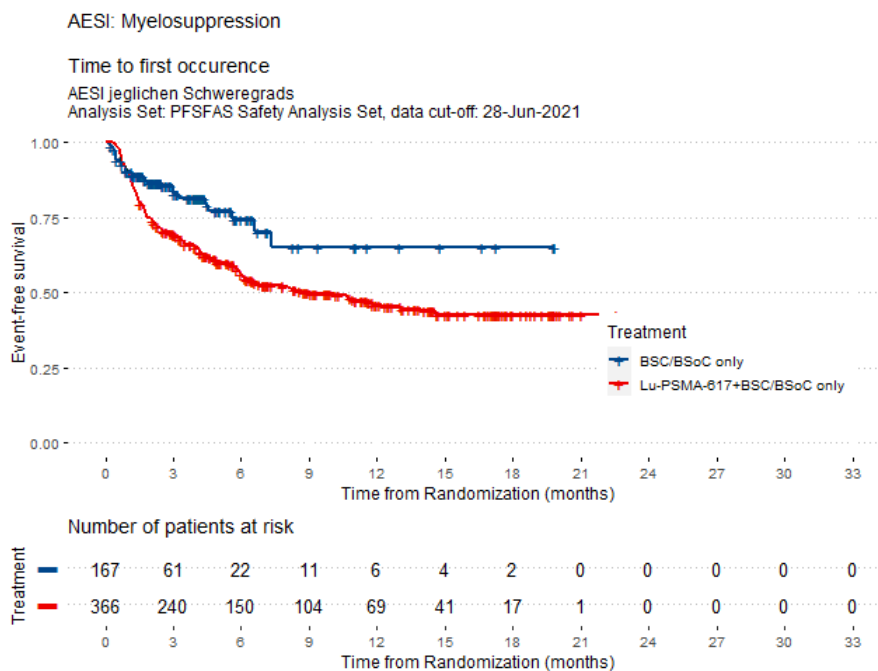


Abbildung 182: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Myelosuppression

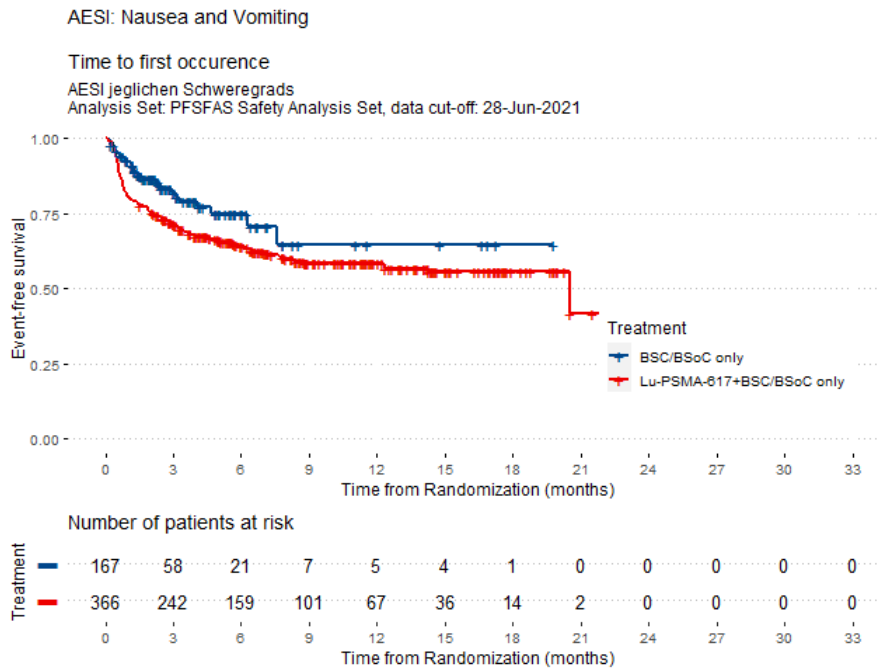


Abbildung 183: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Nausea and Vomiting

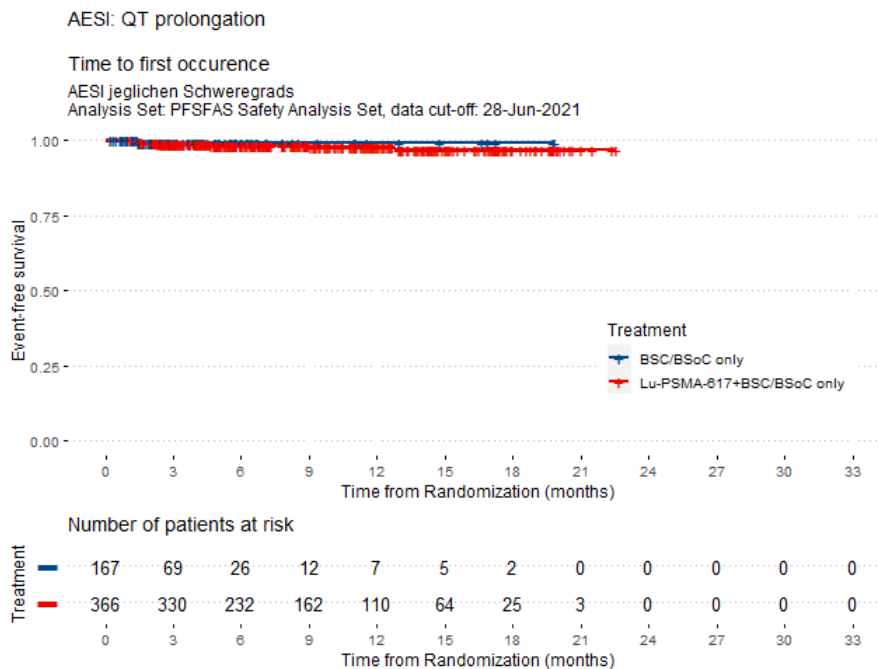


Abbildung 184: AESI jeglichen Schweregrads: Time to first occurrence of AESI: QT prolongation

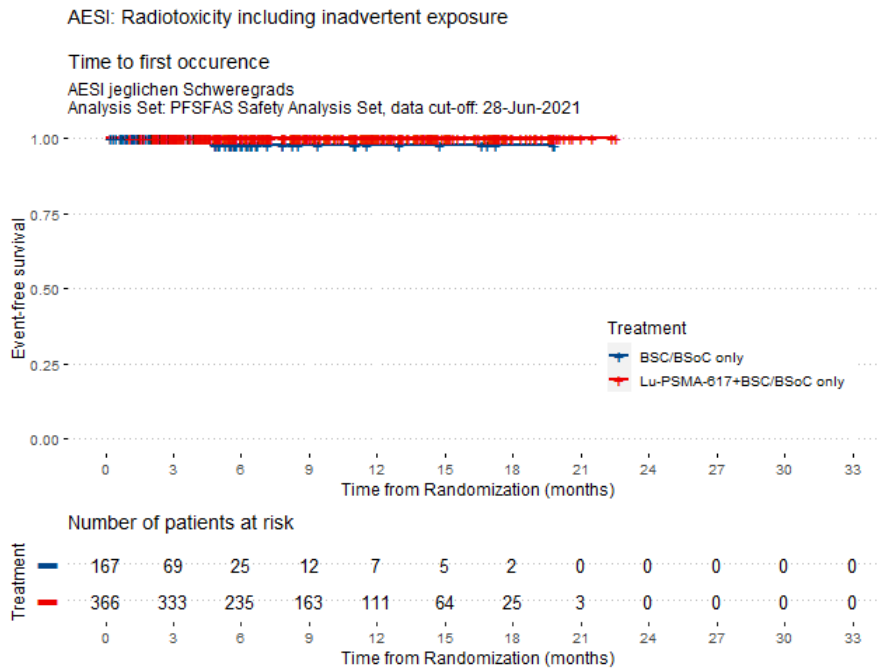


Abbildung 185: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Radiotoxicity including inadvertent exposure

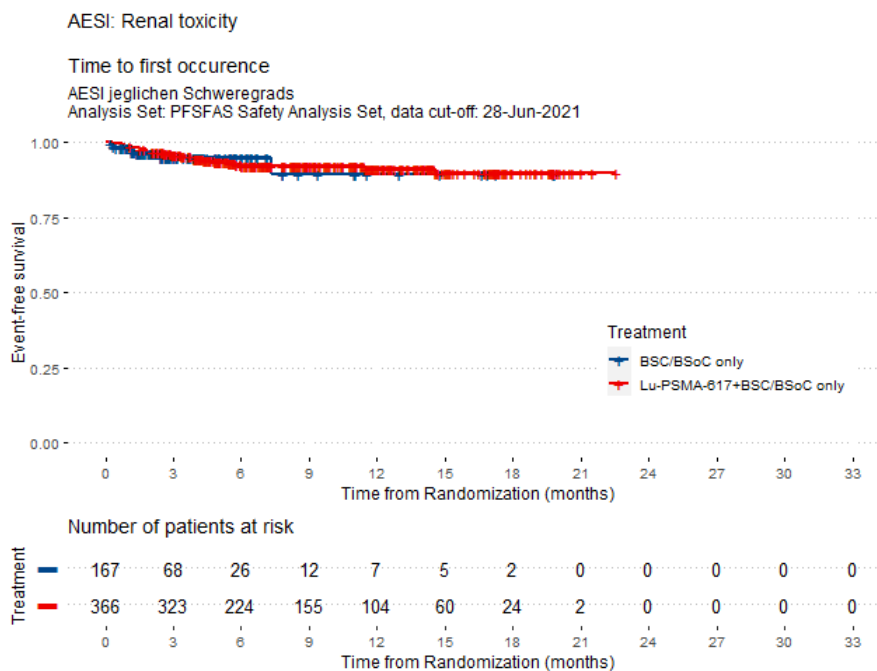


Abbildung 186: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Renal toxicity

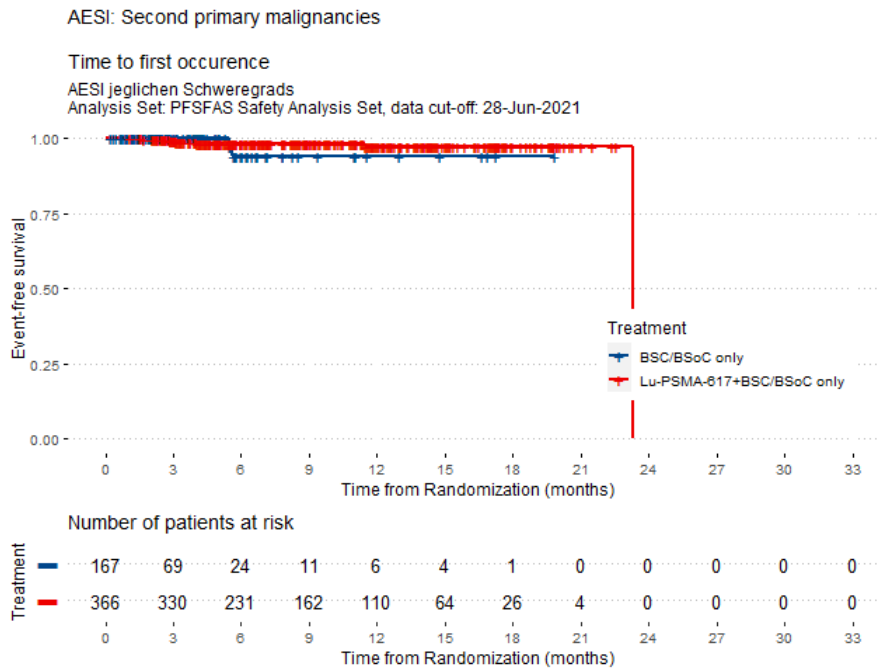


Abbildung 187: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Second primary malignancies



**Anhang 3.3.2: Nicht-schwere UE (CTCAE-Grad 1-2)**

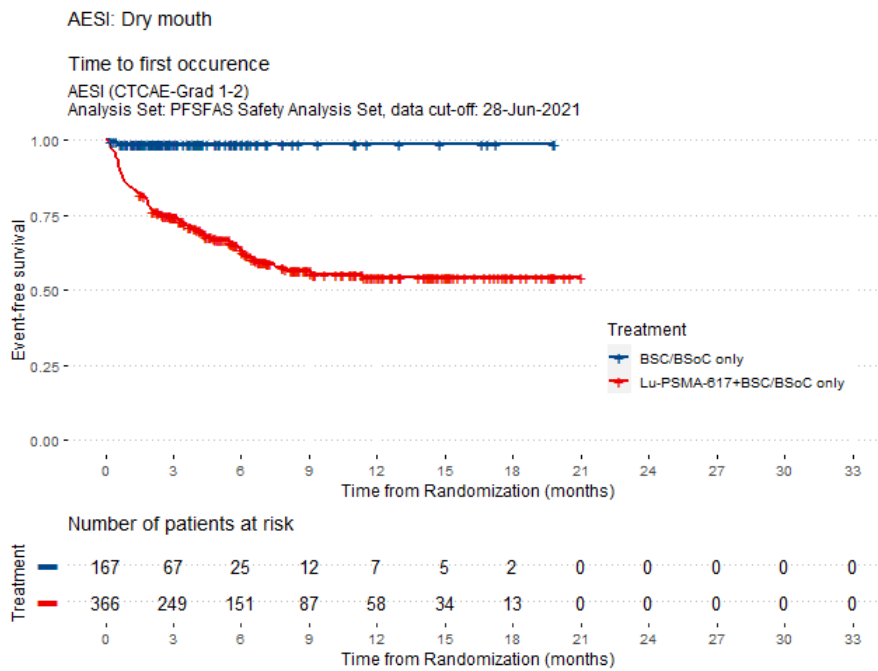


Abbildung 188: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Dry mouth

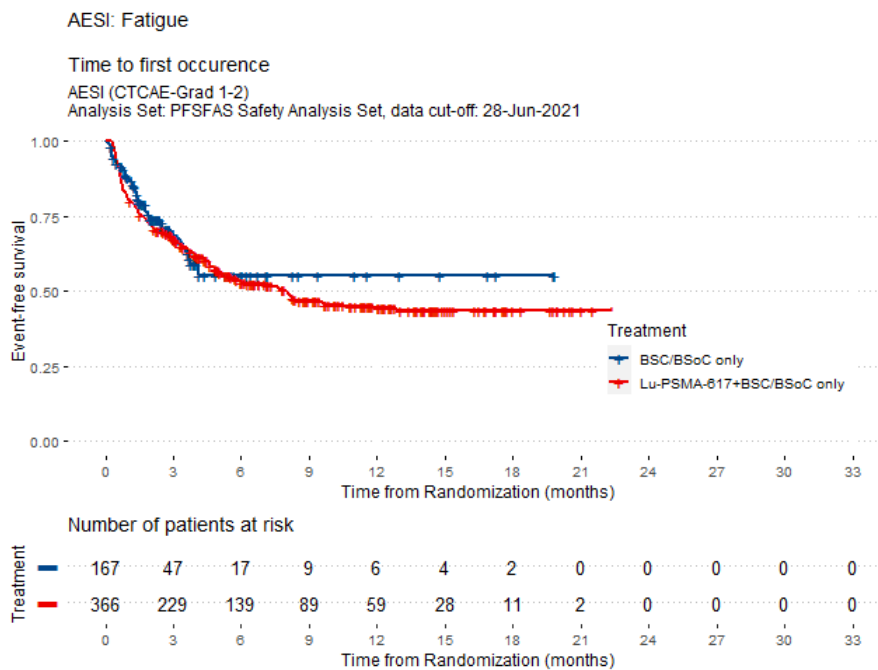


Abbildung 189: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Fatigue

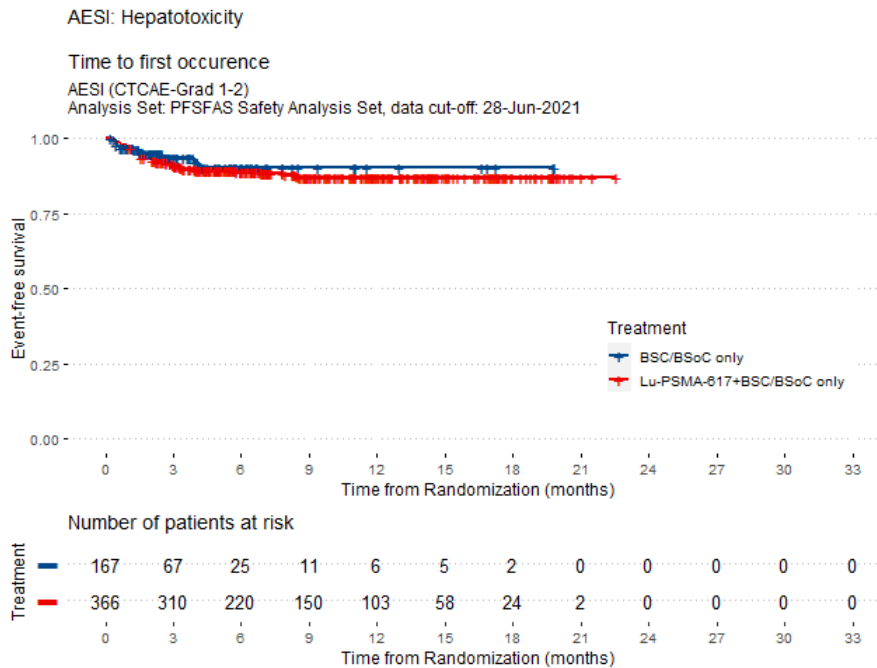


Abbildung 190: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Hepatotoxicity

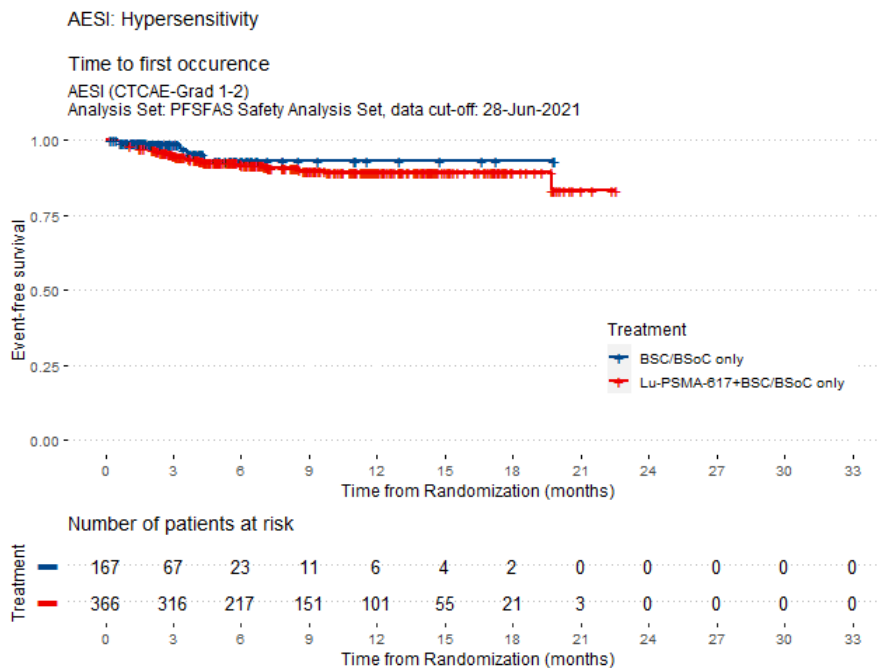


Abbildung 191: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Hypersensitivity

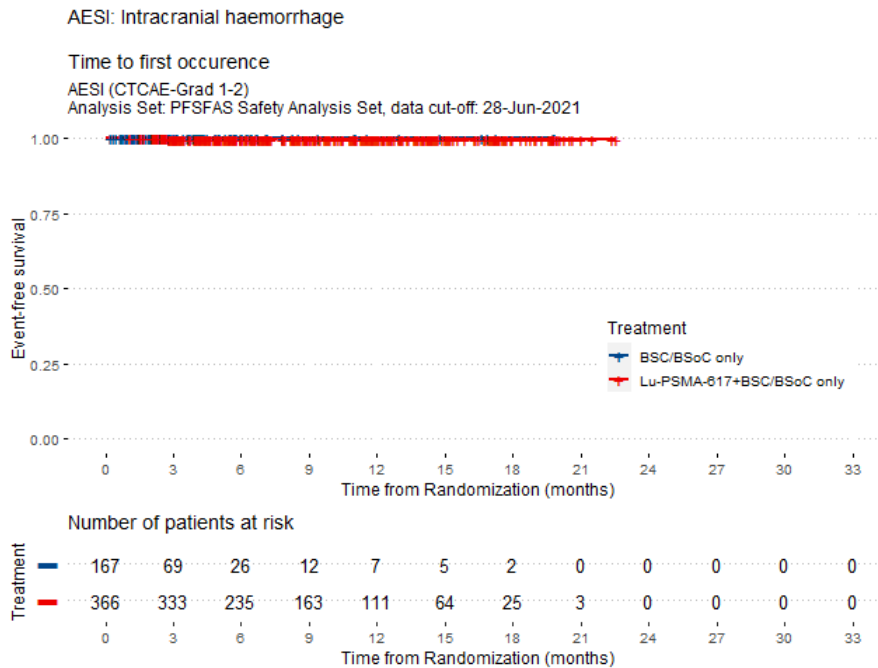


Abbildung 192: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Intracranial haemorrhage

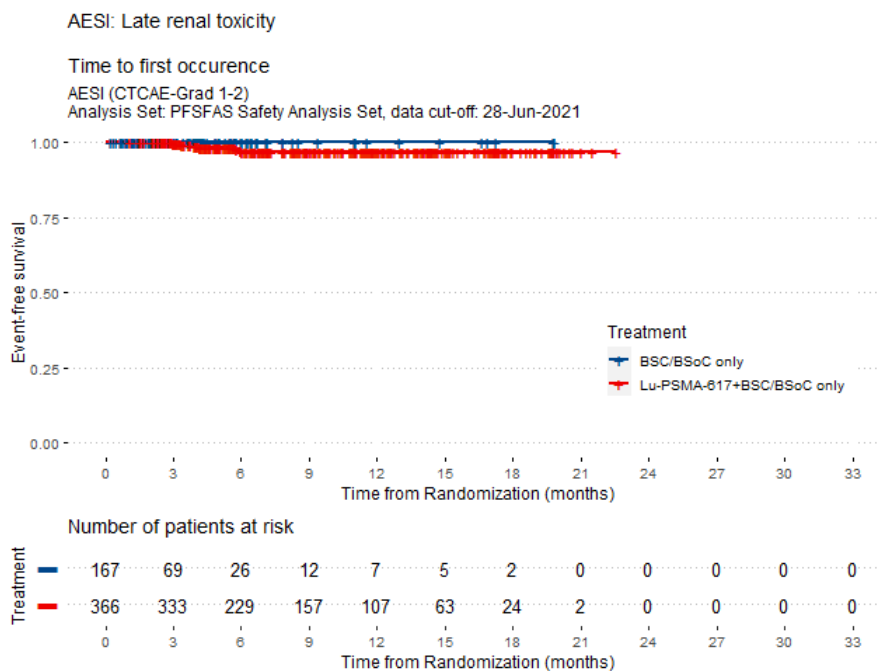


Abbildung 193: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Late renal toxicity

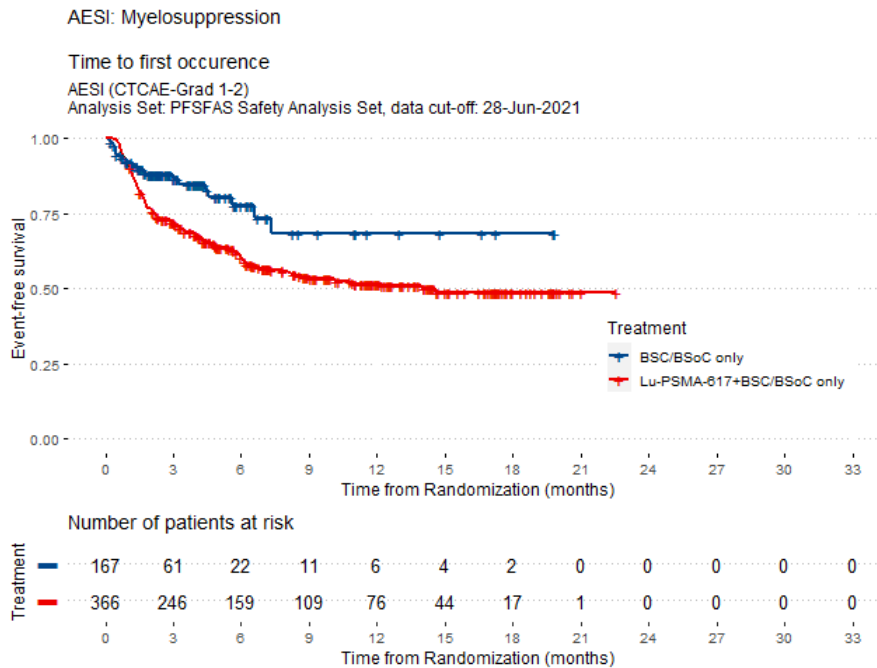


Abbildung 194: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Myelosuppression

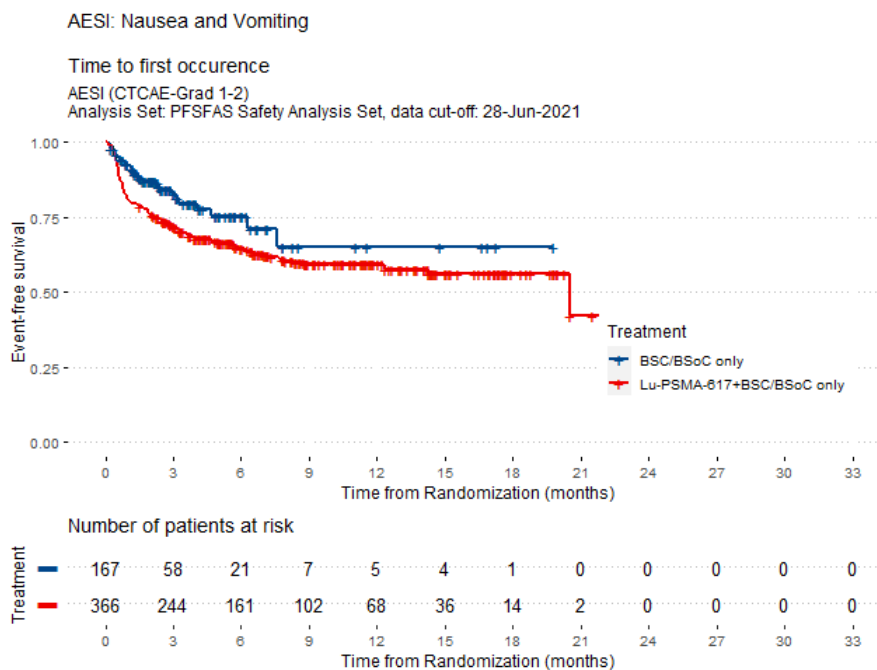


Abbildung 195: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Nausea and Vomiting

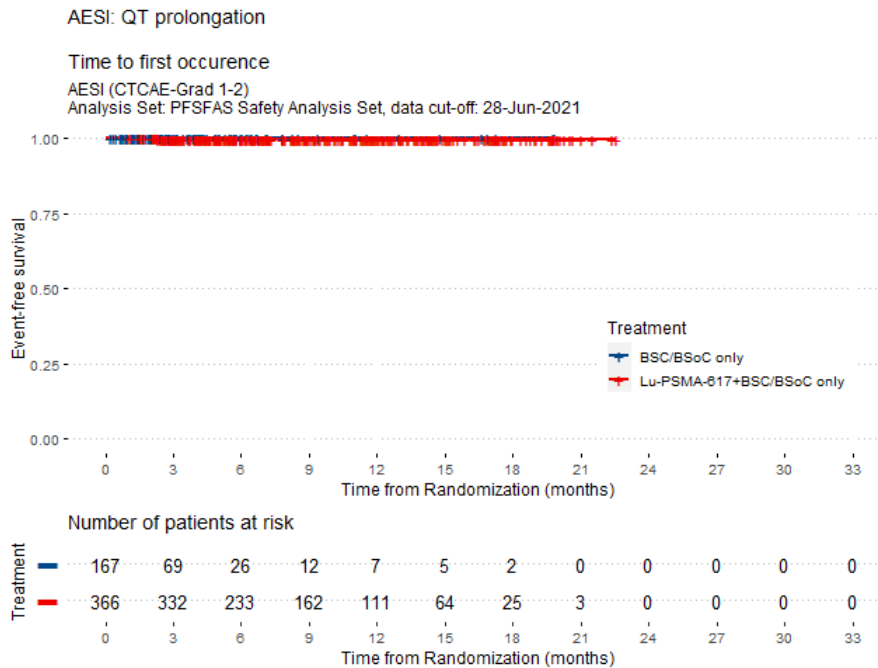


Abbildung 196: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: QT prolongation

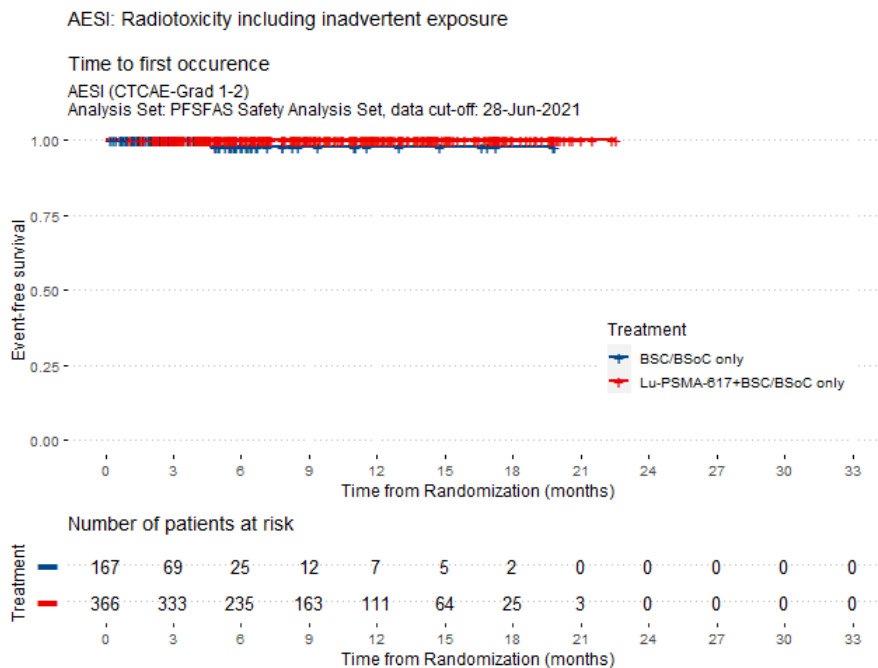


Abbildung 197: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Radiotoxicity including inadvertent exposure

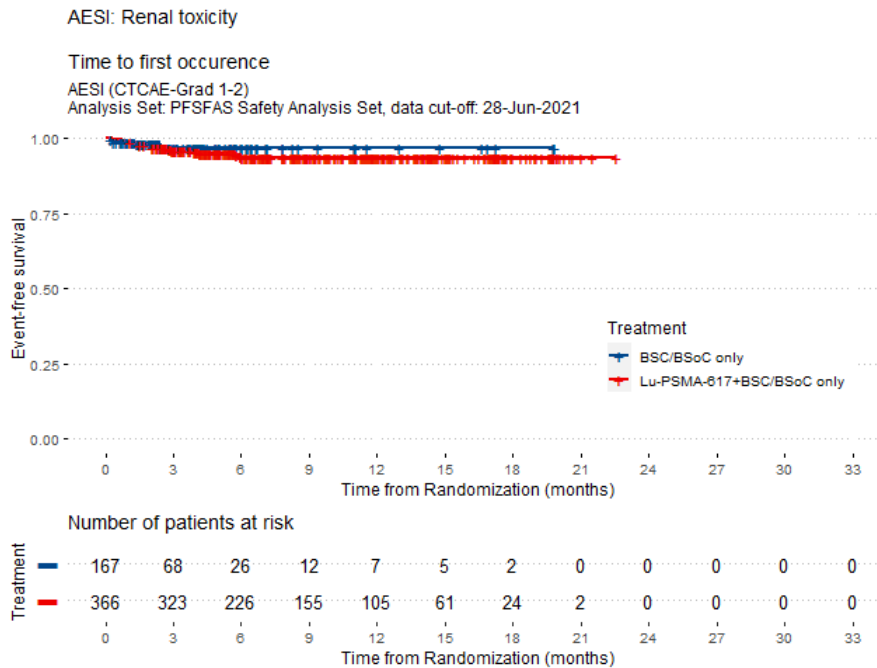


Abbildung 198: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Renal toxicity

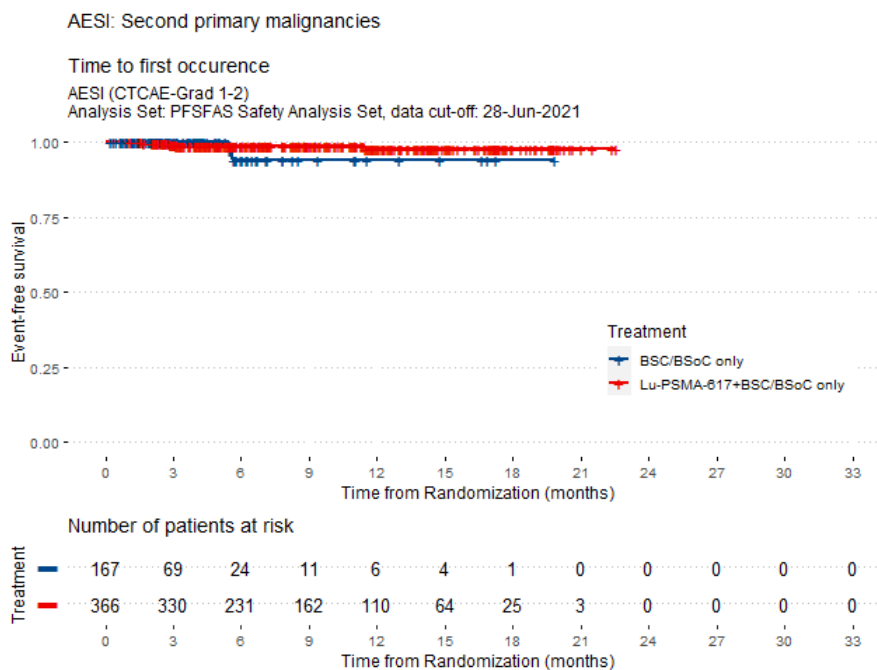


Abbildung 199: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Second primary malignancies

**Anhang 3.3.3: Schwere UE (CTCAE-Grad 3-5)**

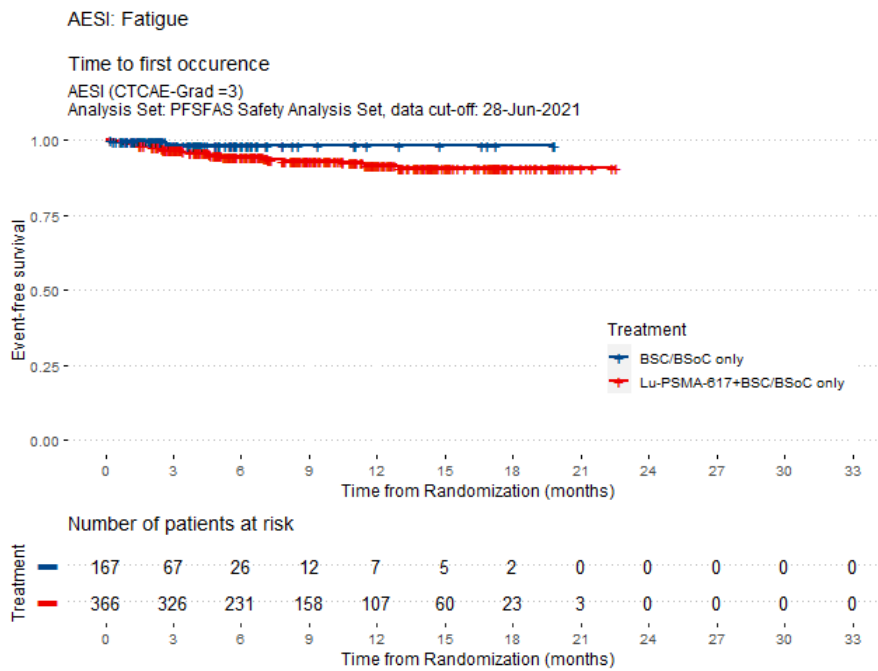


Abbildung 200: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Fatigue

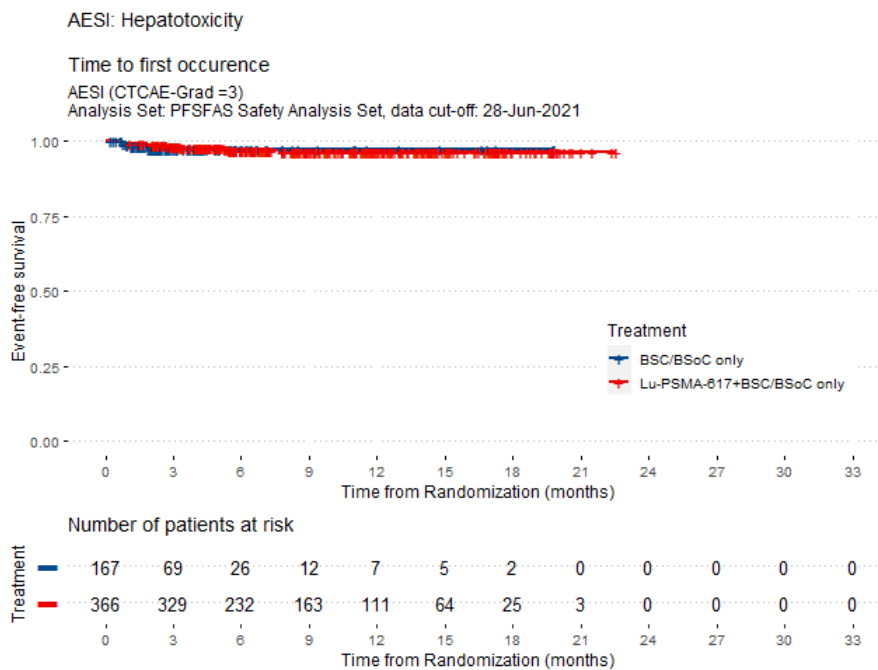


Abbildung 201: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Hepatotoxicity

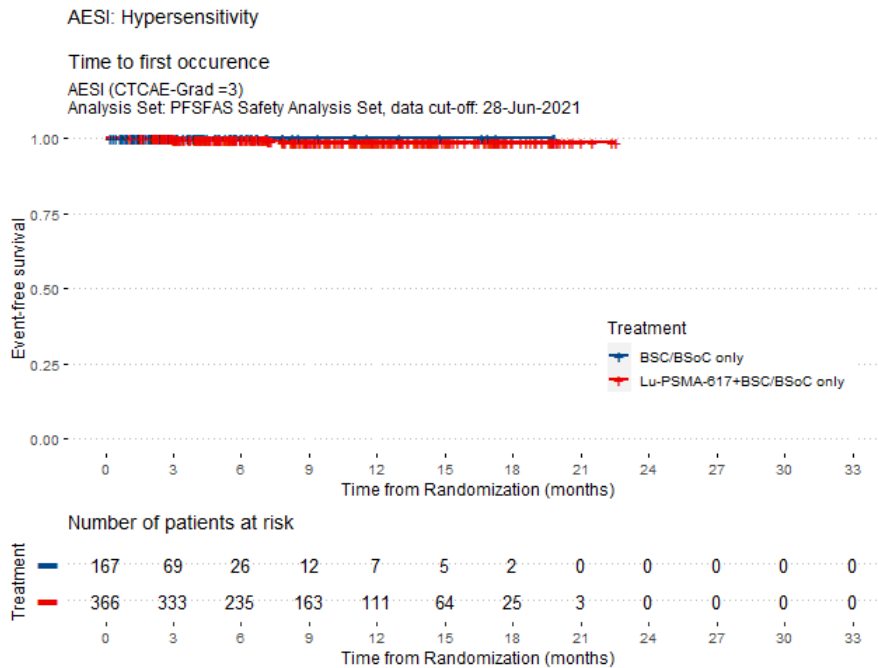


Abbildung 202: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Hypersensitivity

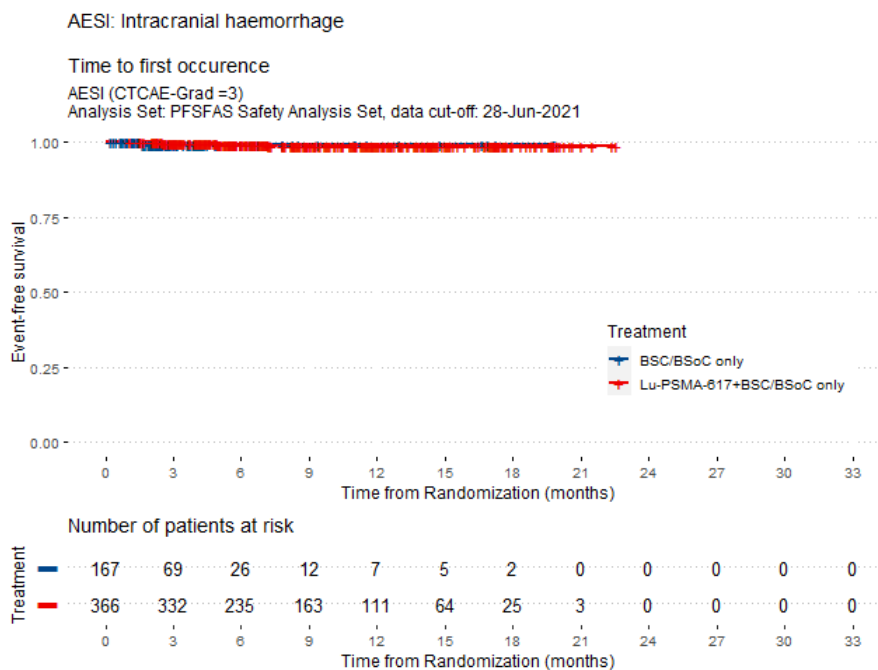


Abbildung 203: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Intracranial haemorrhage



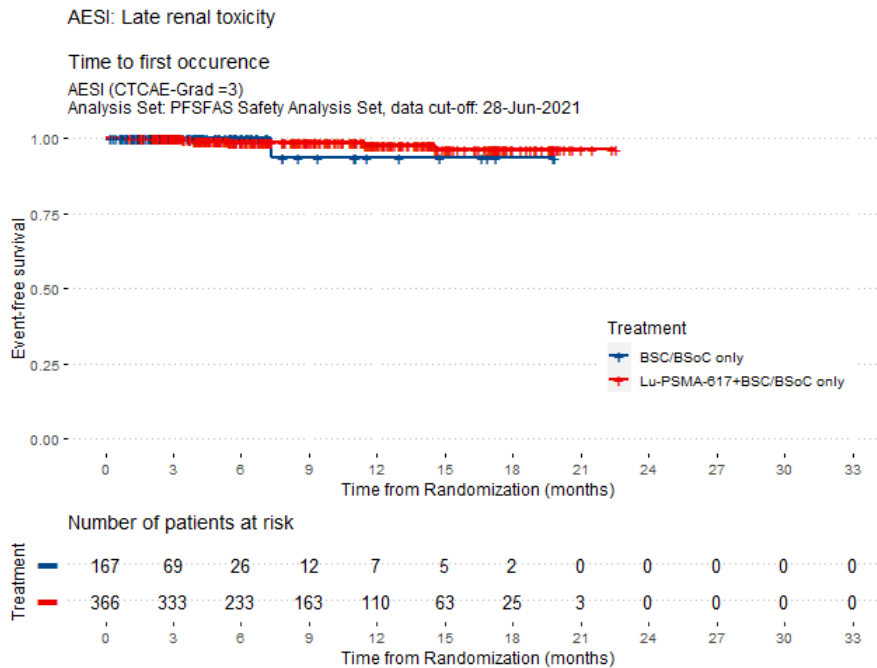


Abbildung 204: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Late renal toxicity

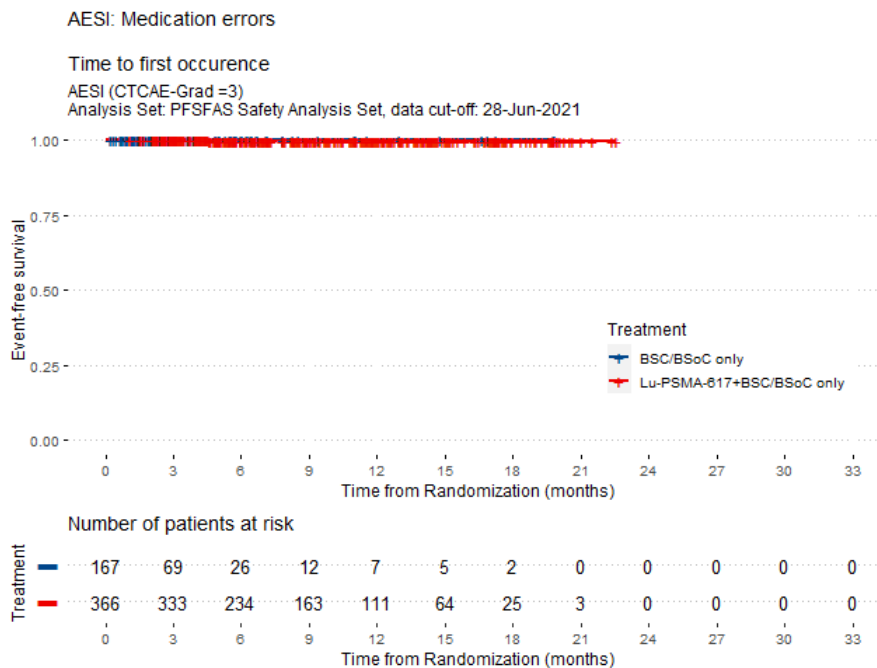


Abbildung 205: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Medication errors

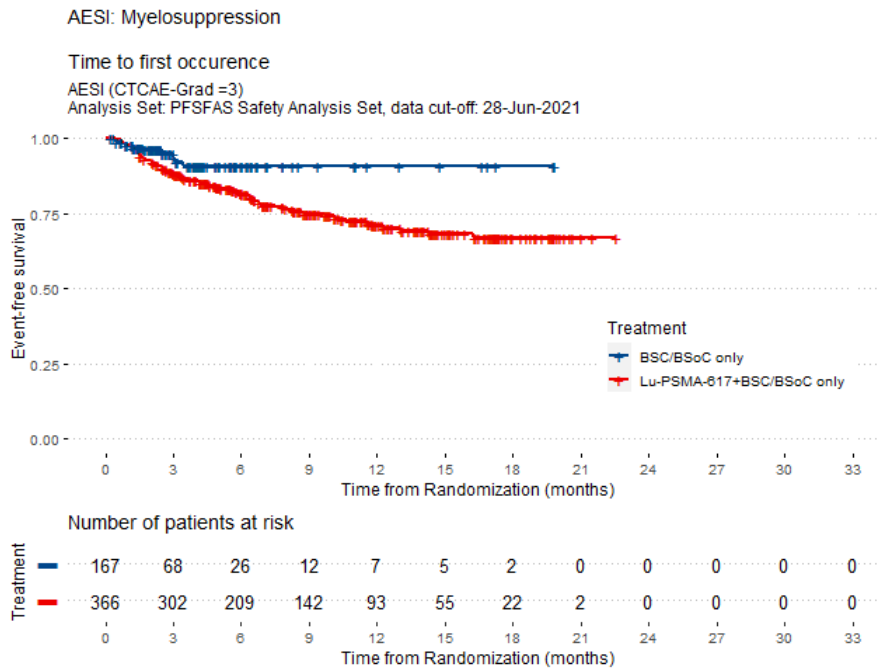


Abbildung 206: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Myelosuppression

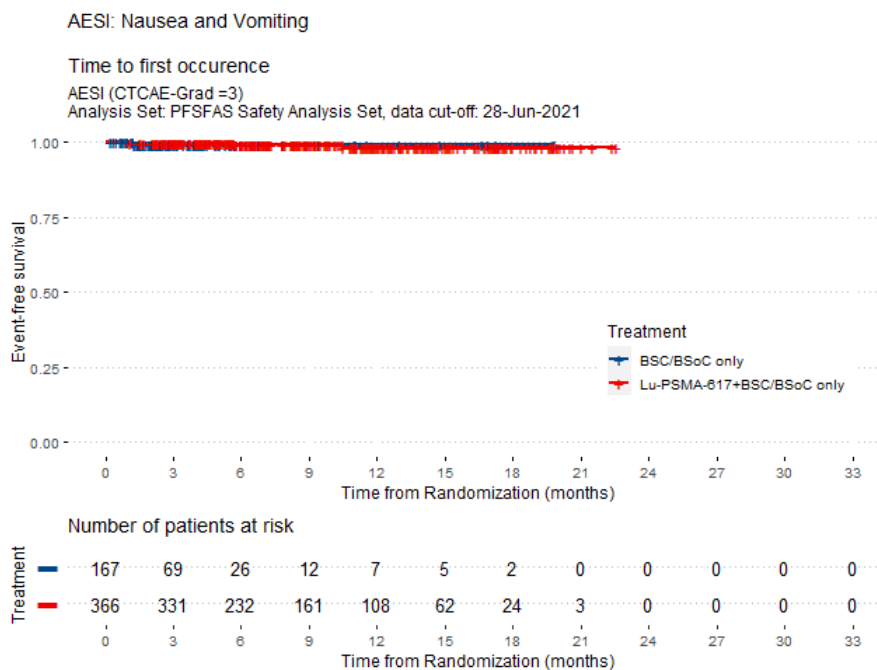


Abbildung 207: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Nausea and Vomiting

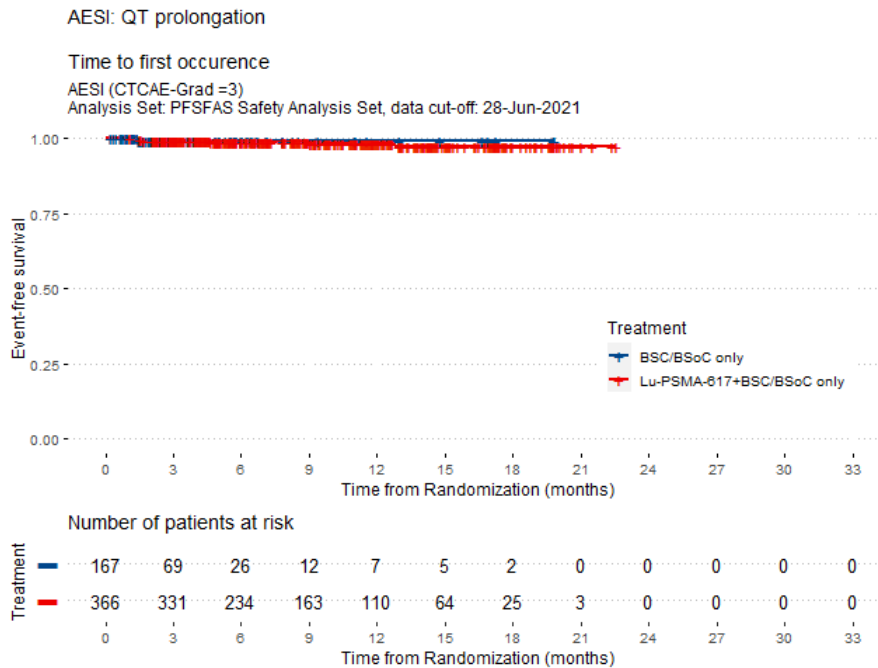


Abbildung 208: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: QT prolongation

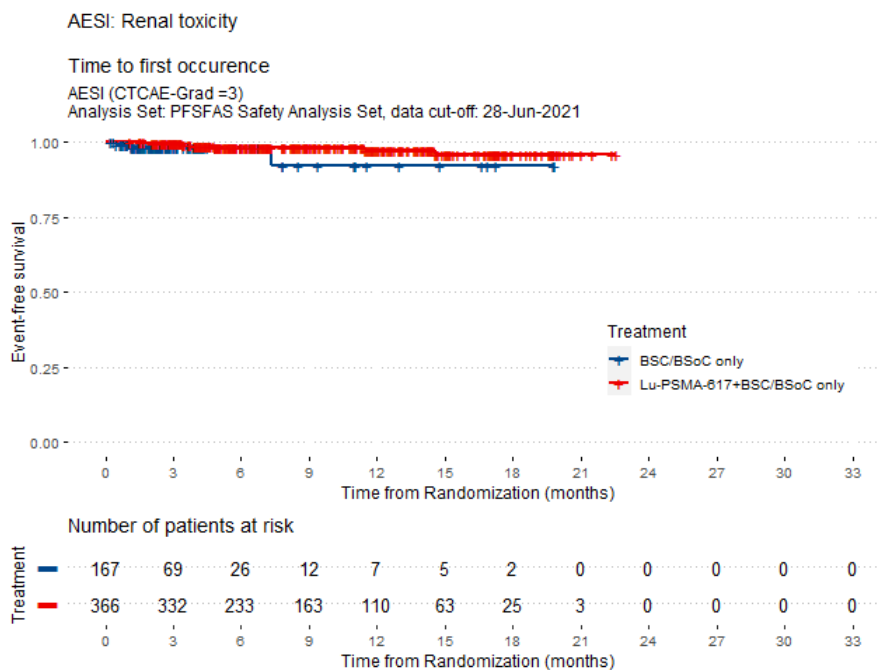


Abbildung 209: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Renal toxicity

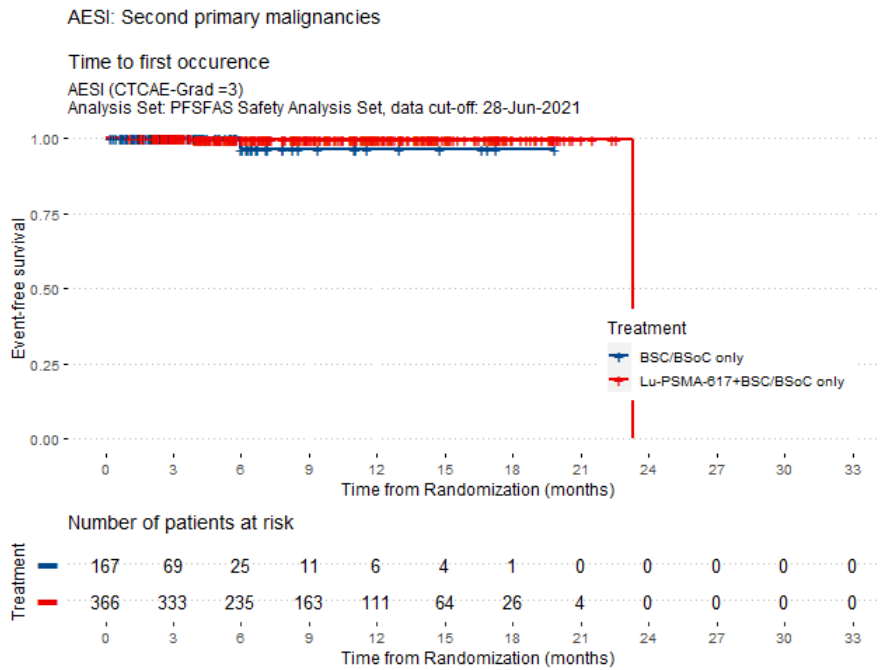


Abbildung 210: AESI (CTCAE-Grad 3-5): Time to first occurrence of AESI: Second primary malignancies

### Anhang 3.3.4: Schwerwiegende UE

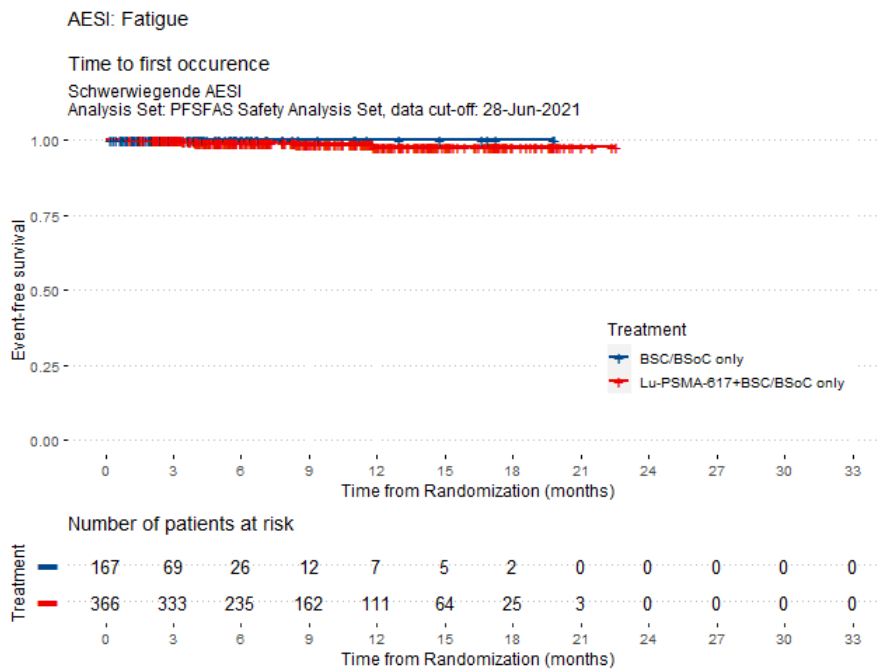


Abbildung 211: Schwerwiegende AESI: Time to first occurrence of AESI: Fatigue

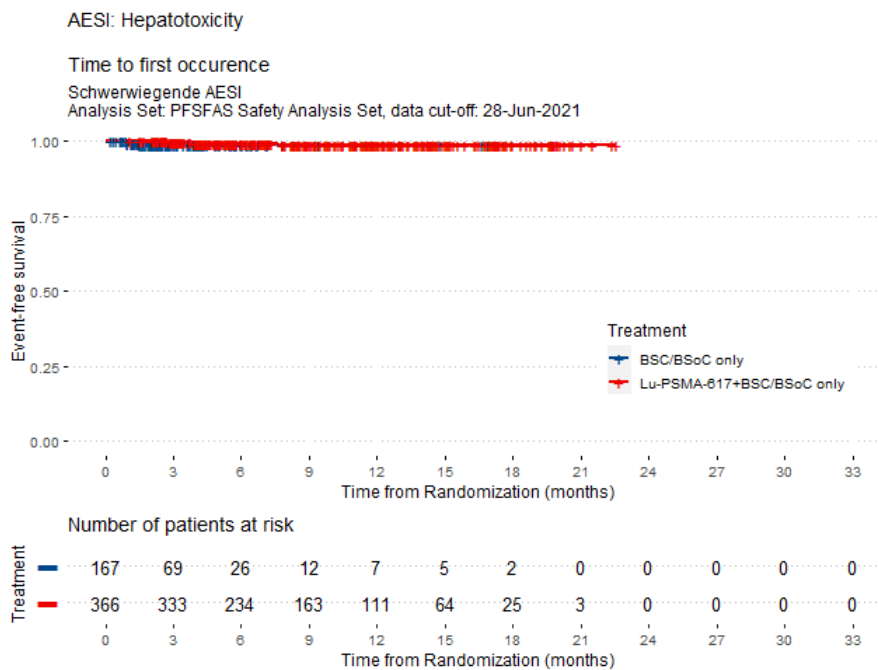


Abbildung 212: Schwerwiegende AESI: Time to first occurrence of AESI: Hepatotoxicity

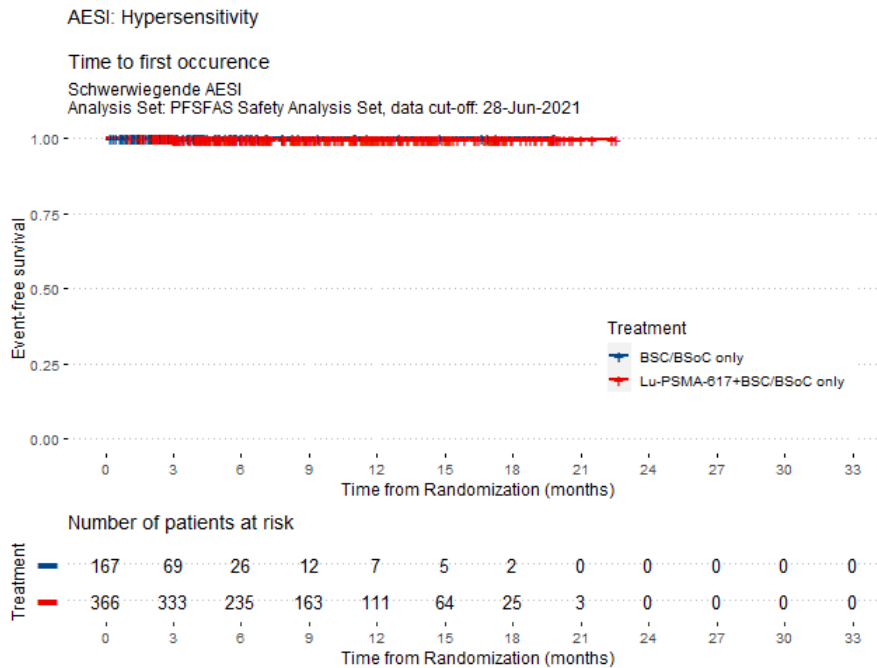


Abbildung 213: Schwerwiegende AESI: Time to first occurrence of AESI: Hypersensitivity

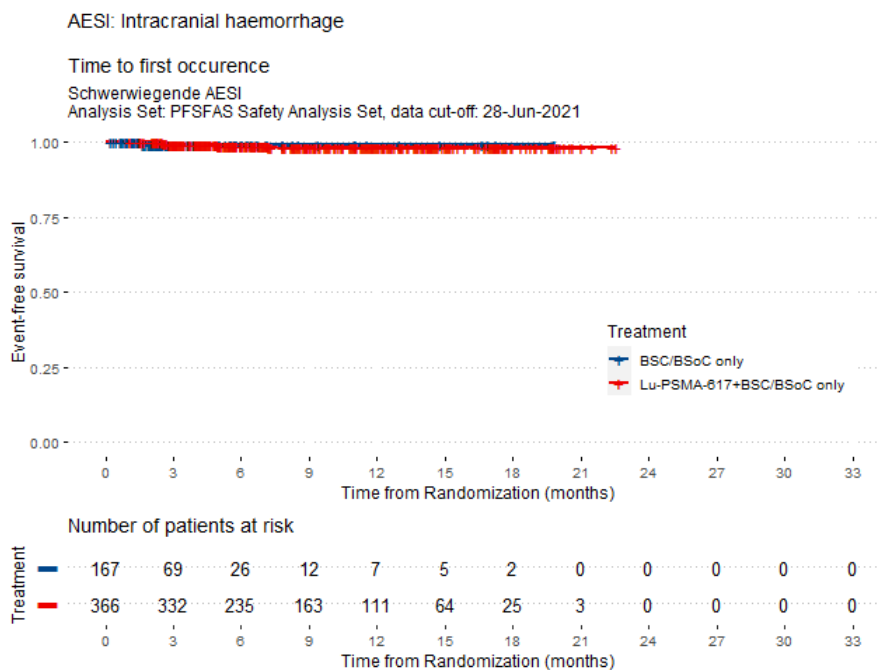


Abbildung 214: Schwerwiegende AESI: Time to first occurrence of AESI: Intracranial haemorrhage

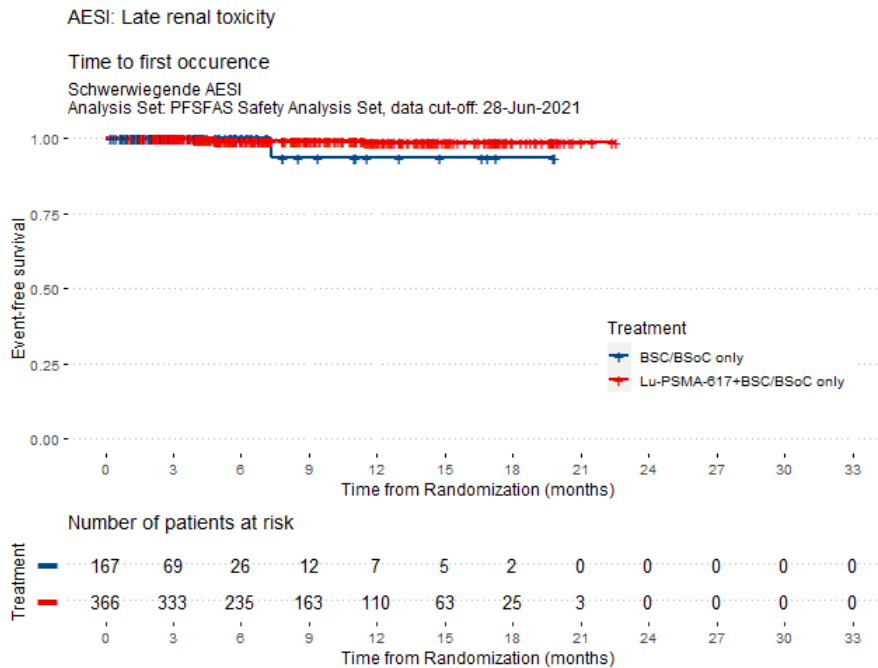


Abbildung 215: Schwerwiegende AESI: Time to first occurrence of AESI: Late renal toxicity

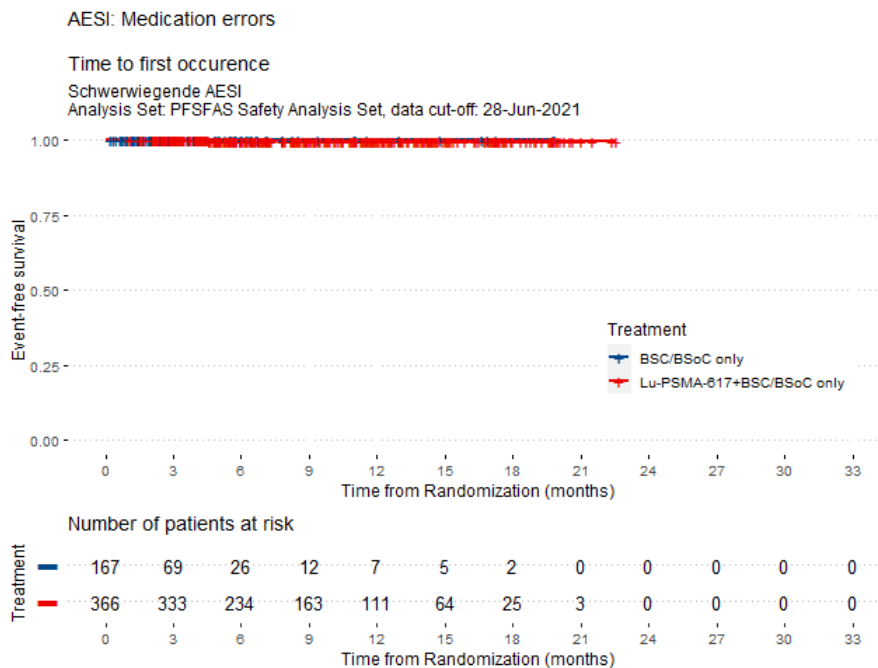


Abbildung 216: Schwerwiegende AESI: Time to first occurrence of AESI: Medication errors

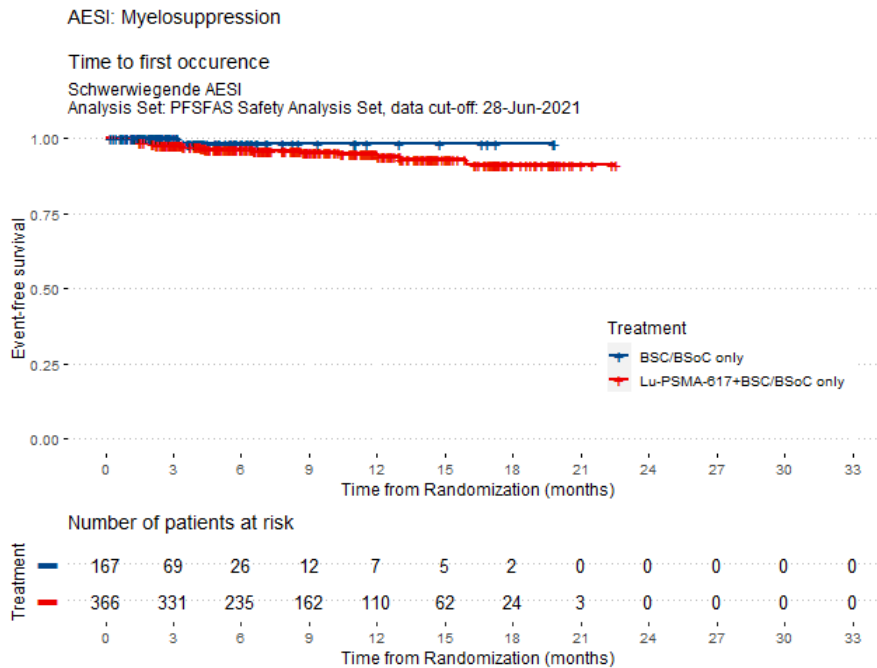


Abbildung 217: Schwerwiegende AESI: Time to first occurrence of AESI: Myelosuppression

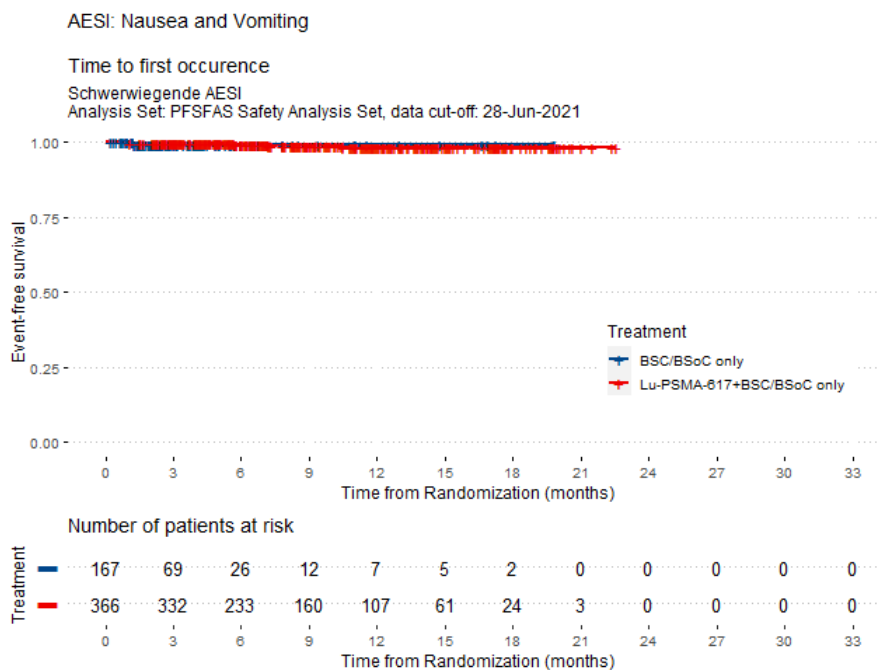


Abbildung 218: Schwerwiegende AESI: Time to first occurrence of AESI: Nausea and Vomiting



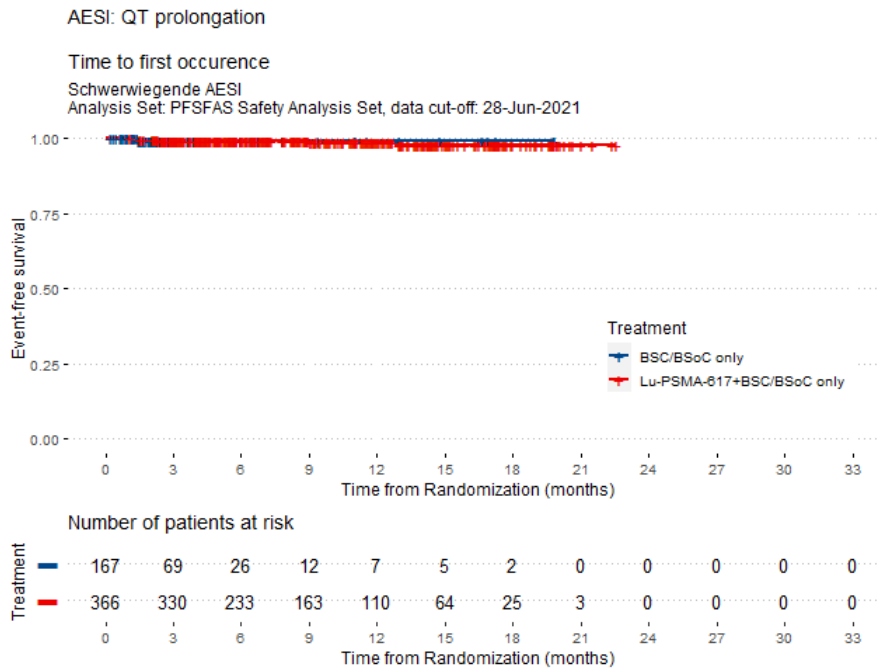


Abbildung 219: Schwerwiegende AESI: Time to first occurrence of AESI: QT prolongation

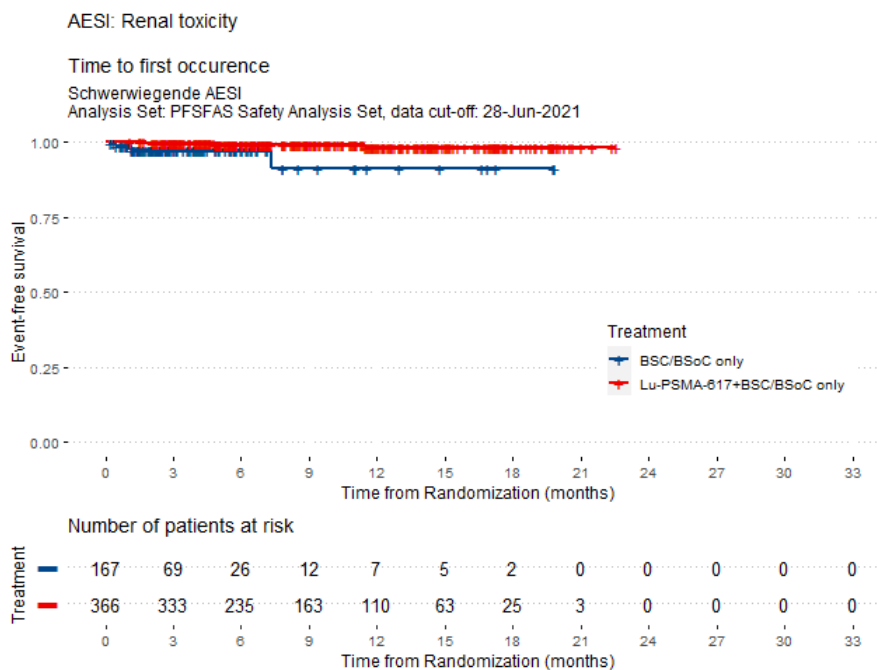


Abbildung 220: Schwerwiegende AESI: Time to first occurrence of AESI: Renal toxicity

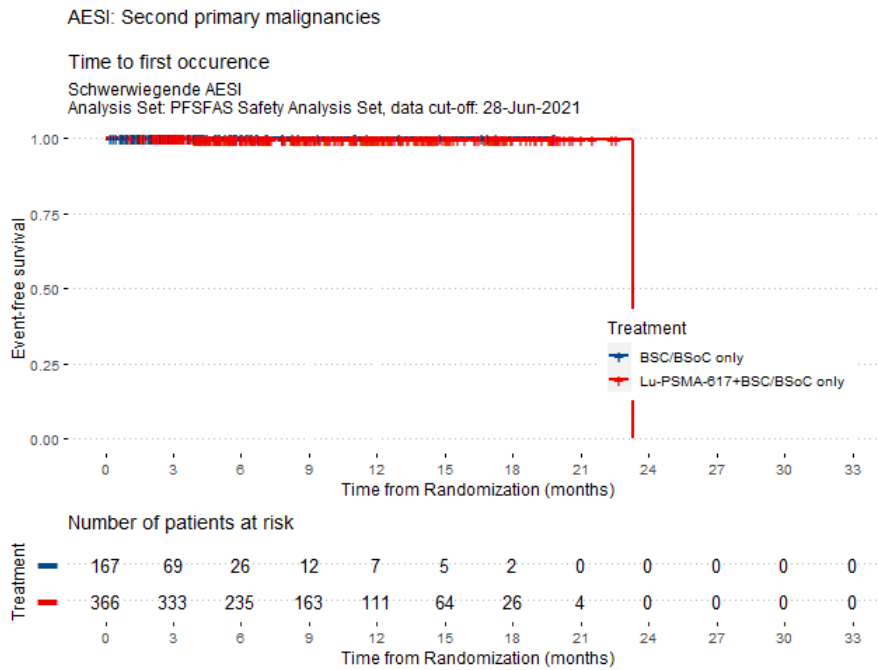


Abbildung 221: Schwerwiegende AESI: Time to first occurrence of AESI: Second primary malignancies

### Anhang 3.4: Unerwünschte Ereignisse nach System Organ Class und Preferred Term

#### Anhang 3.4.1: UE jeglichen Schweregrads

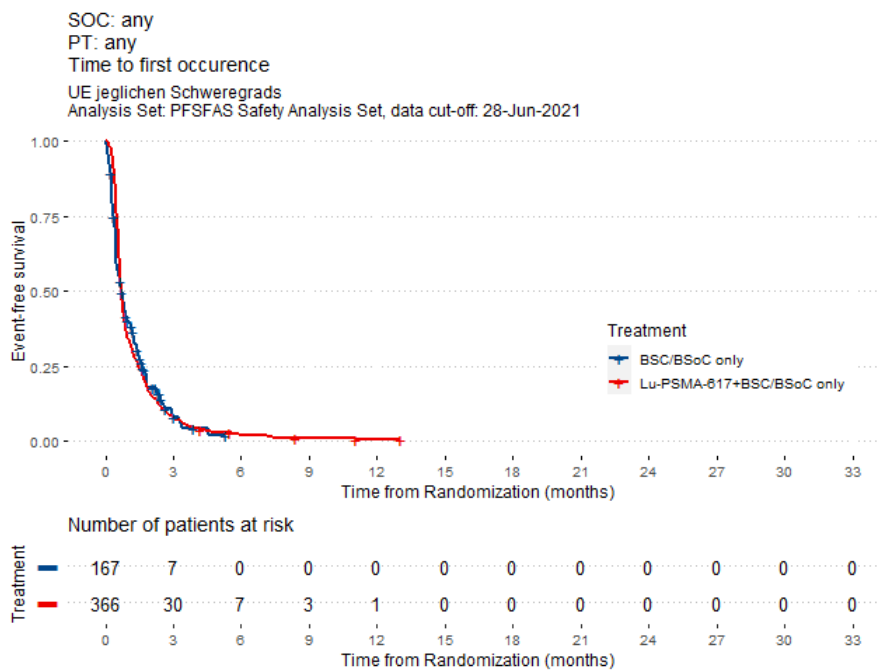


Abbildung 222: UE jeglichen Schweregrads: Time to first occurrence of SOC: any; PT: any

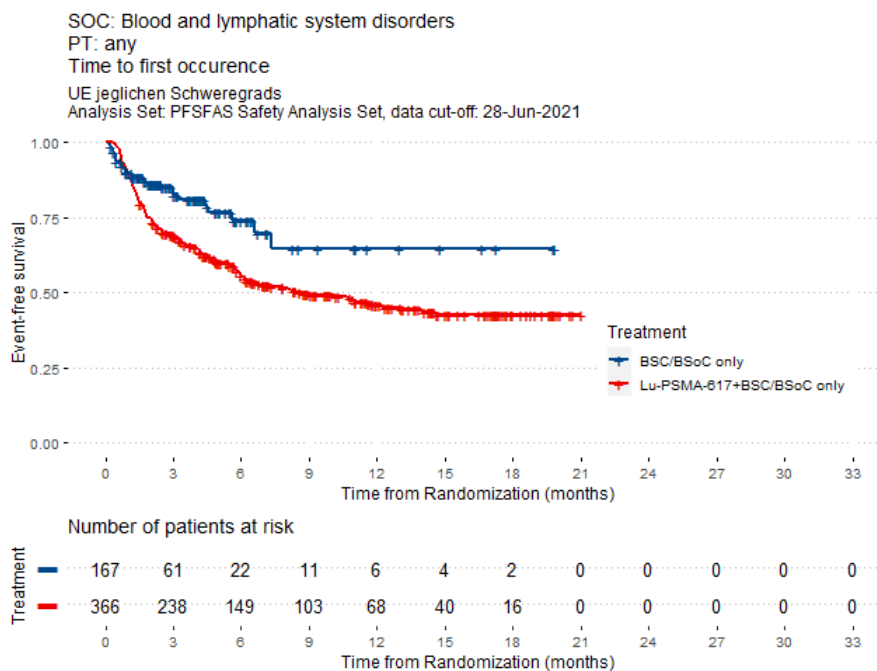


Abbildung 223: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: any

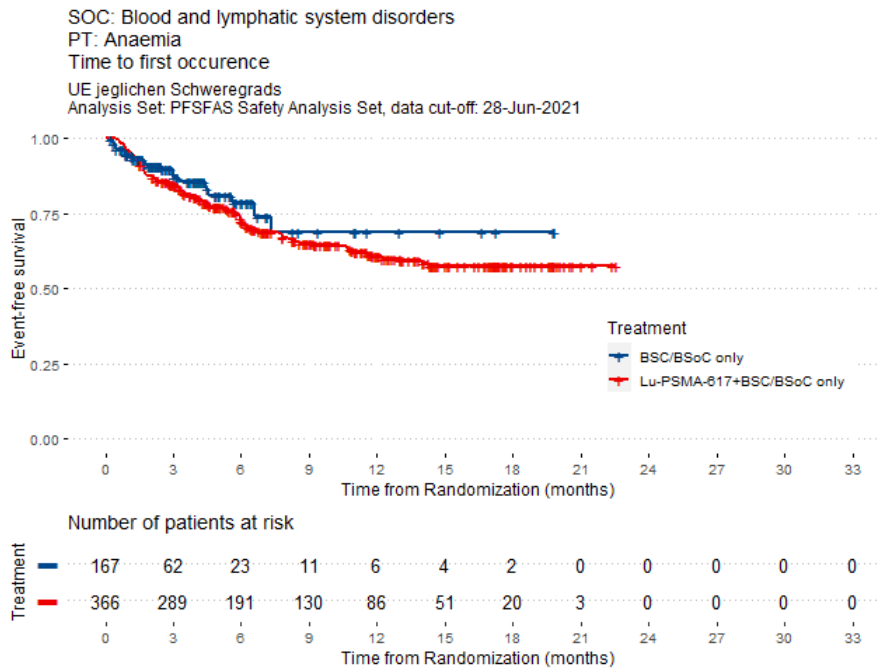


Abbildung 224: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Anaemia

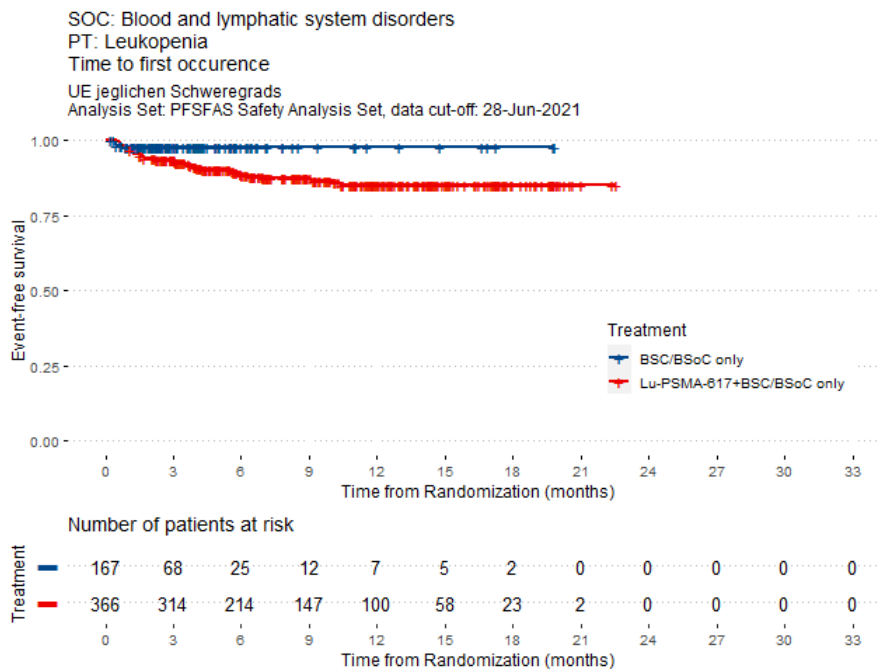


Abbildung 225: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Leukopenia

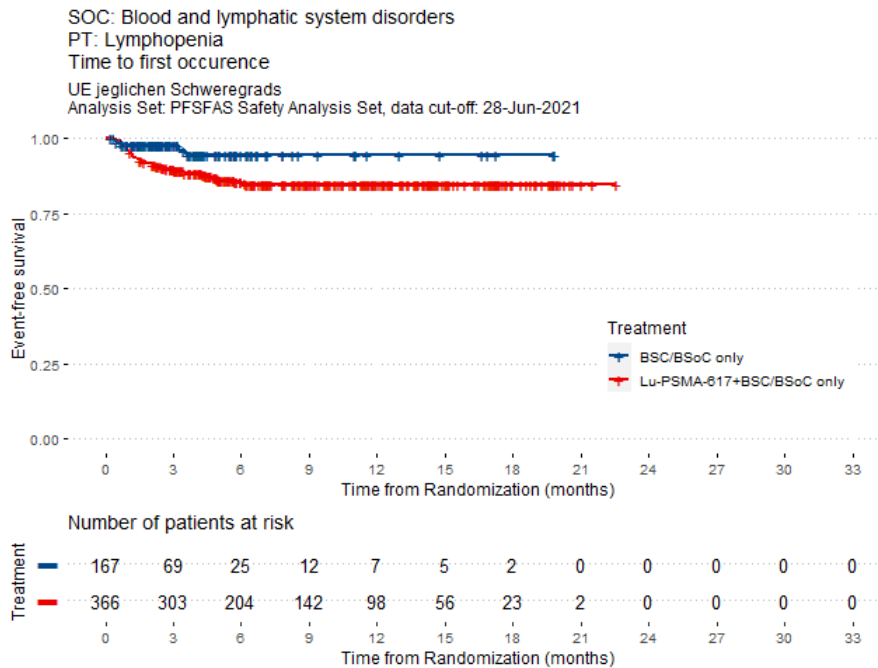


Abbildung 226: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Lymphopenia

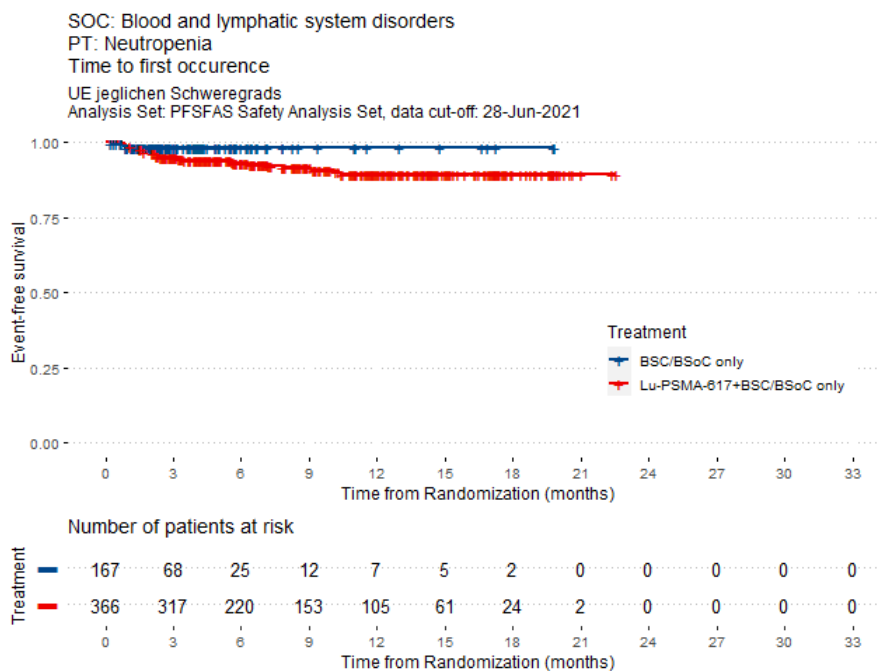


Abbildung 227: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Neutropenia

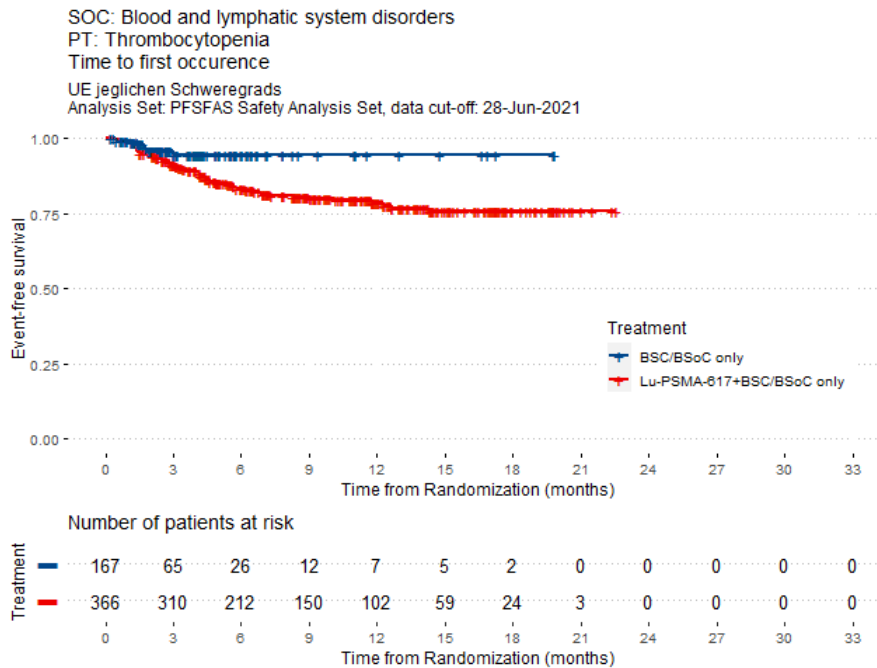


Abbildung 228: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Thrombocytopenia

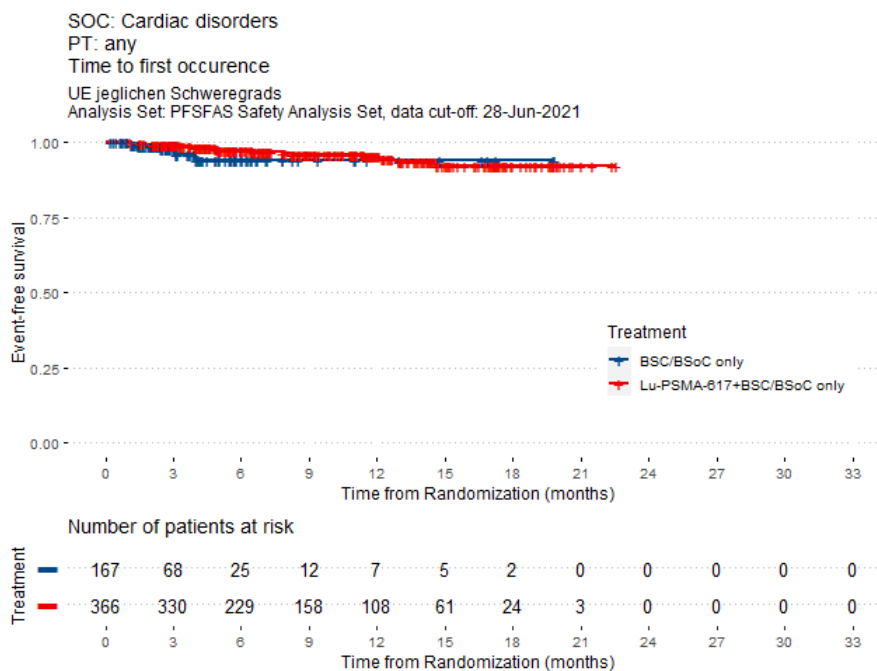


Abbildung 229: UE jeglichen Schweregrads: Time to first occurrence of SOC: Cardiac disorders; PT: any

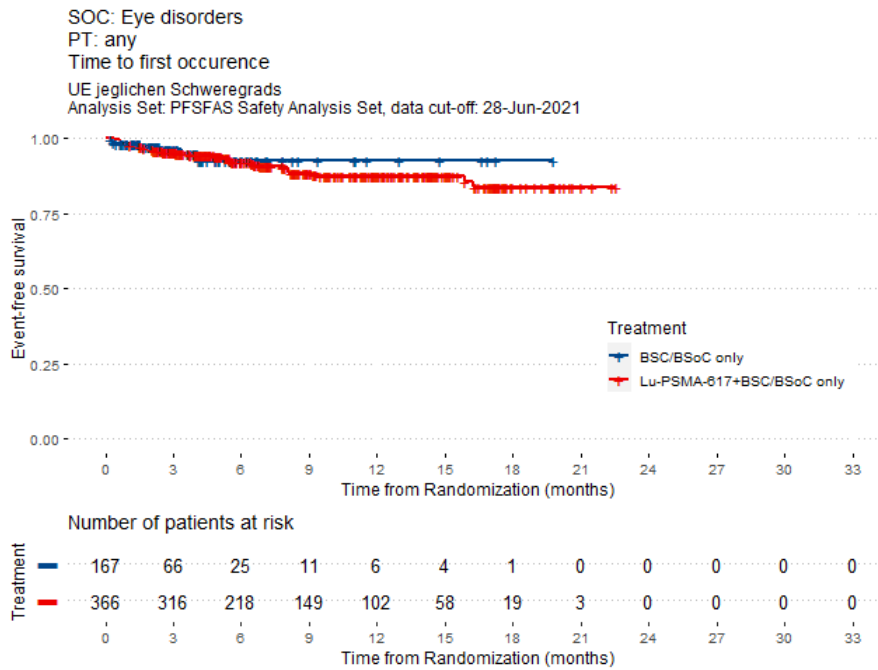


Abbildung 230: UE jeglichen Schweregrads: Time to first occurrence of SOC: Eye disorders; PT: any

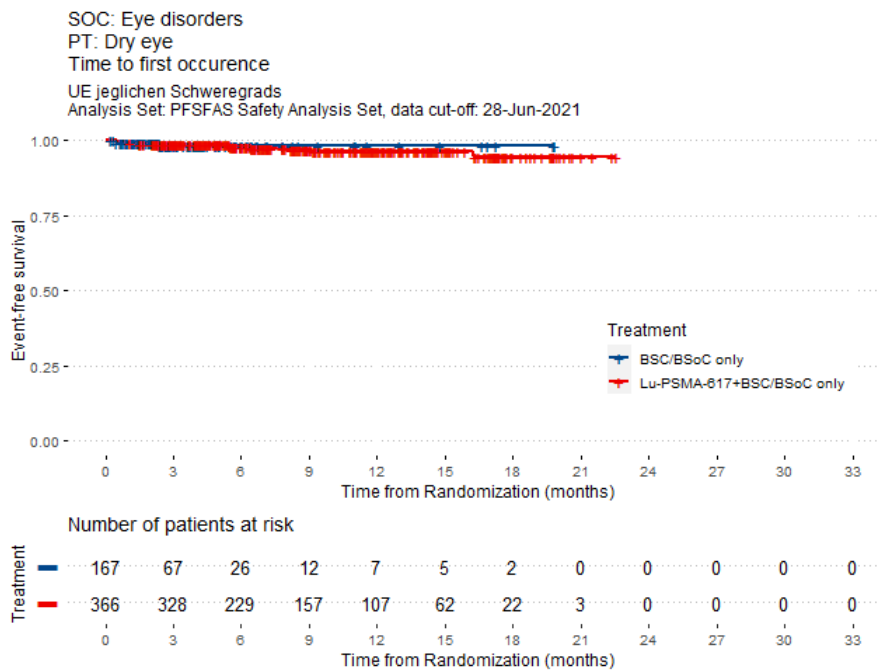


Abbildung 231: UE jeglichen Schweregrads: Time to first occurrence of SOC: Eye disorders; PT: Dry eye

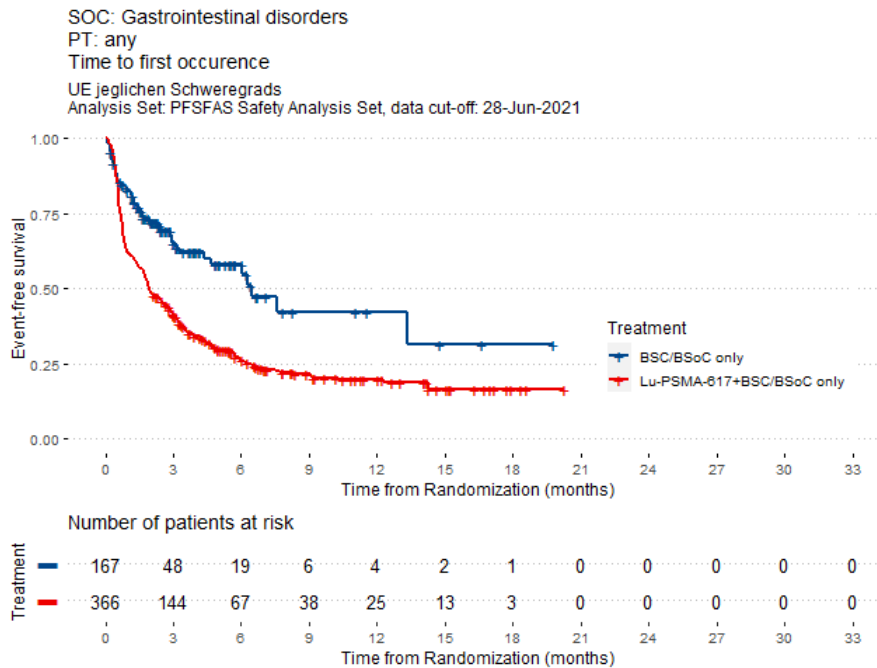


Abbildung 232: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: any

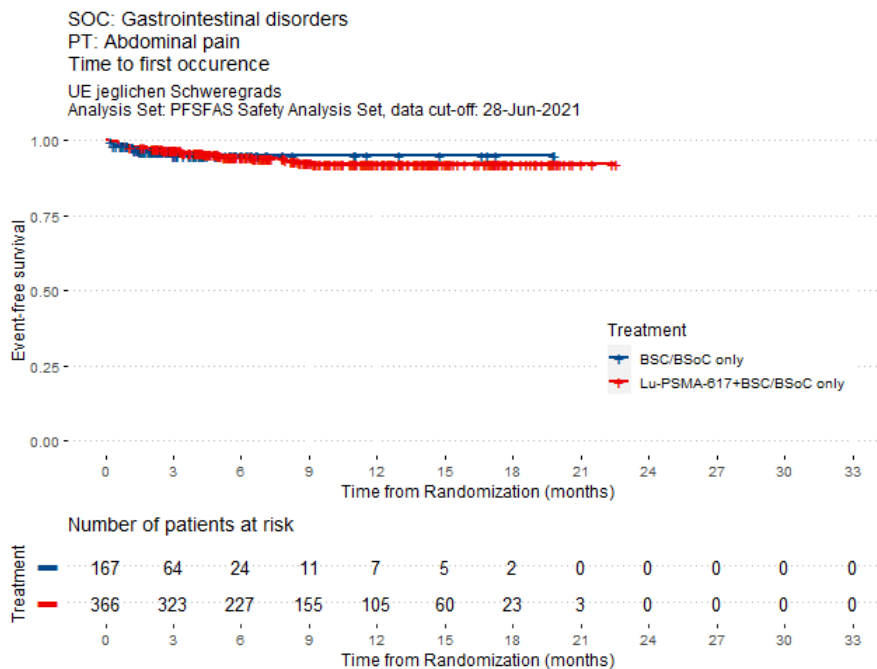


Abbildung 233: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Abdominal pain



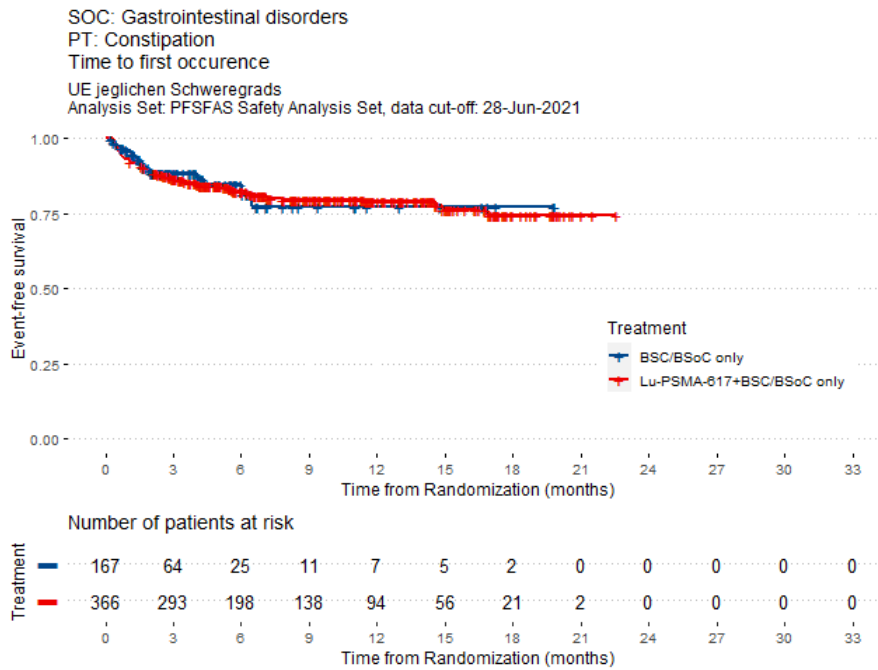


Abbildung 234: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Constipation

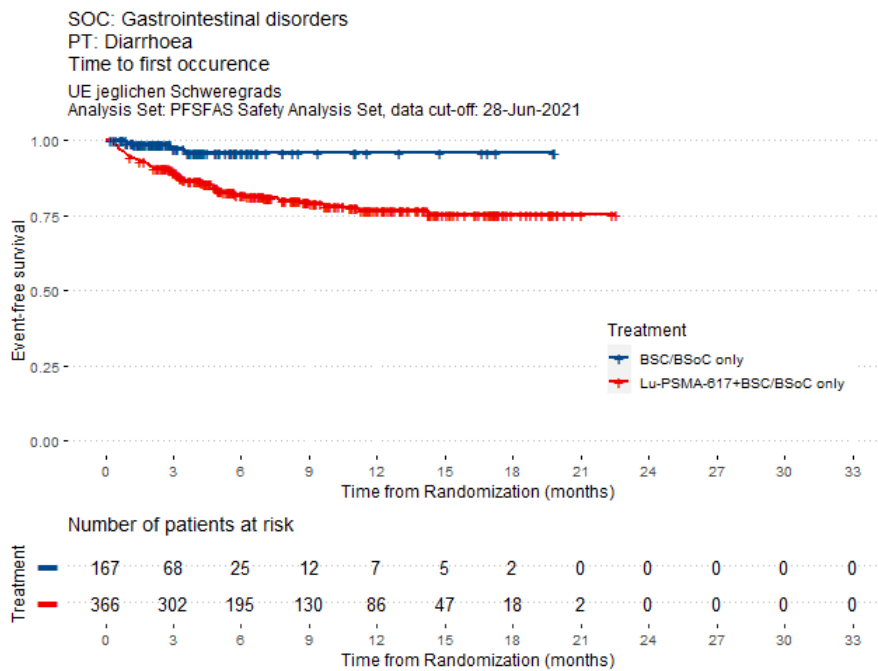


Abbildung 235: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Diarrhoea

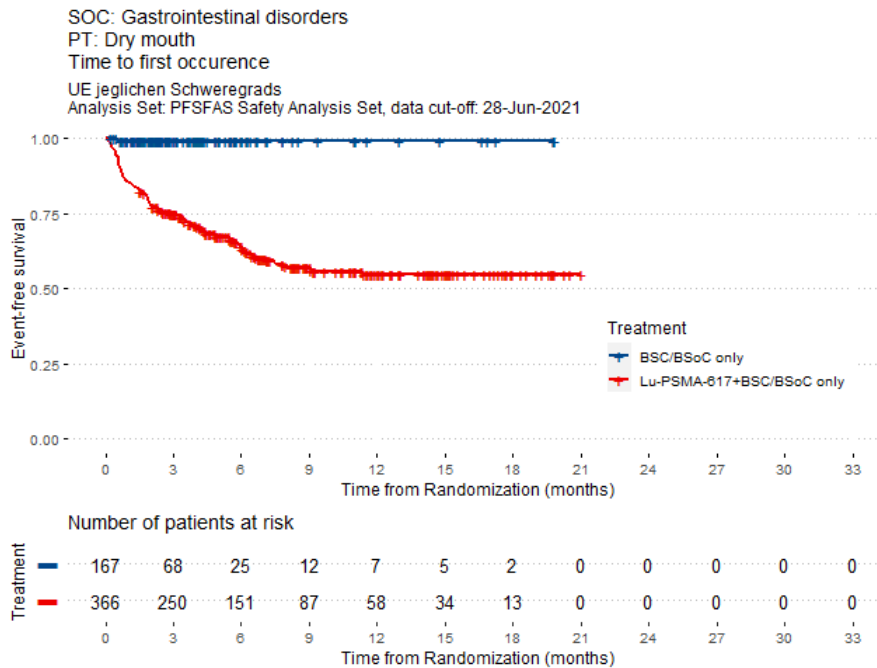


Abbildung 236: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Dry mouth

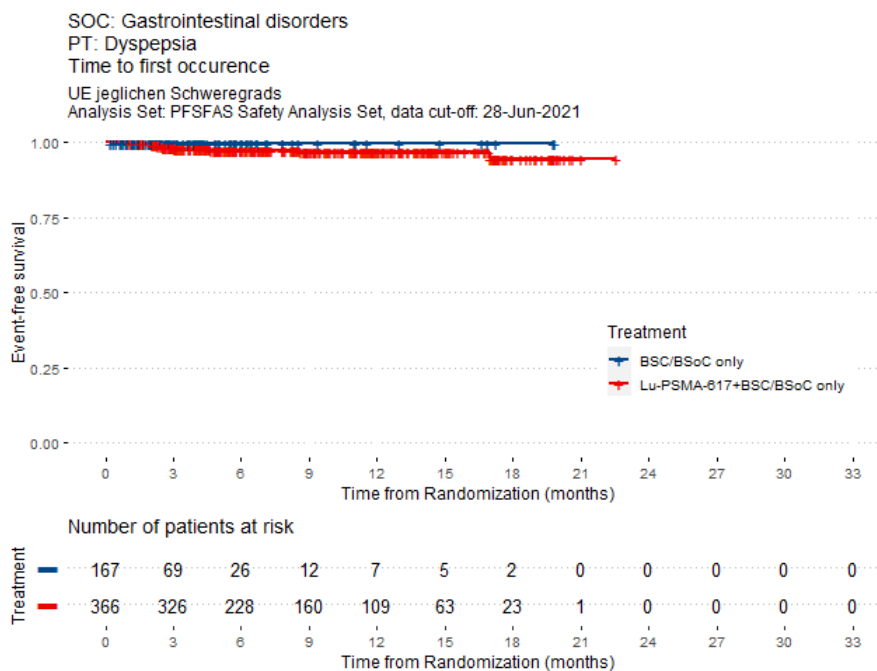


Abbildung 237: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Dyspepsia

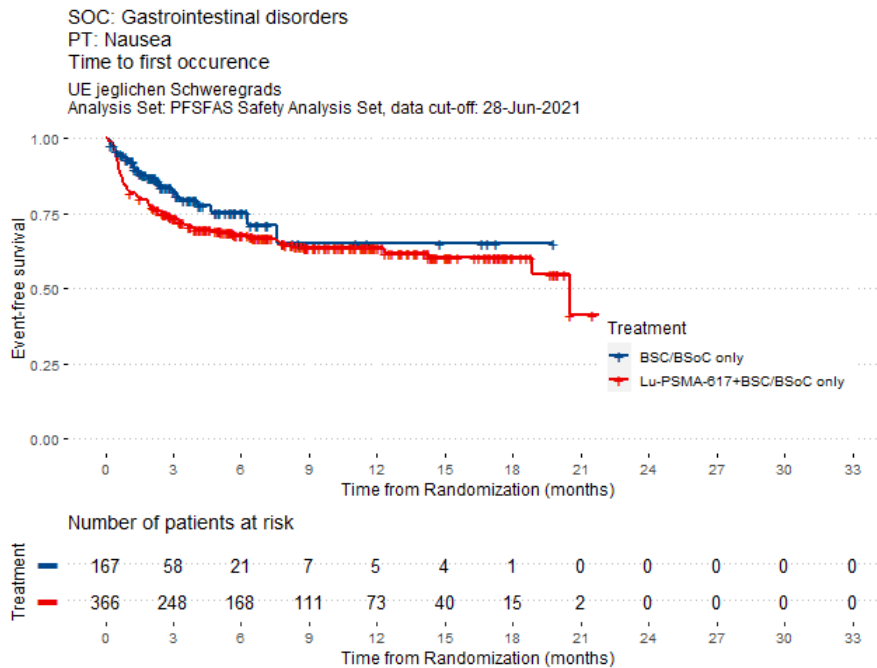


Abbildung 238: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Nausea

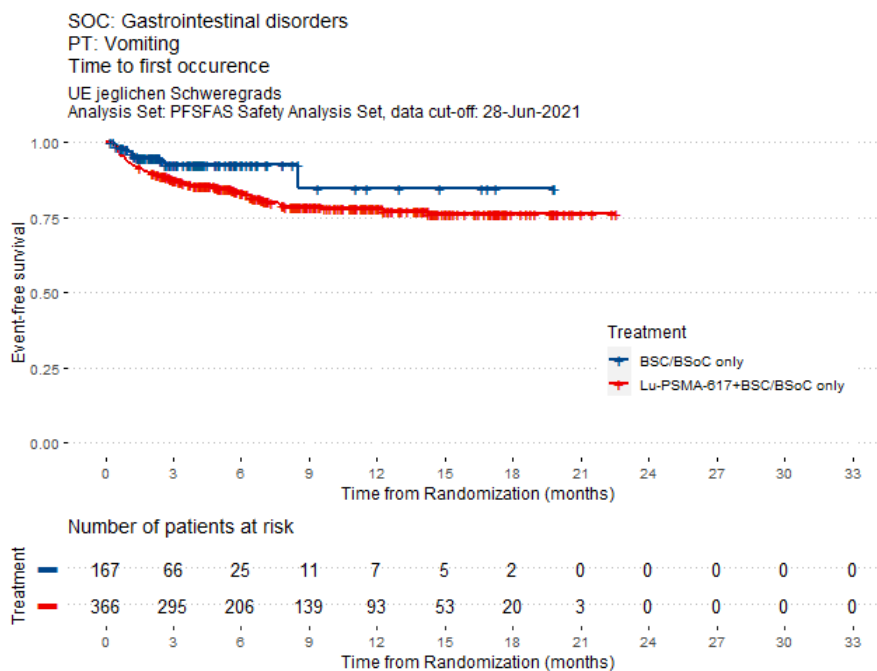


Abbildung 239: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Vomiting

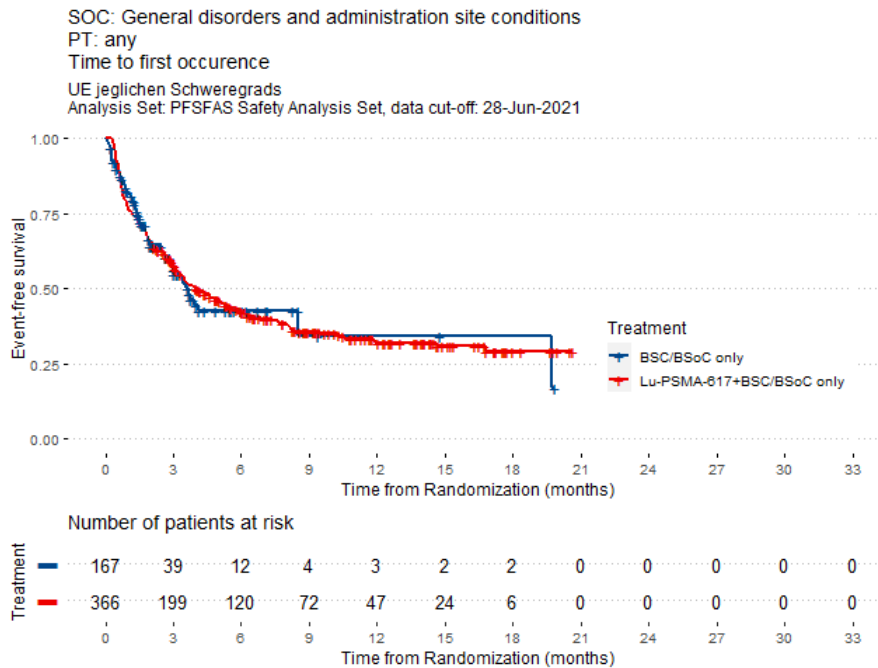


Abbildung 240: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: any

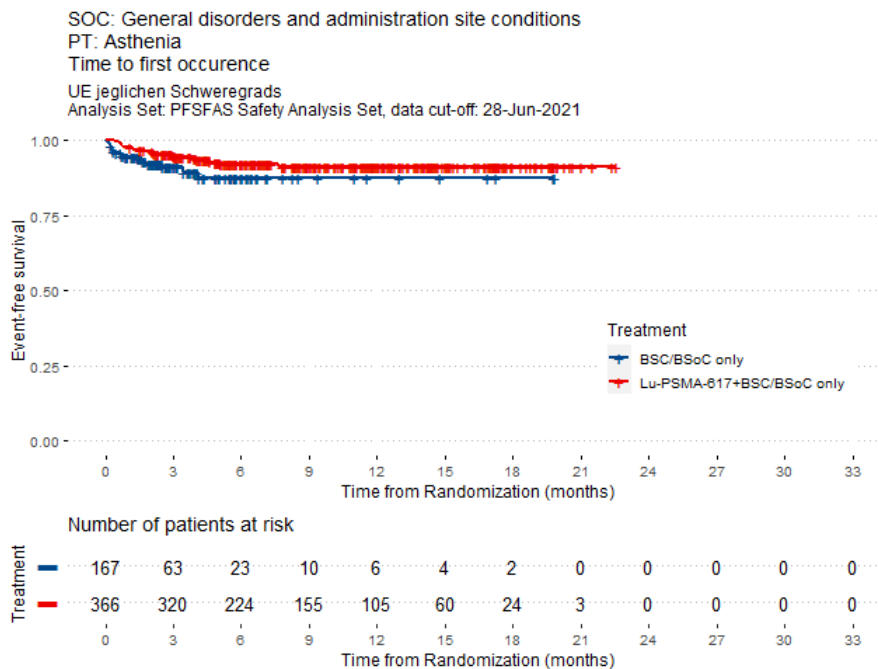


Abbildung 241: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Asthenia

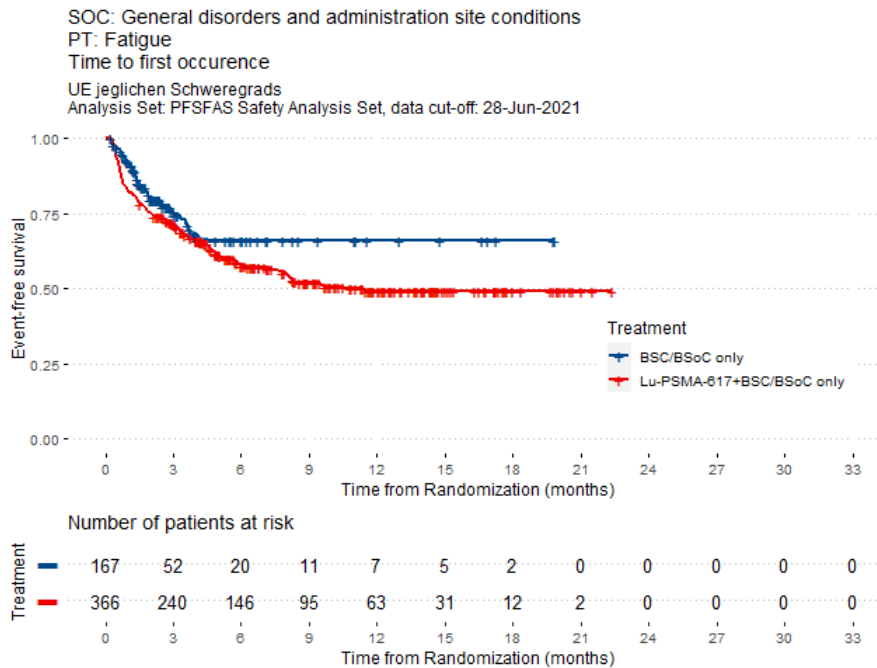


Abbildung 242: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Fatigue

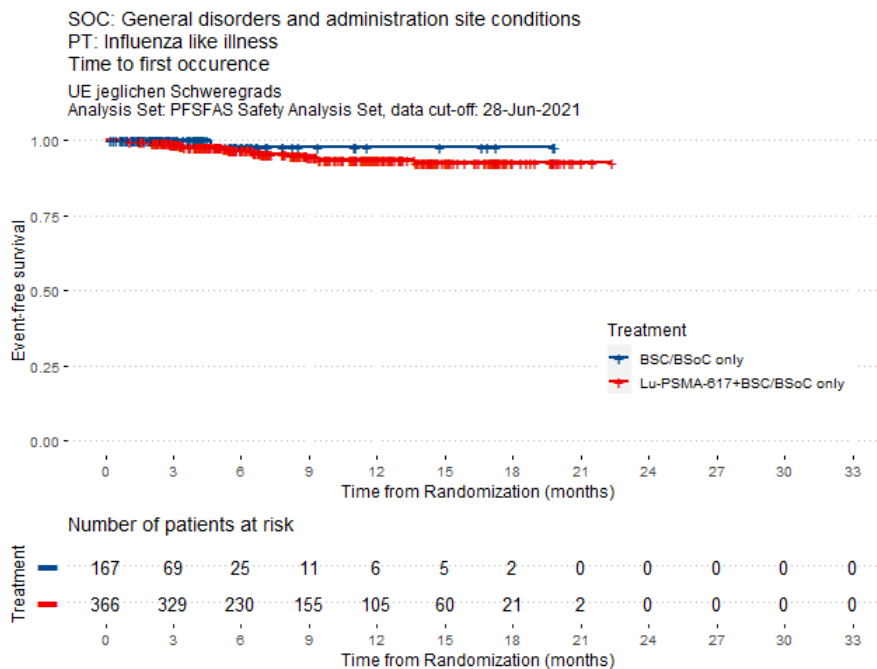


Abbildung 243: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Influenza like illness

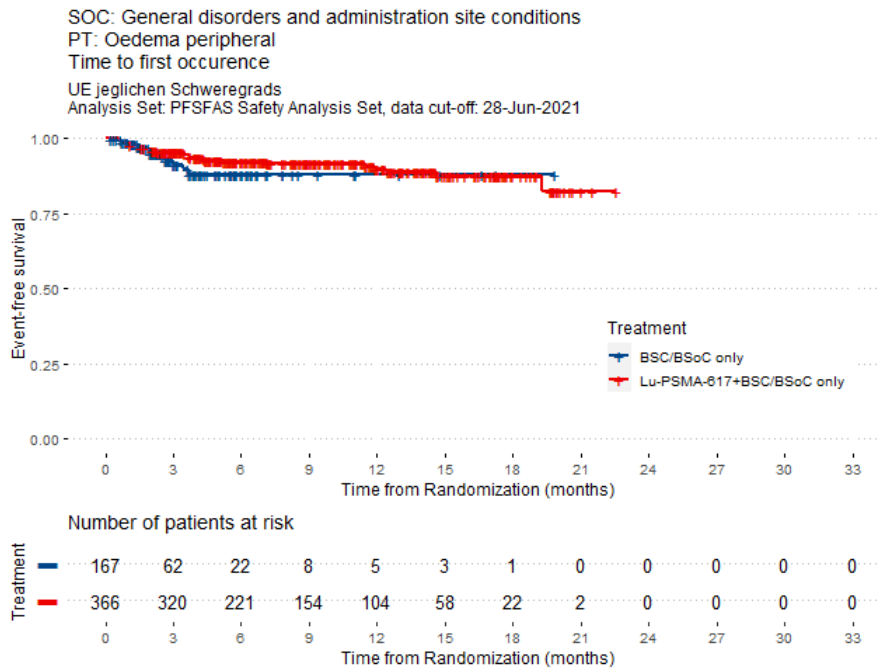


Abbildung 244: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Oedema peripheral

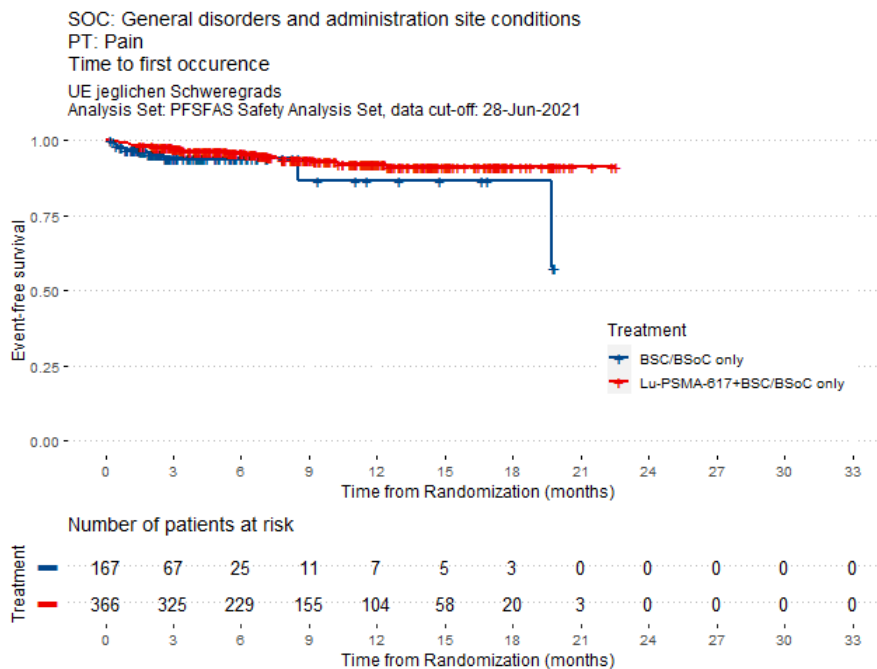


Abbildung 245: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Pain

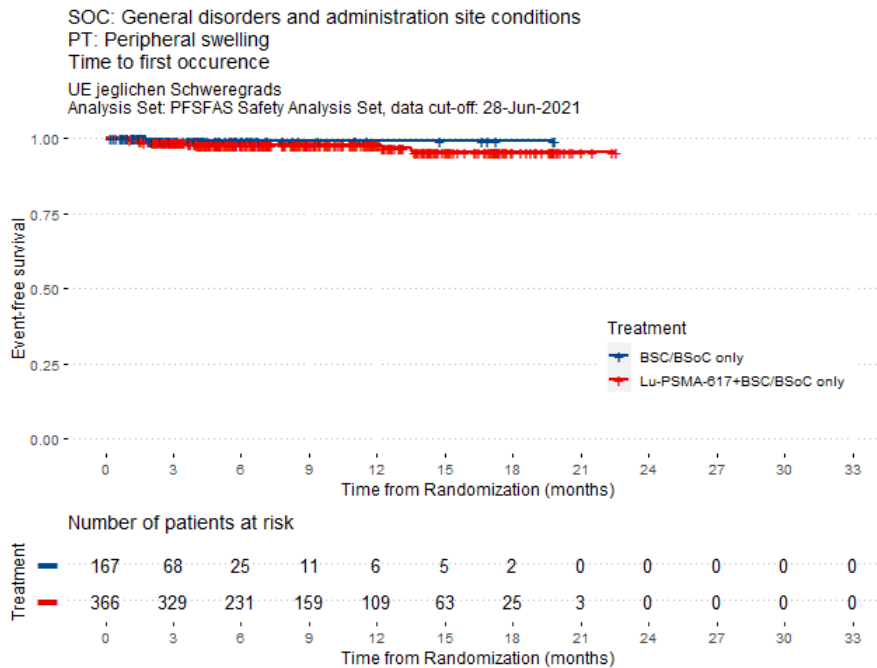


Abbildung 246: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Peripheral swelling

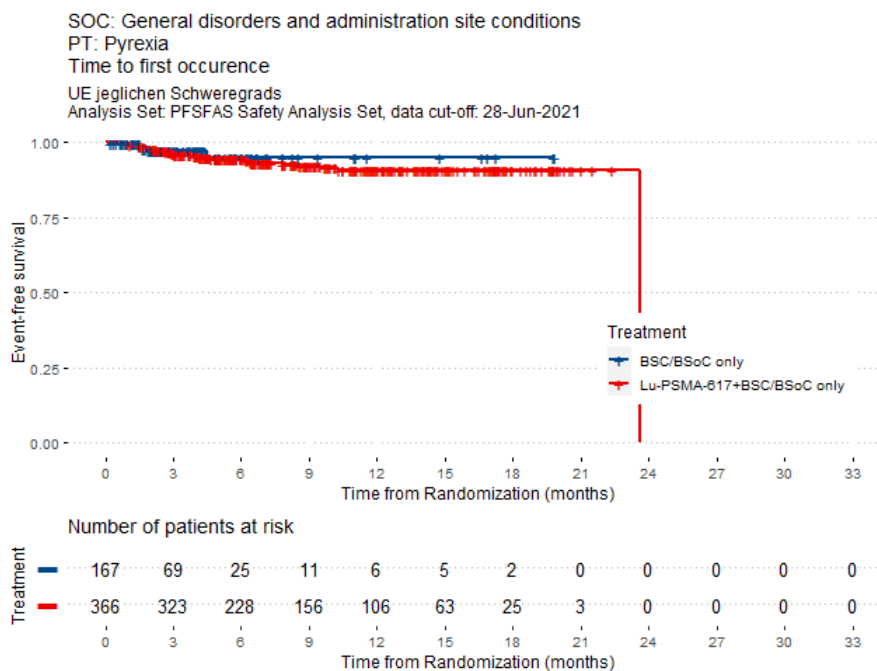


Abbildung 247: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Pyrexia

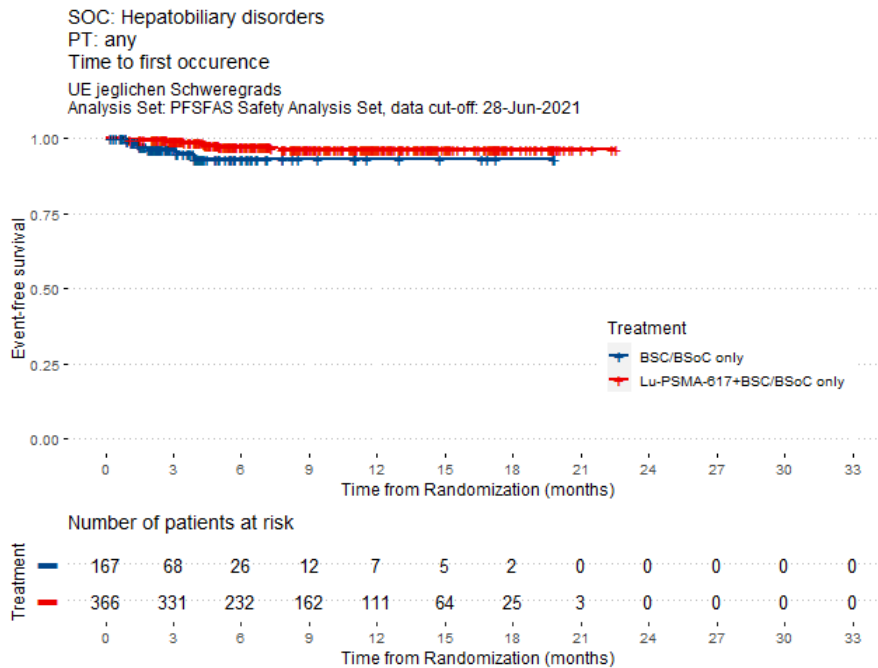


Abbildung 248: UE jeglichen Schweregrads: Time to first occurrence of SOC: Hepatobiliary disorders; PT: any

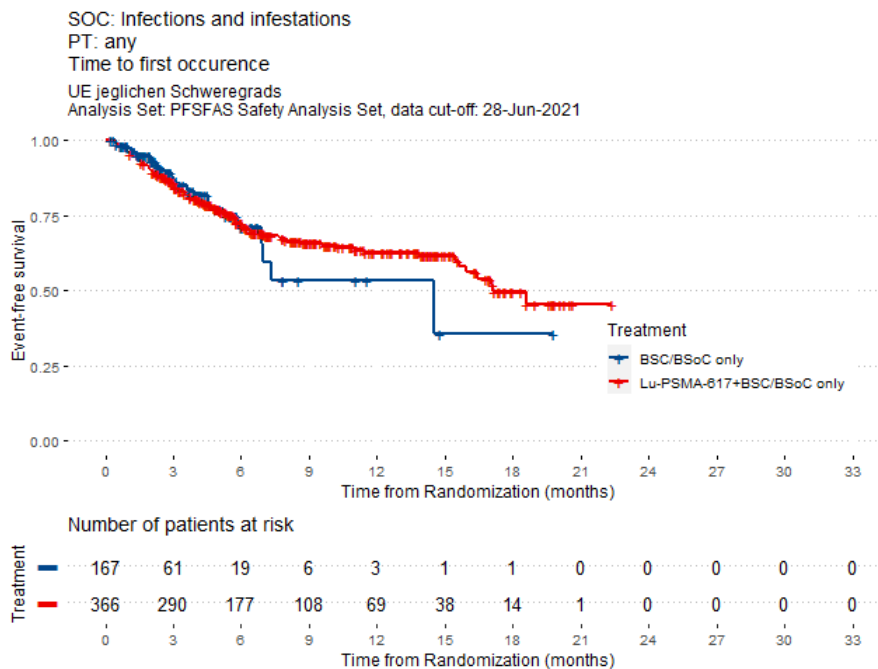


Abbildung 249: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: any



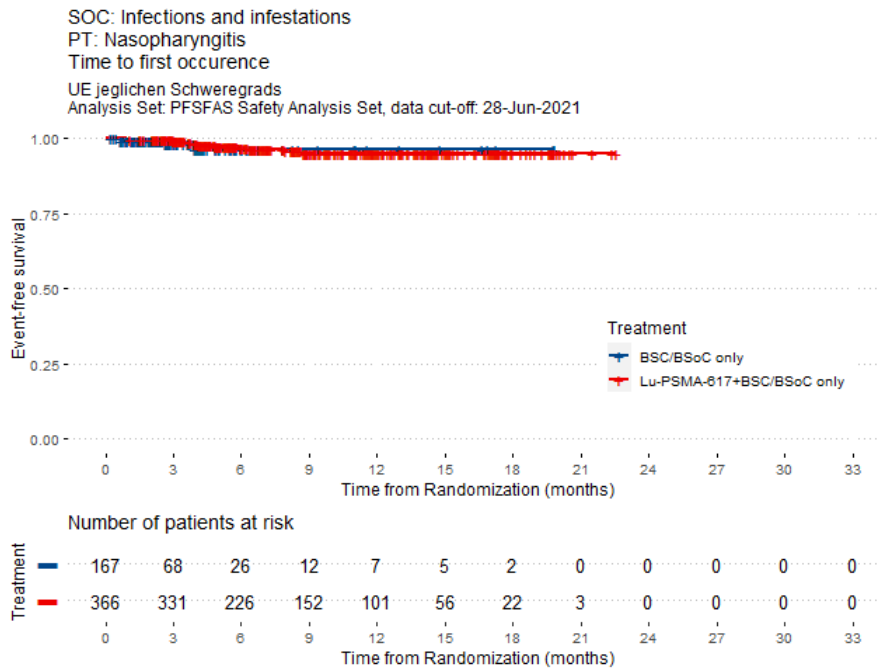


Abbildung 250: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Nasopharyngitis

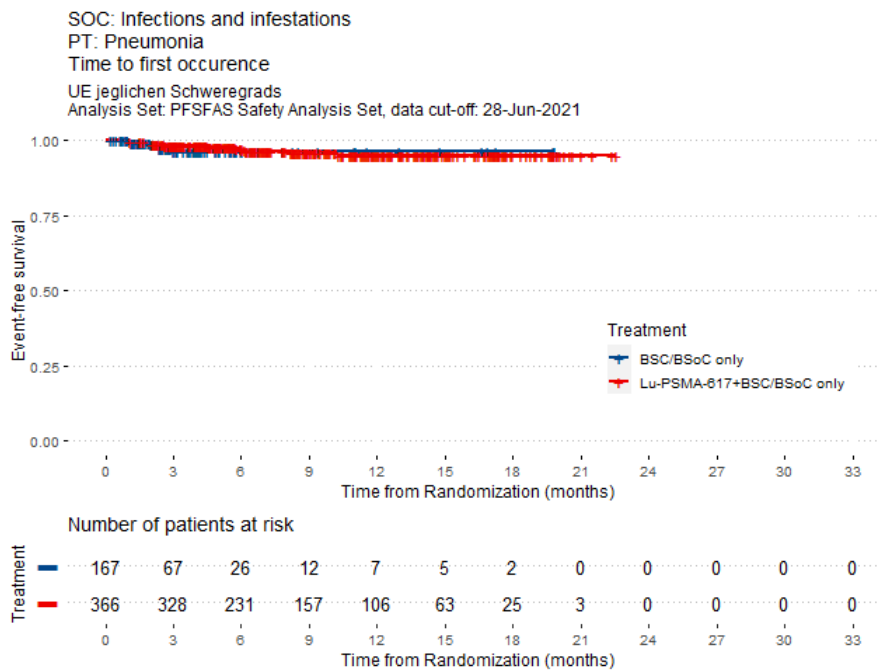


Abbildung 251: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Pneumonia

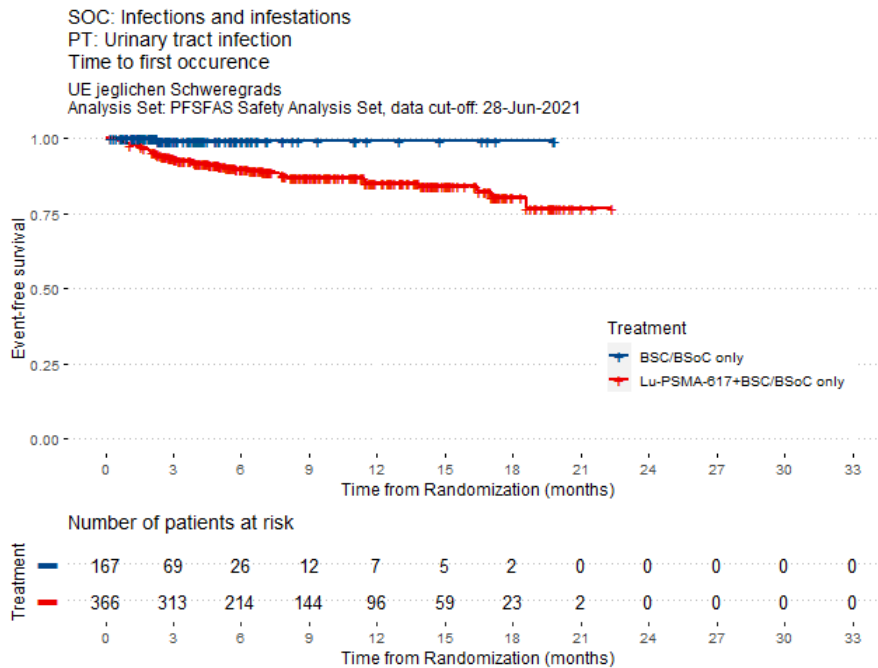


Abbildung 252: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Urinary tract infection

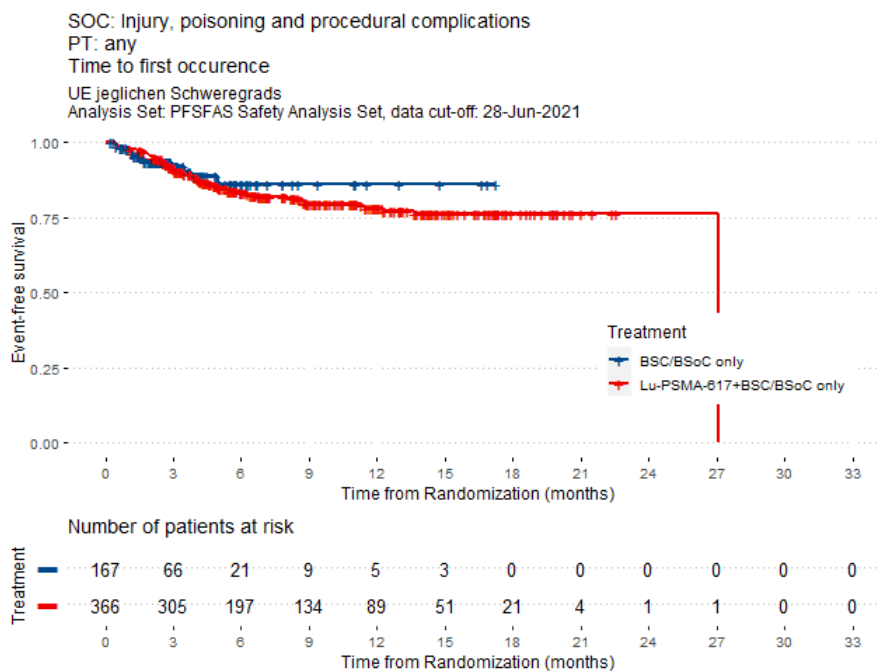


Abbildung 253: UE jeglichen Schweregrads: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: any

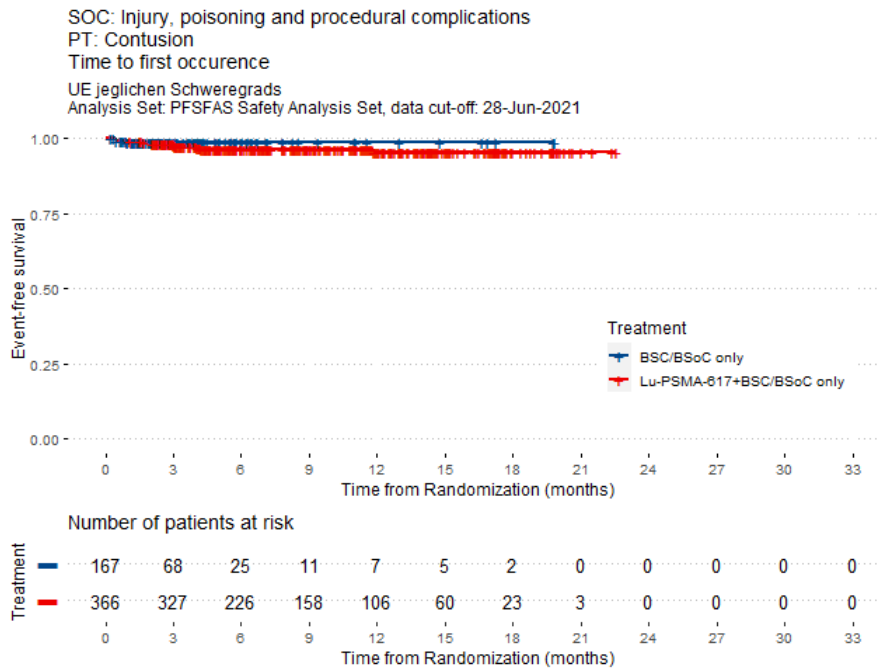


Abbildung 254: UE jeglichen Schweregrads: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: Contusion

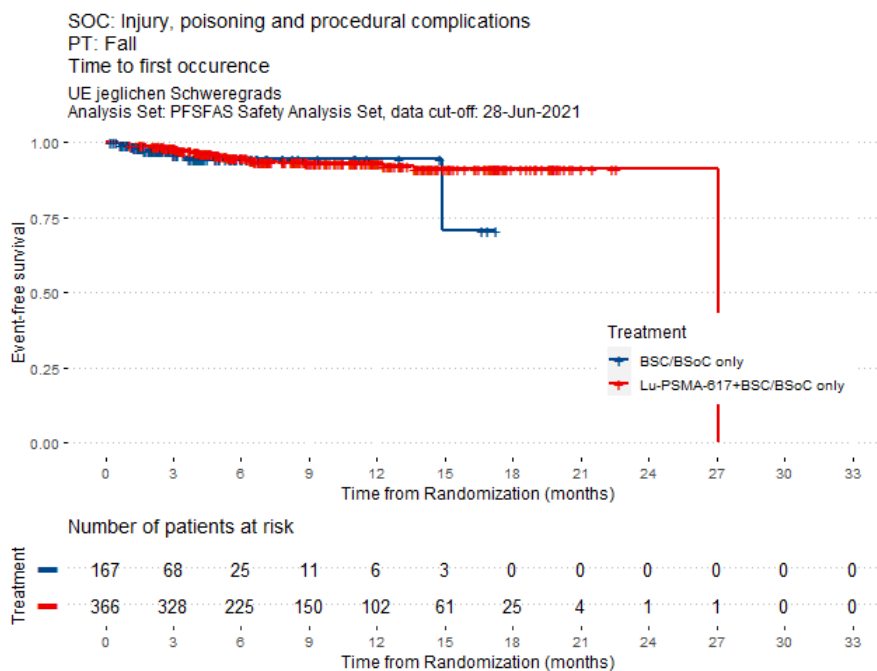


Abbildung 255: UE jeglichen Schweregrads: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: Fall

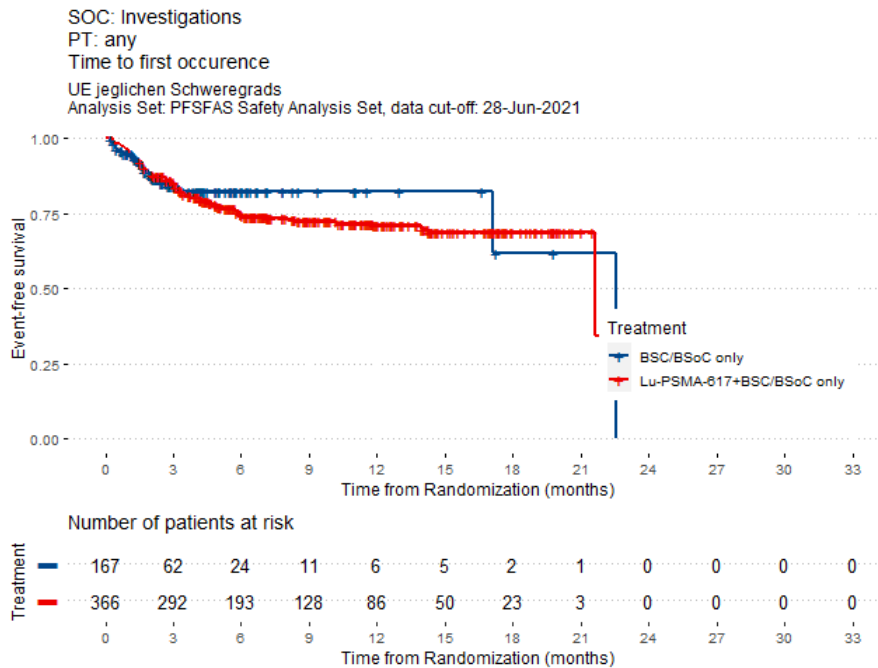


Abbildung 256: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: any

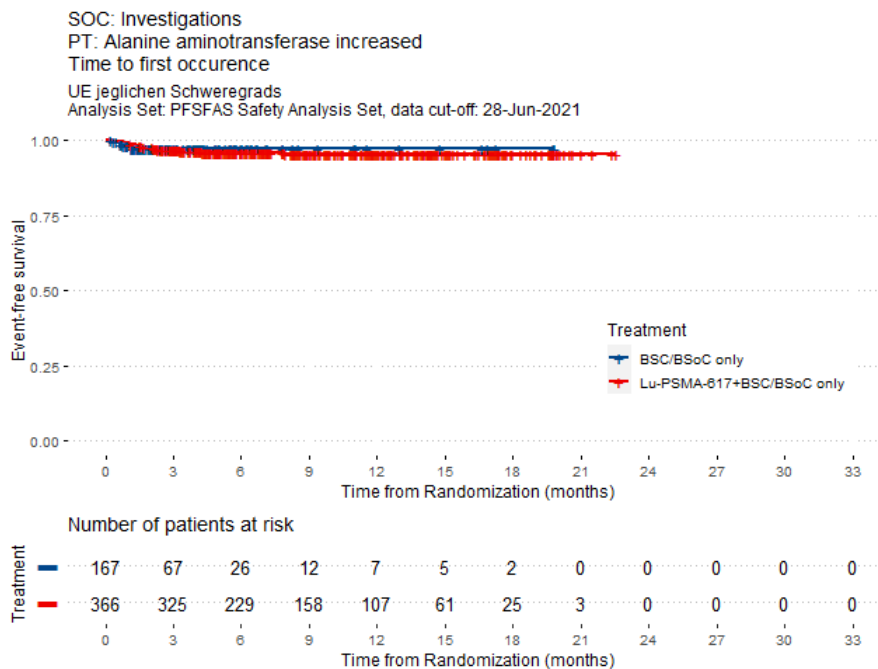


Abbildung 257: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: Alanine aminotransferase increased

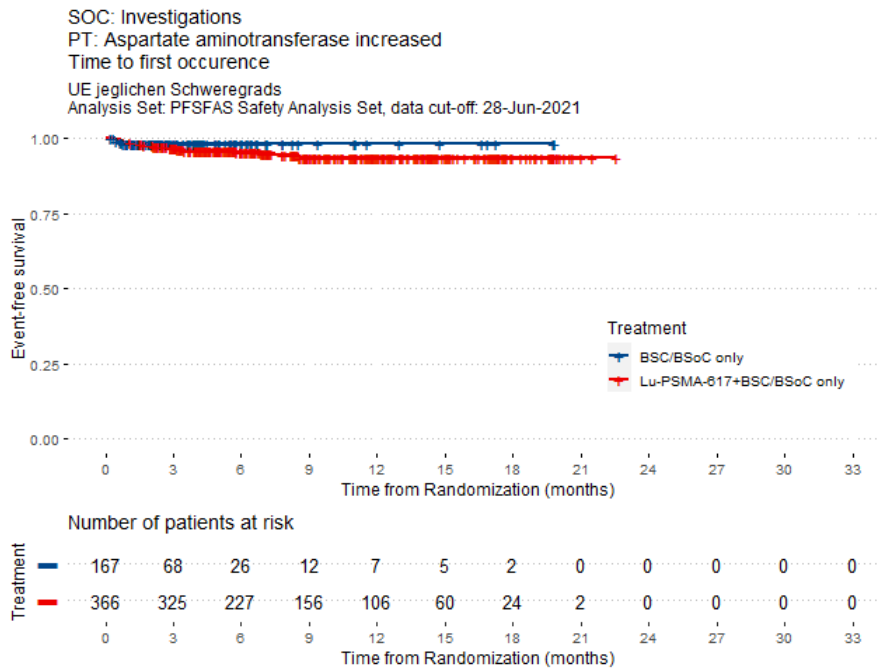


Abbildung 258: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: Aspartate aminotransferase increased

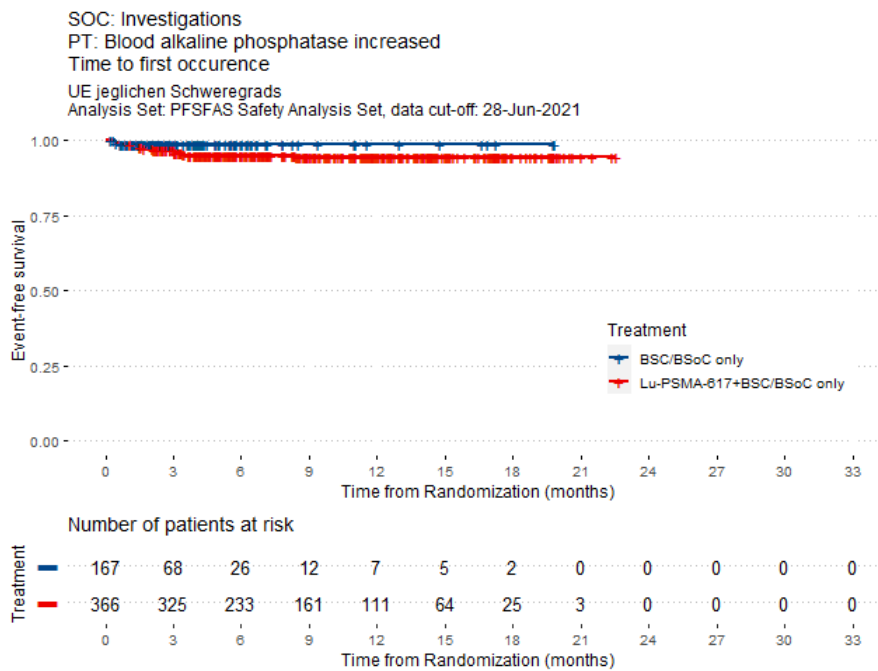


Abbildung 259: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: Blood alkaline phosphatase increased

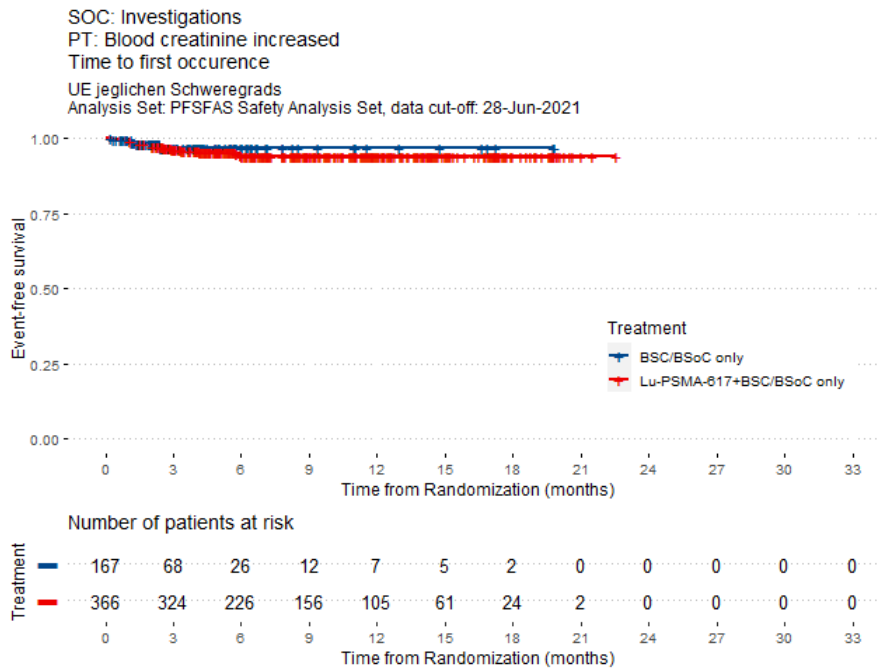


Abbildung 260: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: Blood creatinine increased

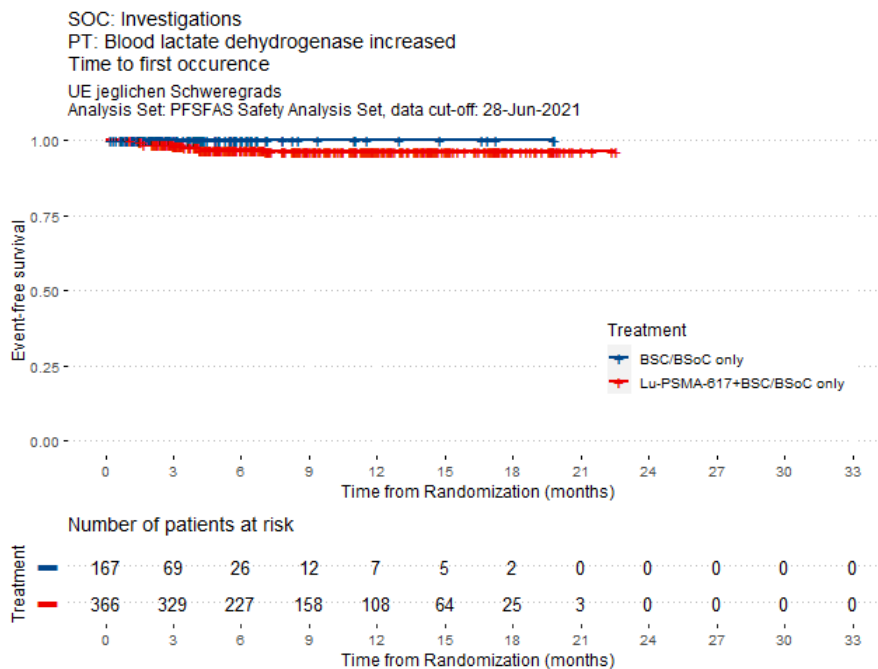


Abbildung 261: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: Blood lactate dehydrogenase increased

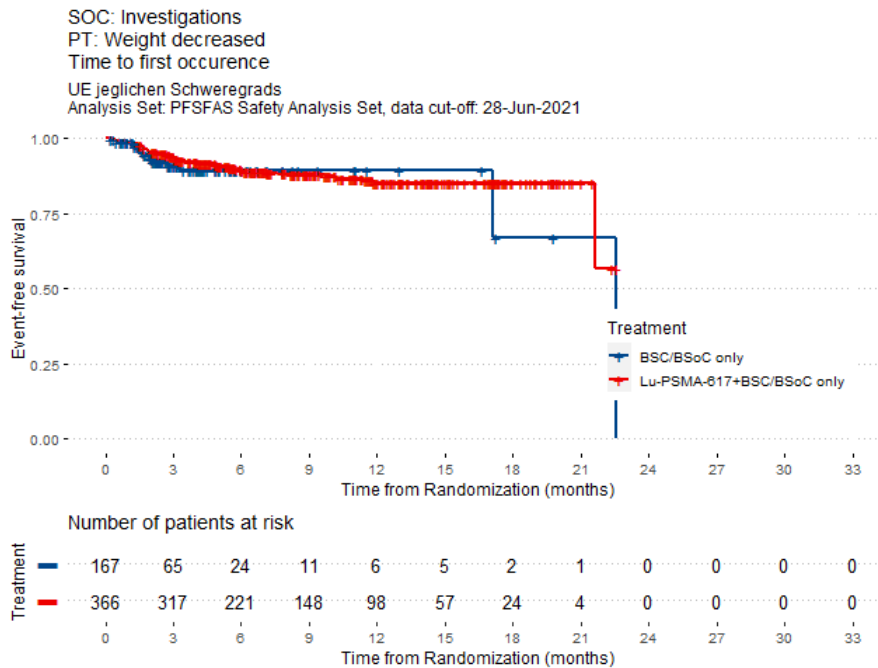


Abbildung 262: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: Weight decreased

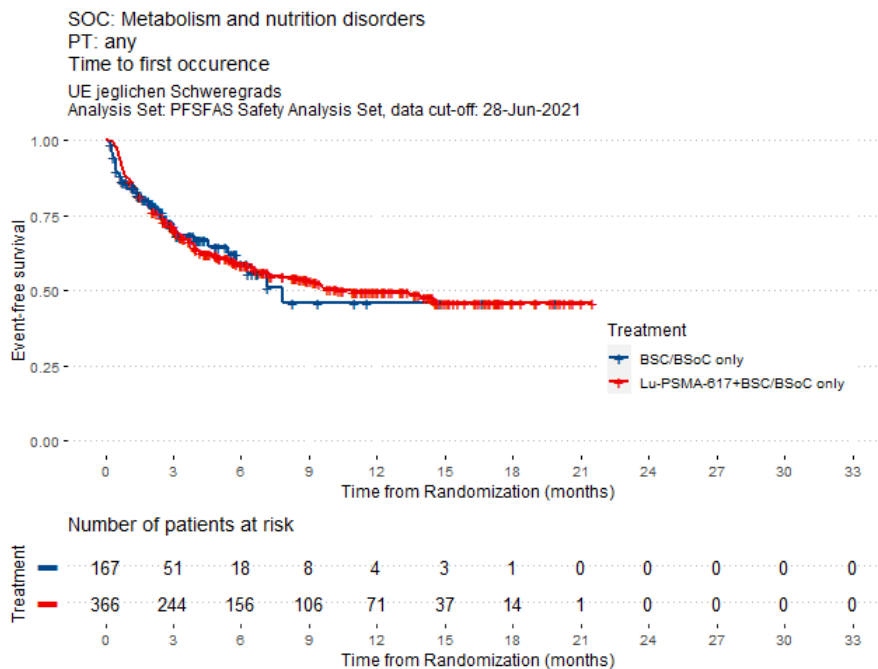


Abbildung 263: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: any

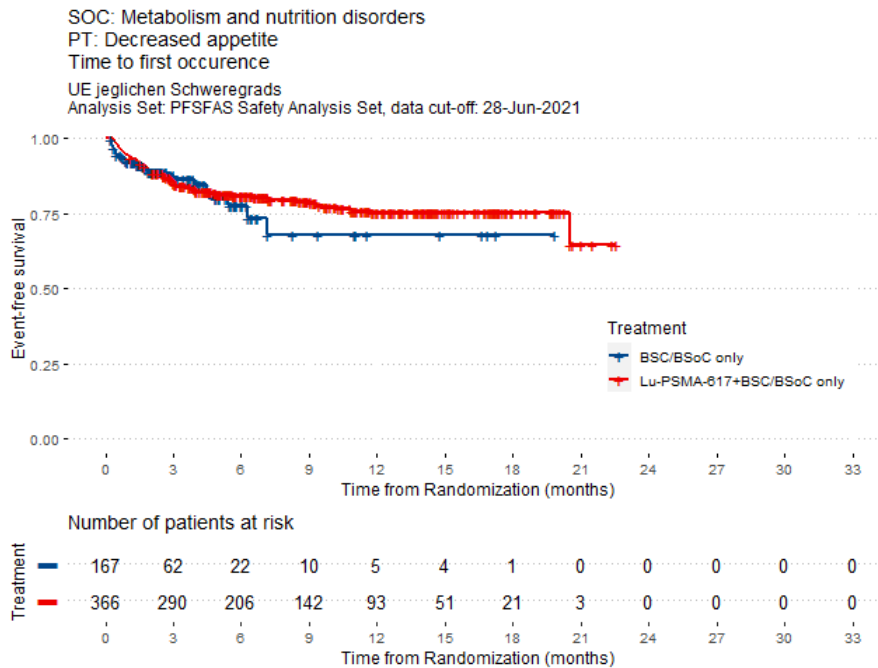


Abbildung 264: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Decreased appetite

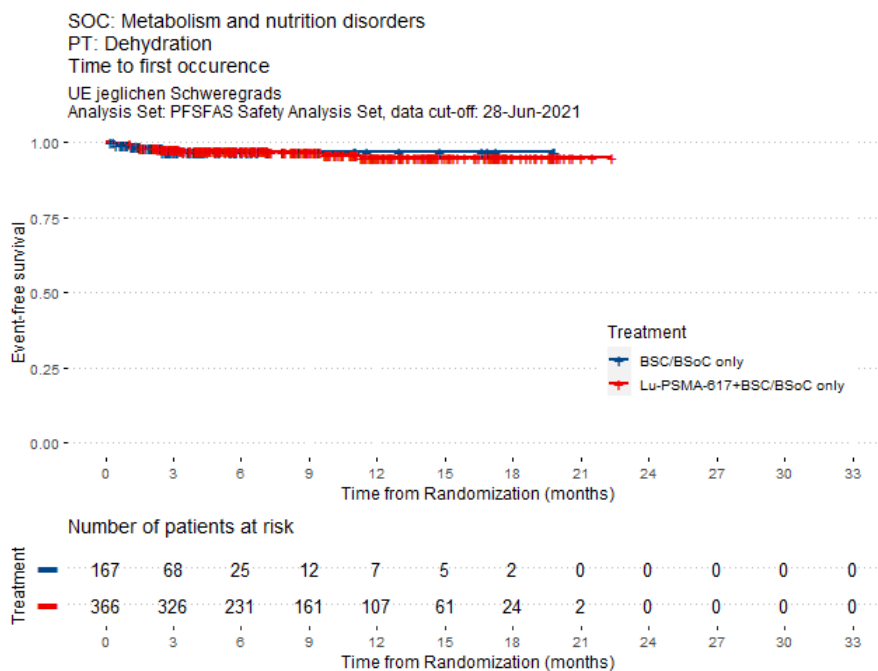


Abbildung 265: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Dehydration



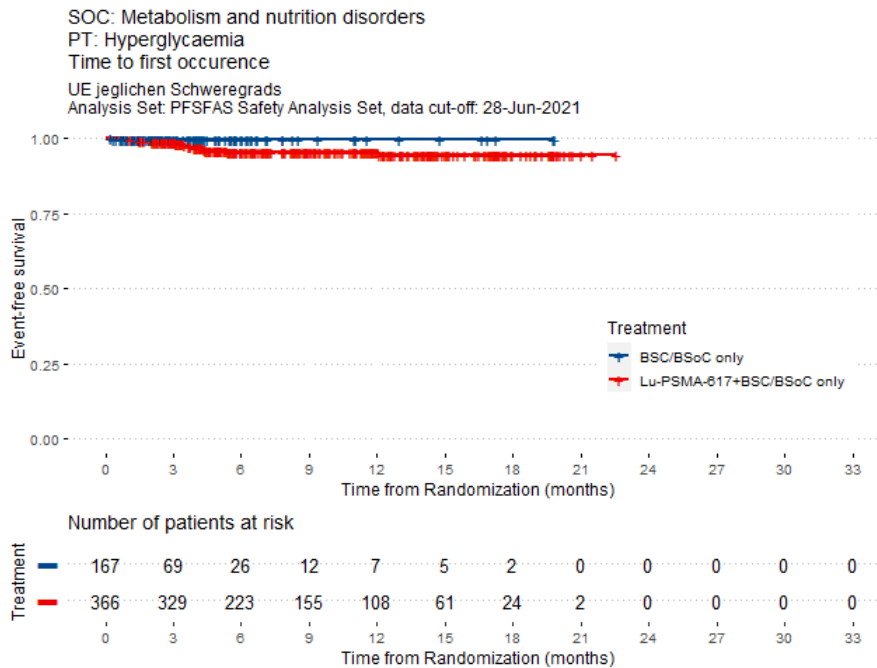


Abbildung 266: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hyperglycaemia

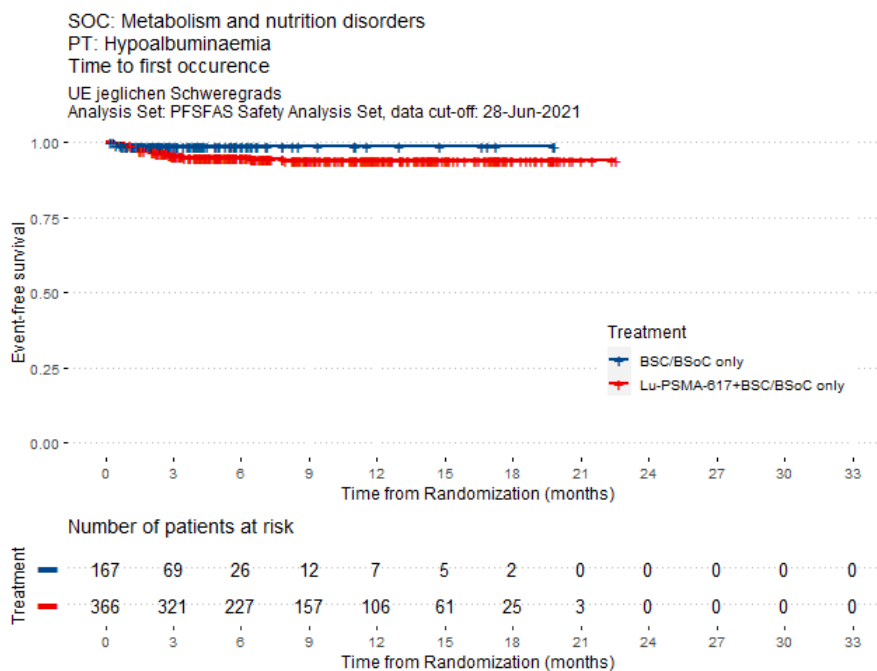


Abbildung 267: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypoalbuminaemia

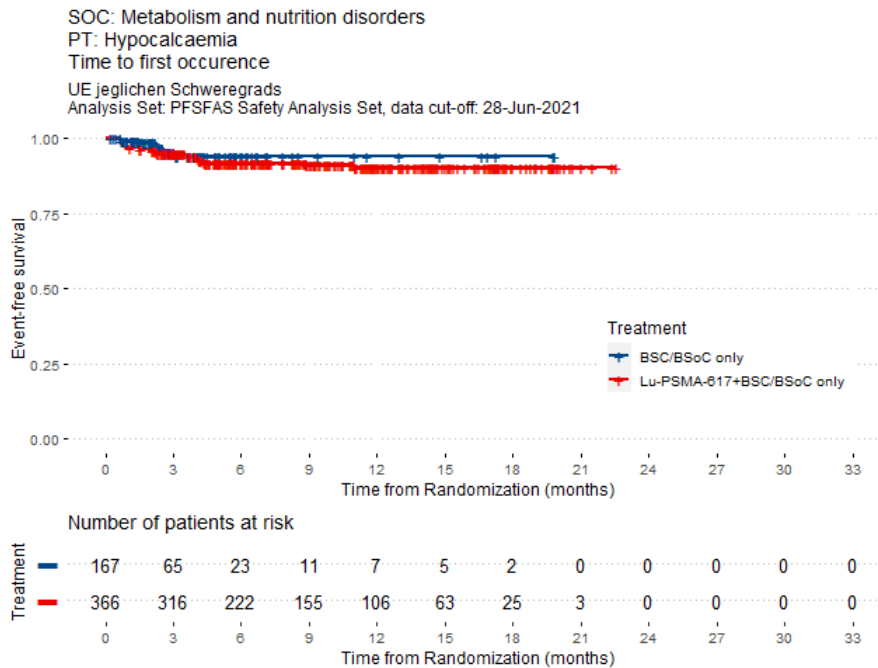


Abbildung 268: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypocalcaemia

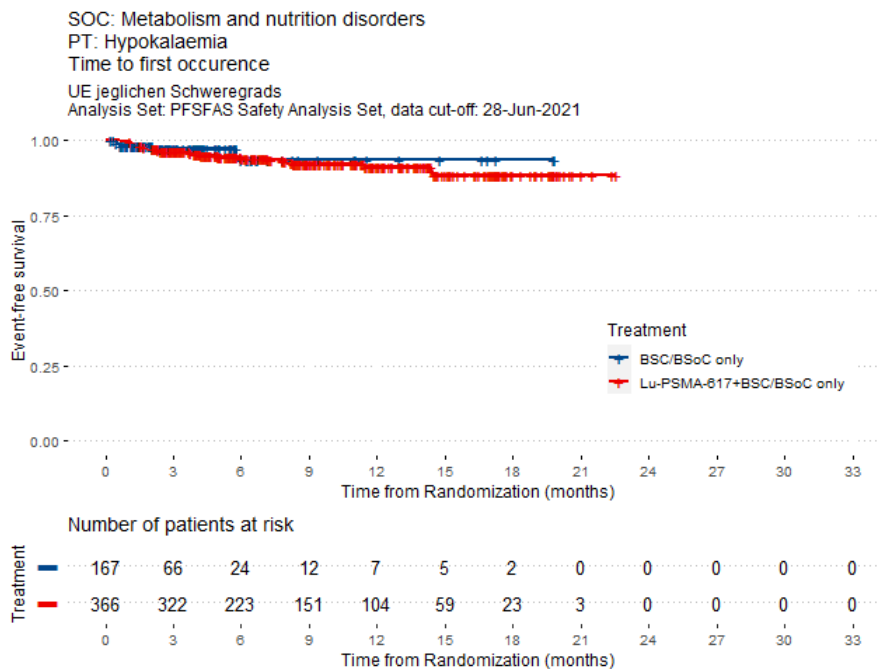


Abbildung 269: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

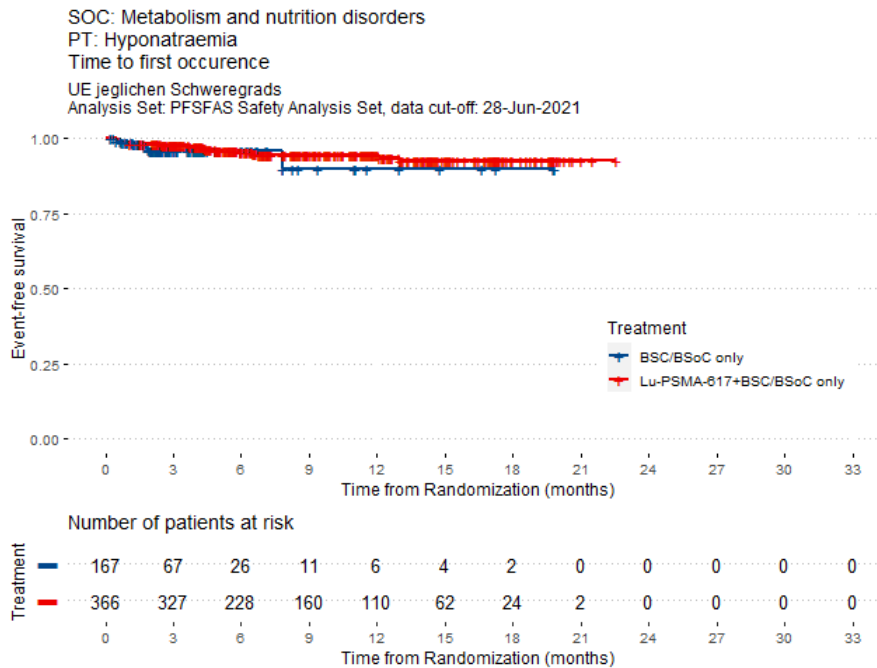


Abbildung 270: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hyponatraemia

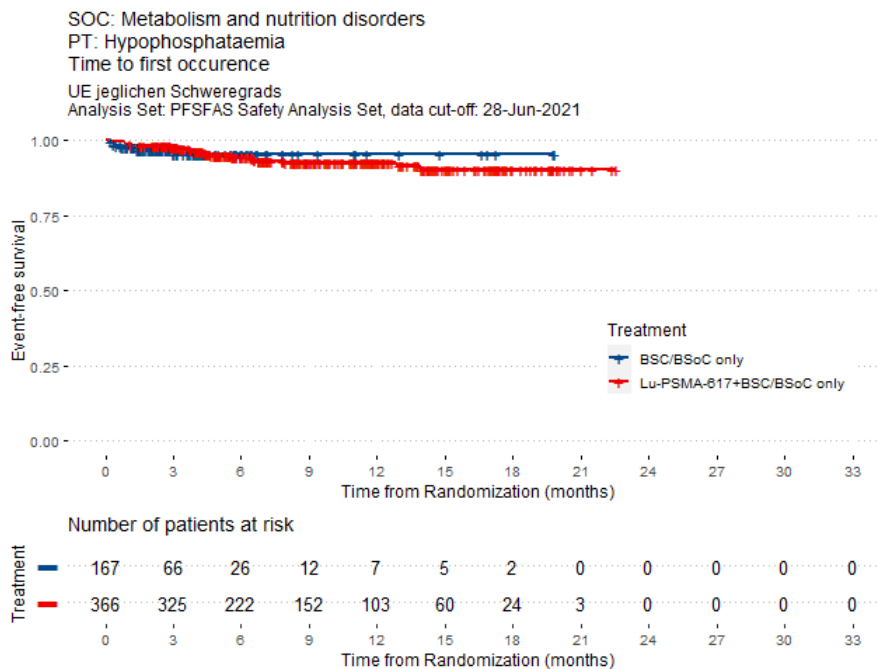


Abbildung 271: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypophosphataemia

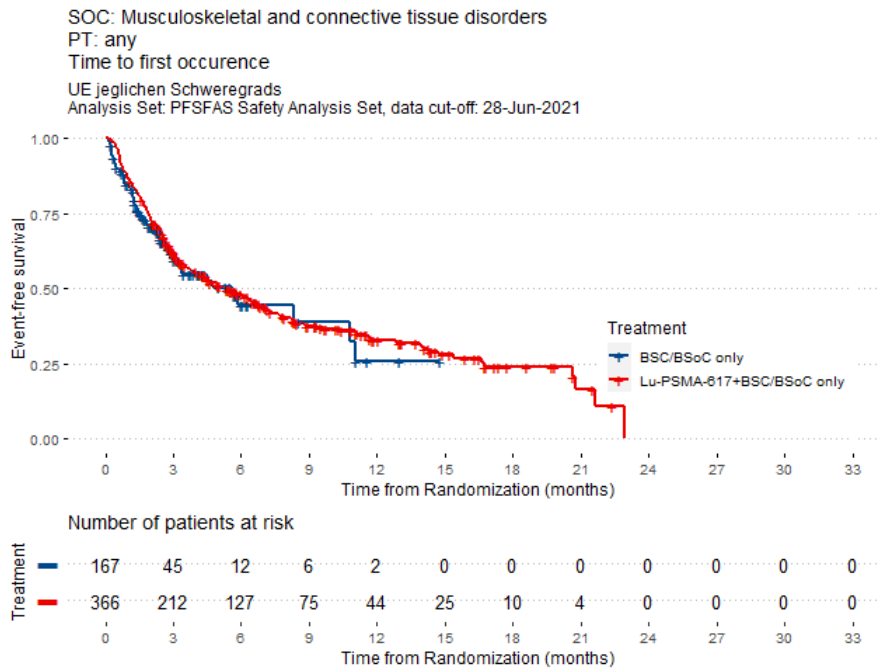


Abbildung 272: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: any

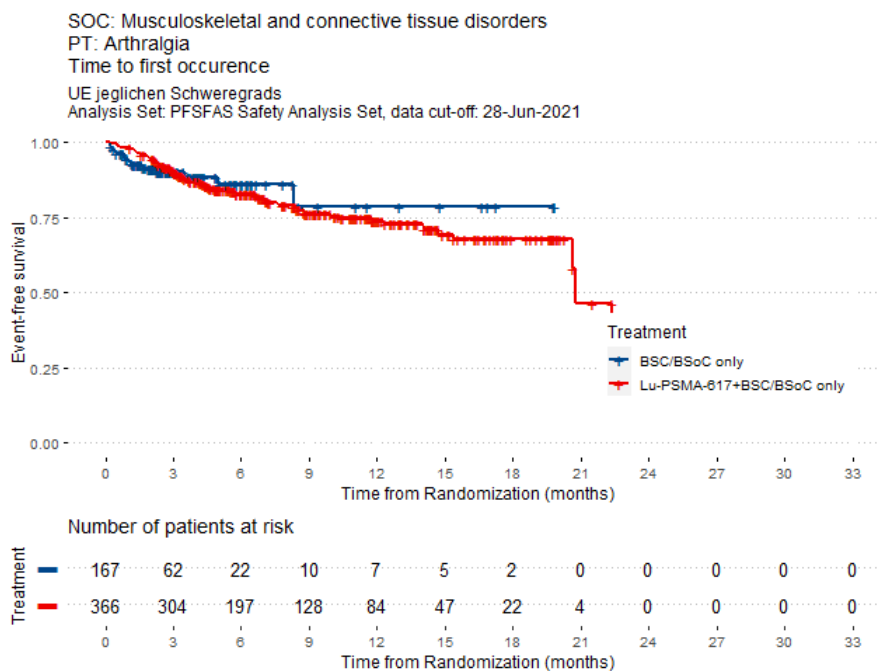


Abbildung 273: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Arthralgia

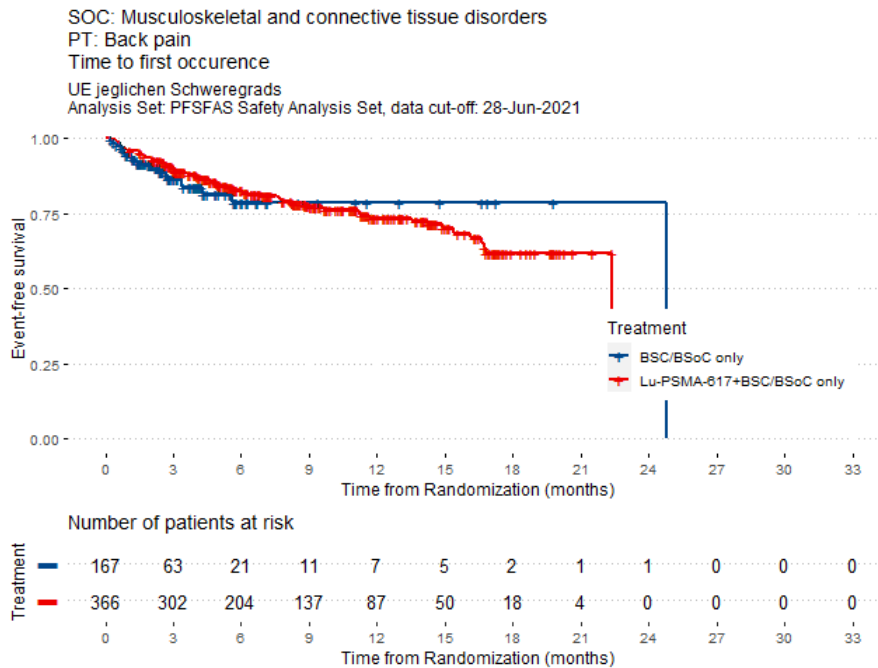


Abbildung 274: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Back pain

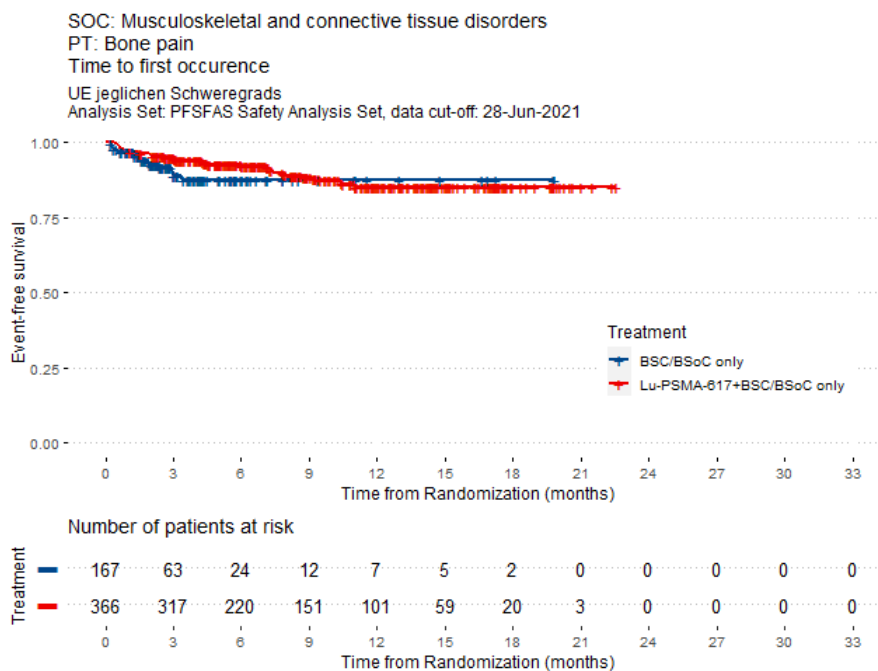


Abbildung 275: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Bone pain

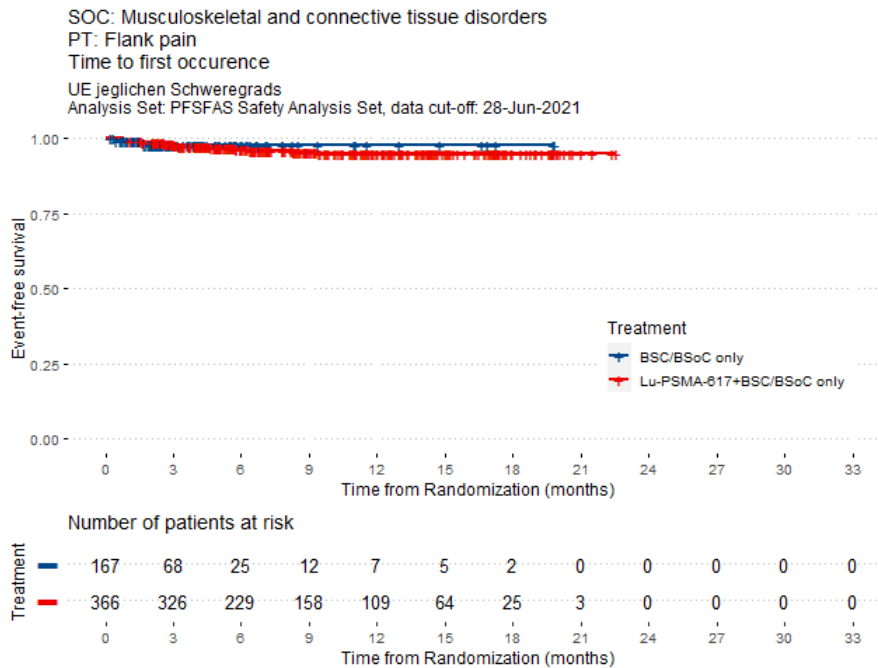


Abbildung 276: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Flank pain

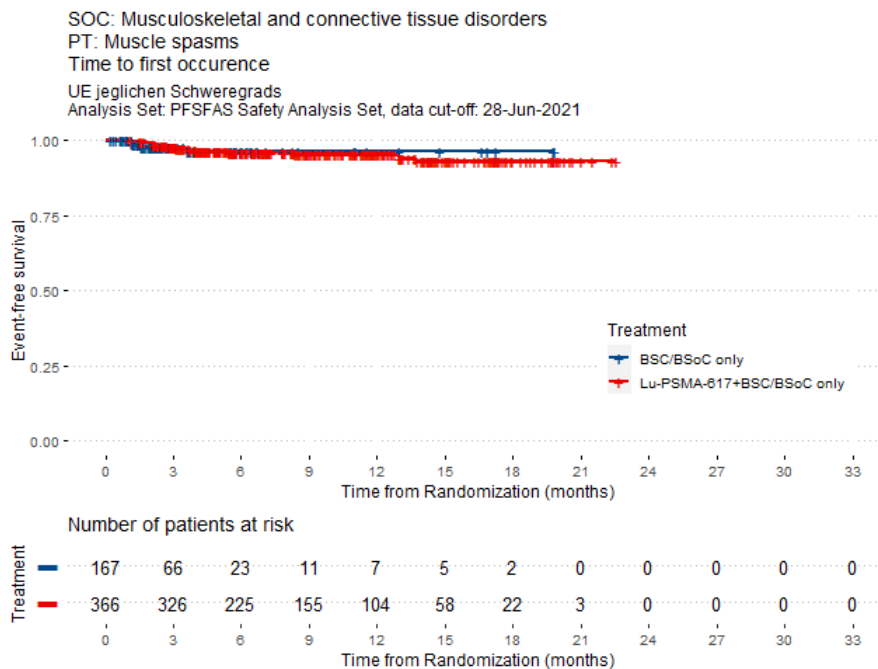


Abbildung 277: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Muscle spasms

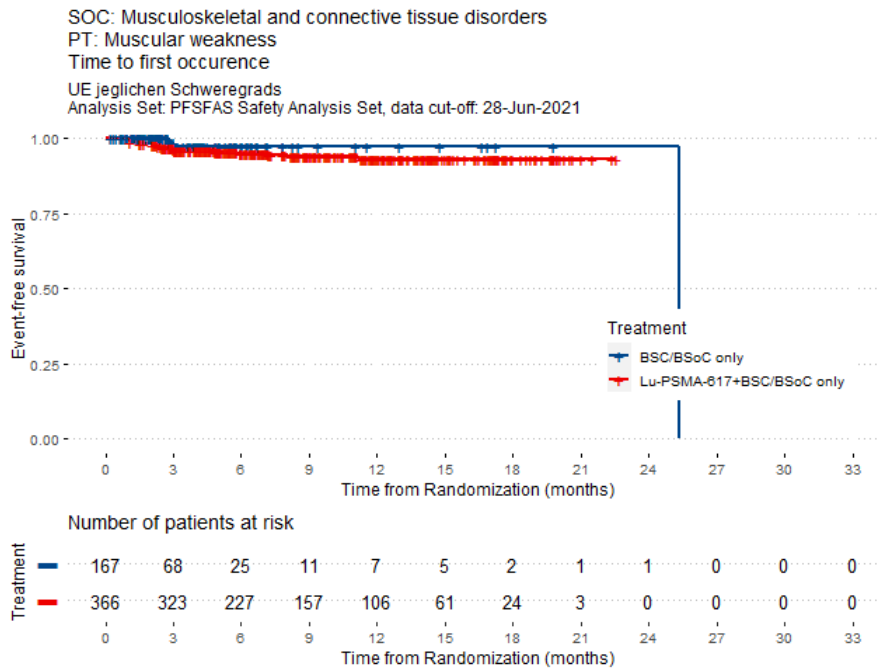


Abbildung 278: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Muscular weakness

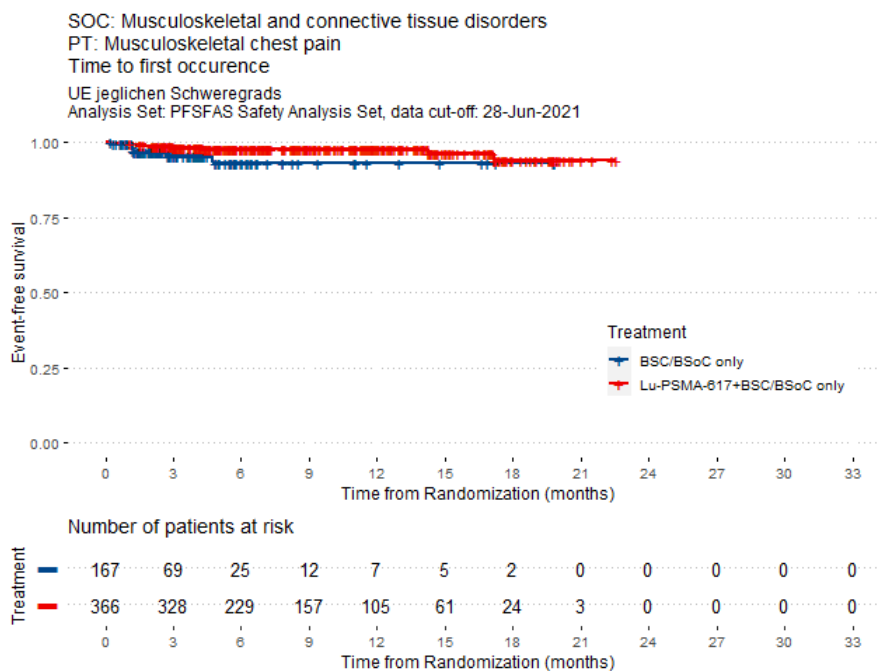


Abbildung 279: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Musculoskeletal chest pain

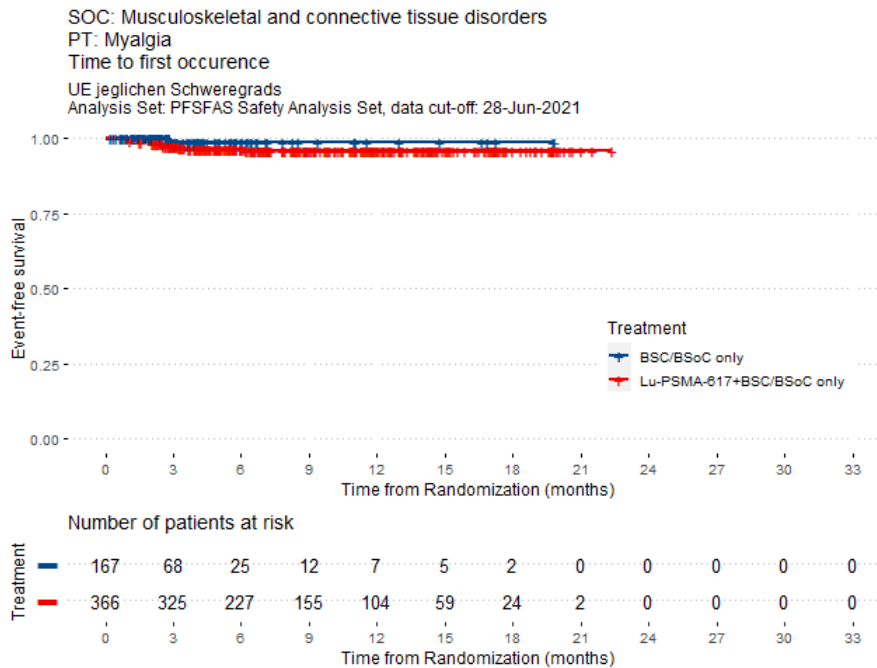


Abbildung 280: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Myalgia

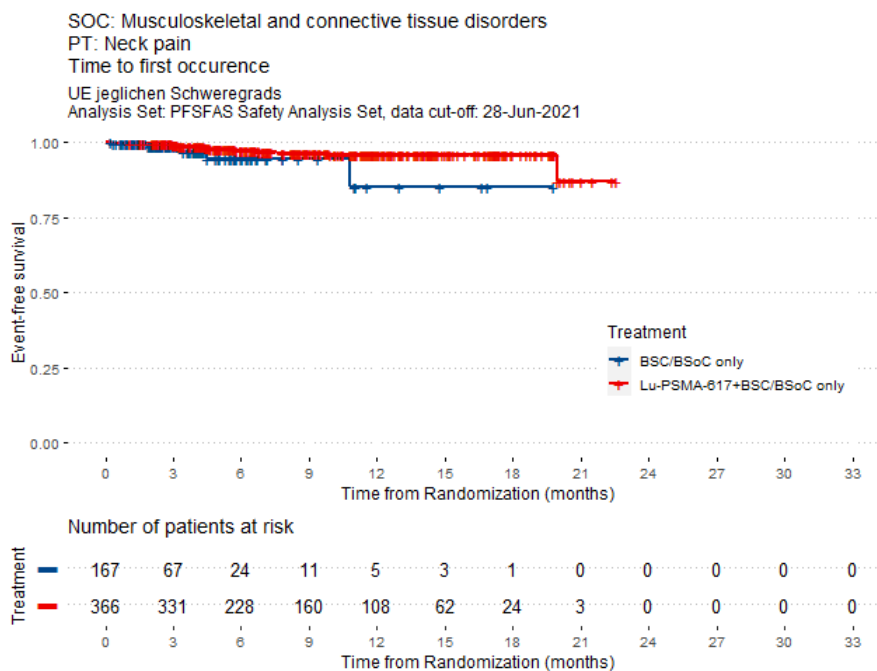


Abbildung 281: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Neck pain



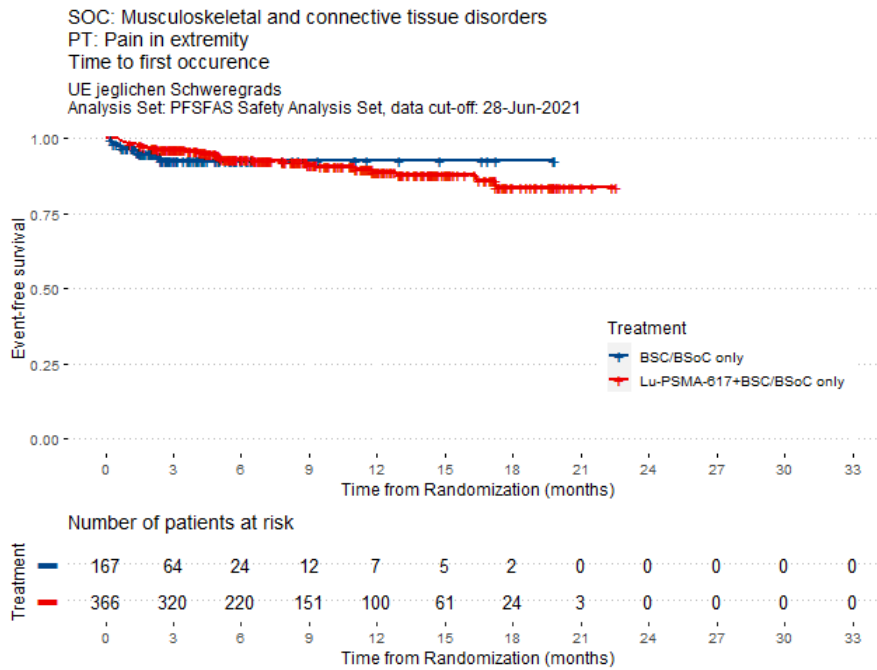


Abbildung 282: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Pain in extremity

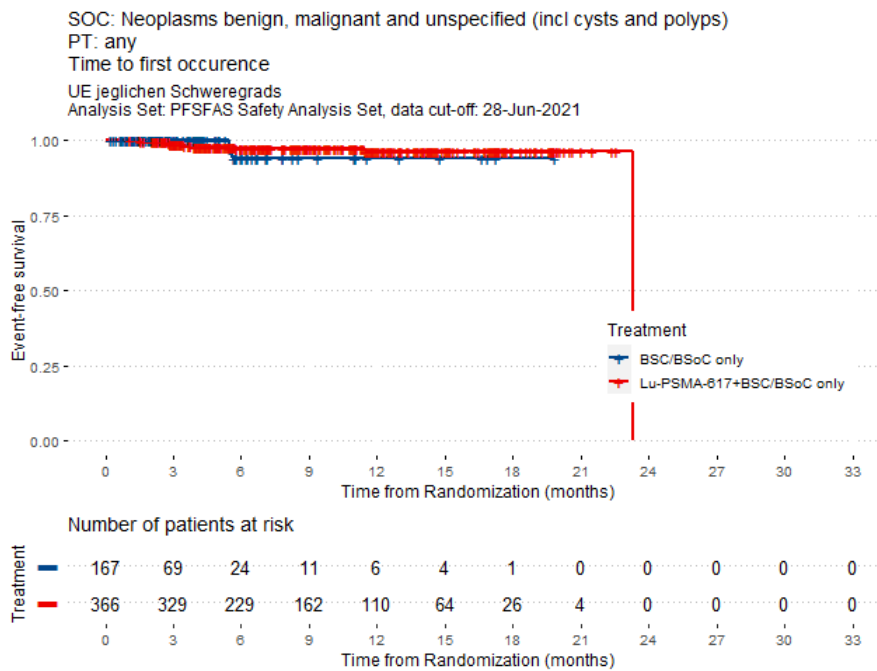


Abbildung 283: UE jeglichen Schweregrads: Time to first occurrence of SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: any

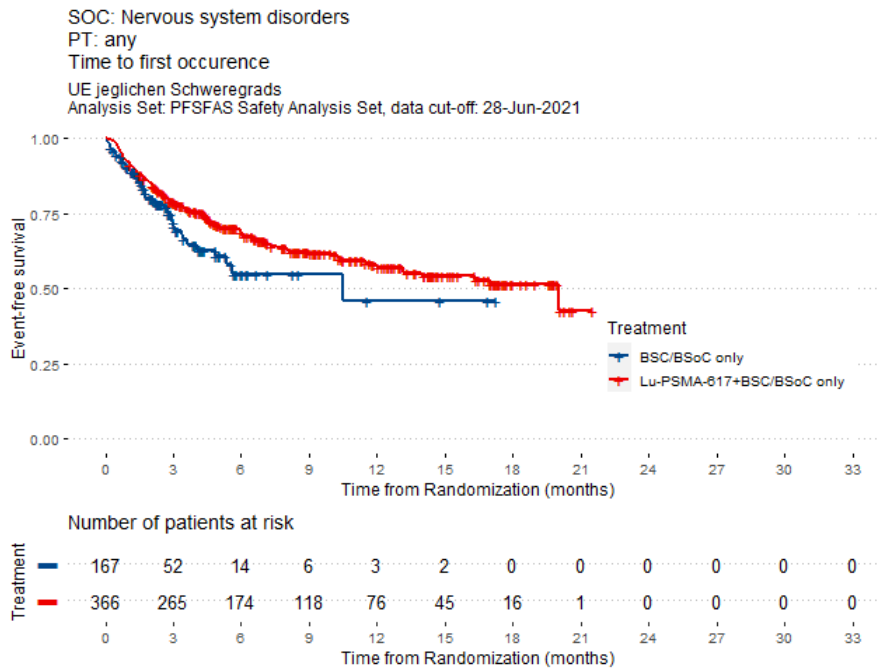


Abbildung 284: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: any

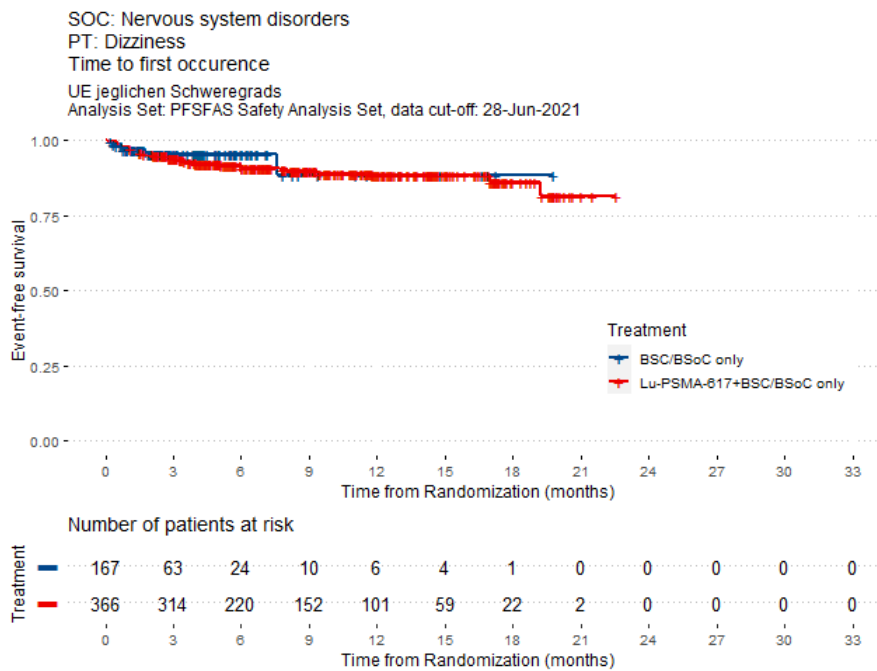


Abbildung 285: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Dizziness

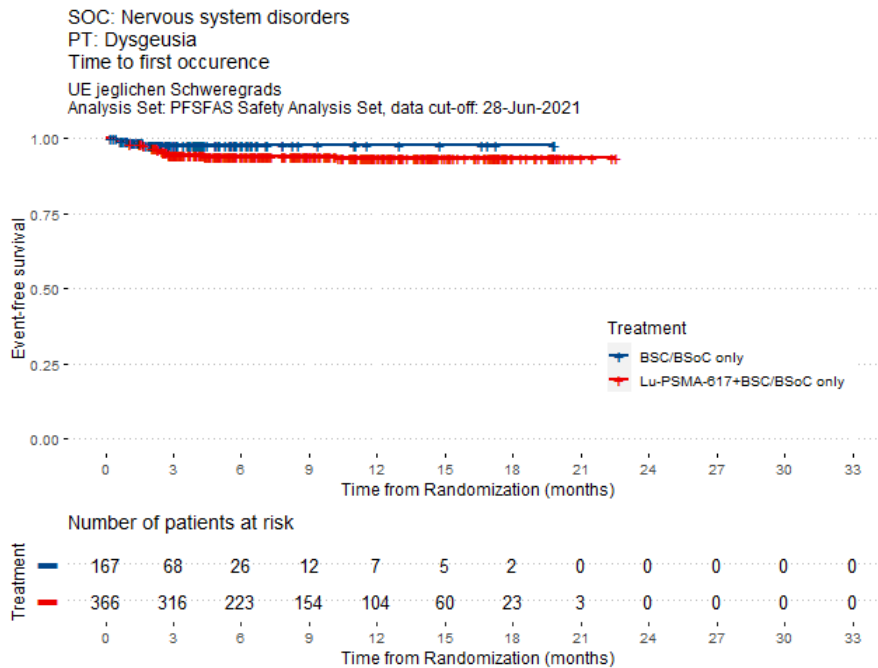


Abbildung 286: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Dysgeusia

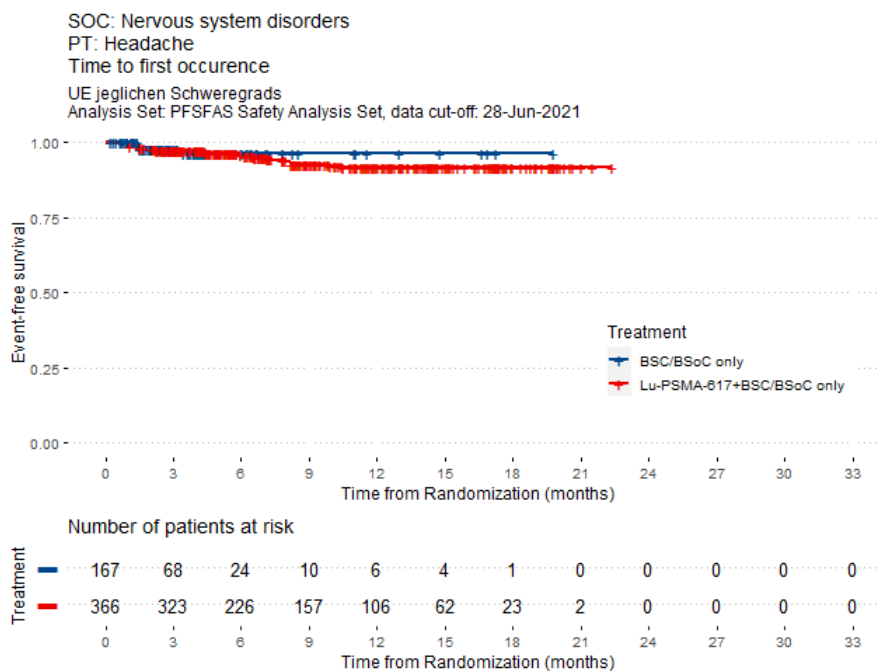


Abbildung 287: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Headache

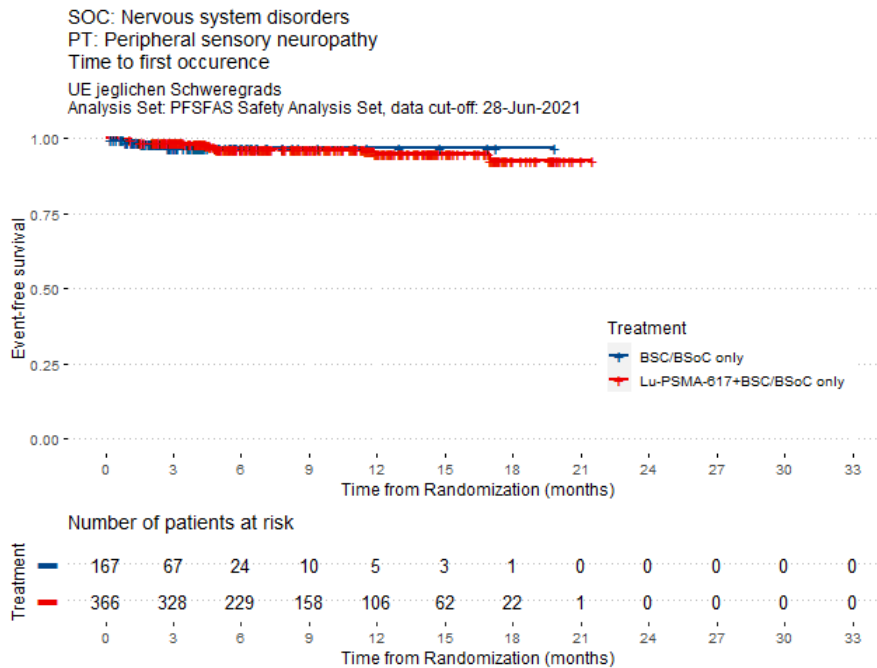


Abbildung 288: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Peripheral sensory neuropathy

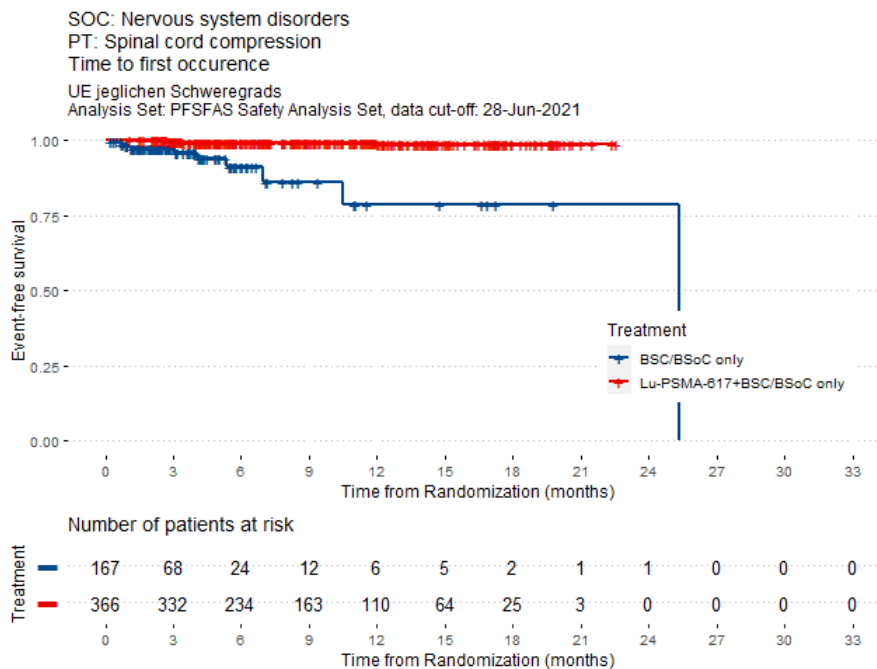


Abbildung 289: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Spinal cord compression

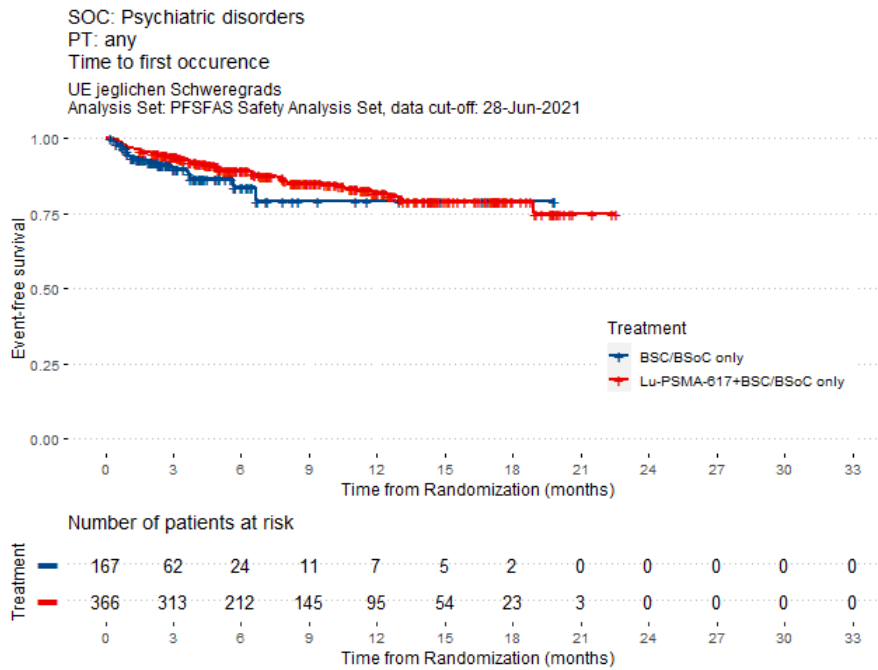


Abbildung 290: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: any

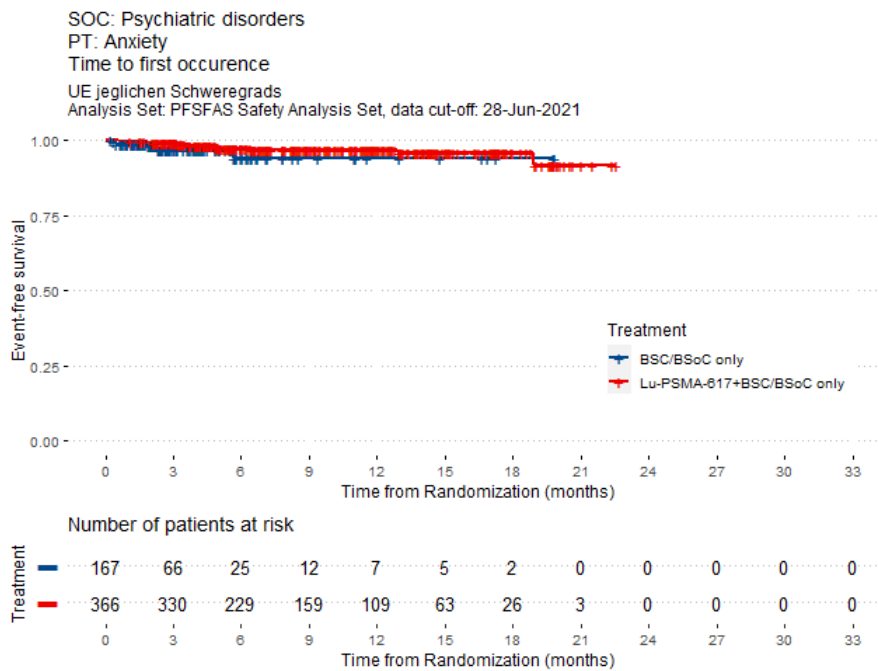


Abbildung 291: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Anxiety

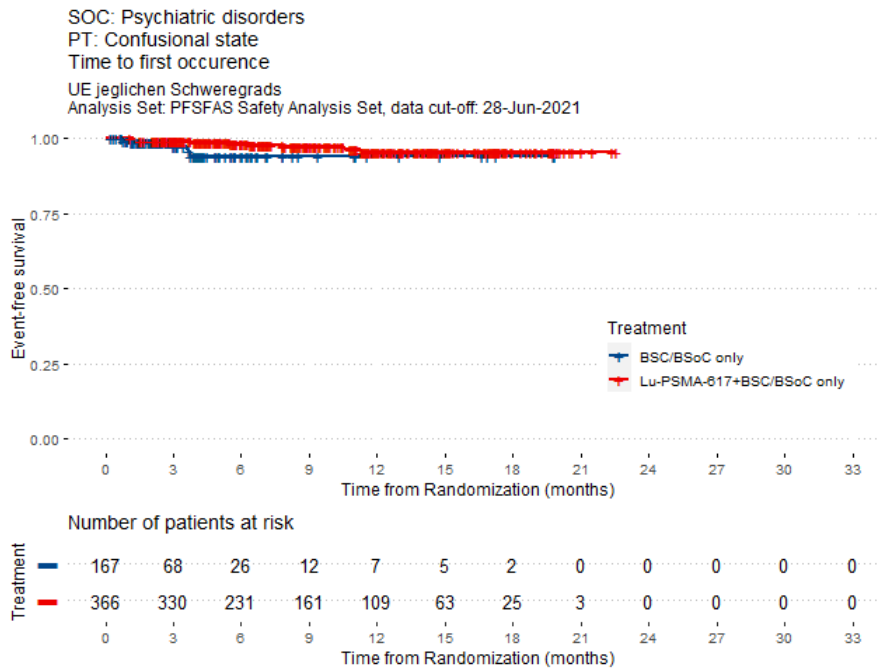


Abbildung 292: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Confusional state

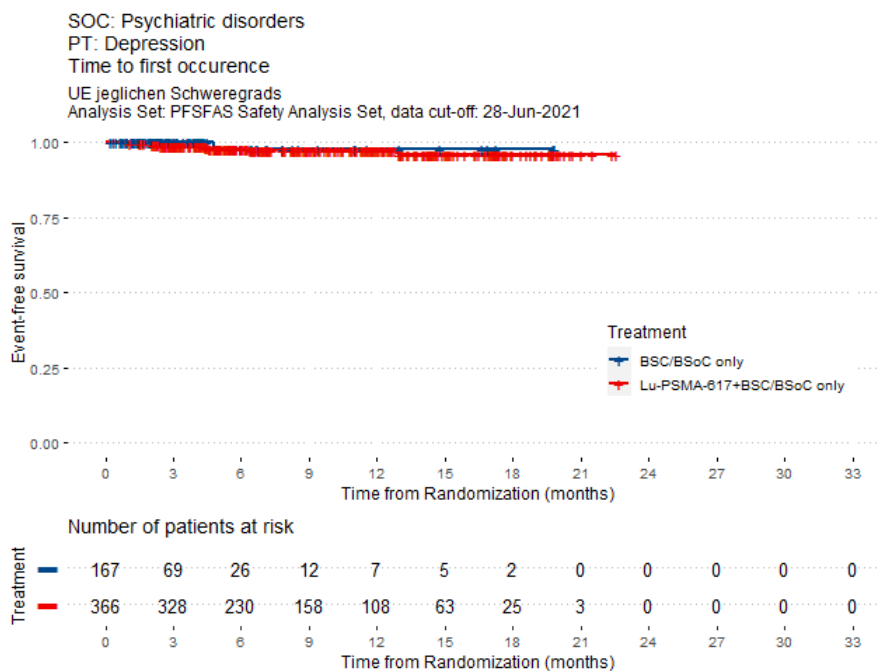


Abbildung 293: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Depression

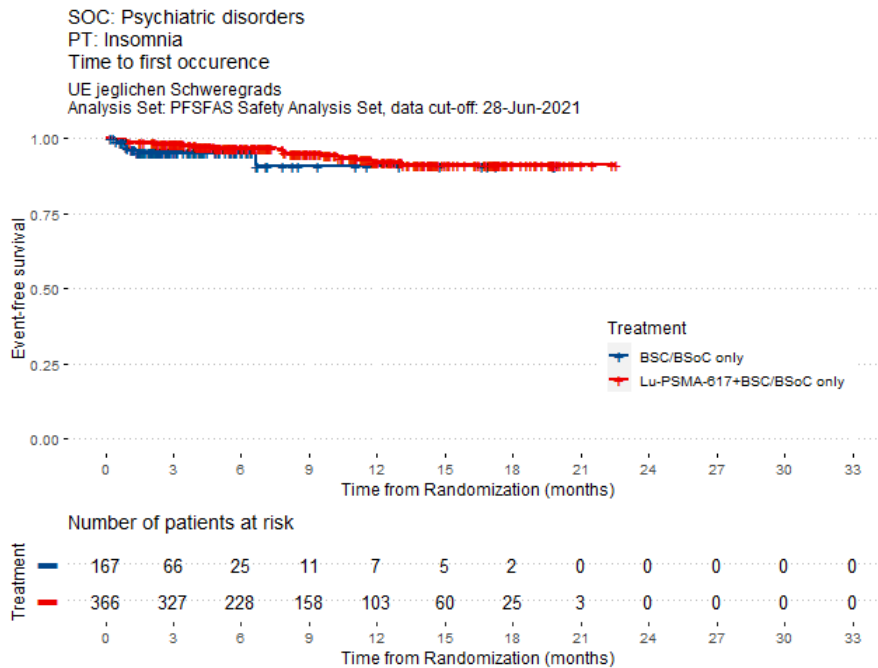


Abbildung 294: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Insomnia

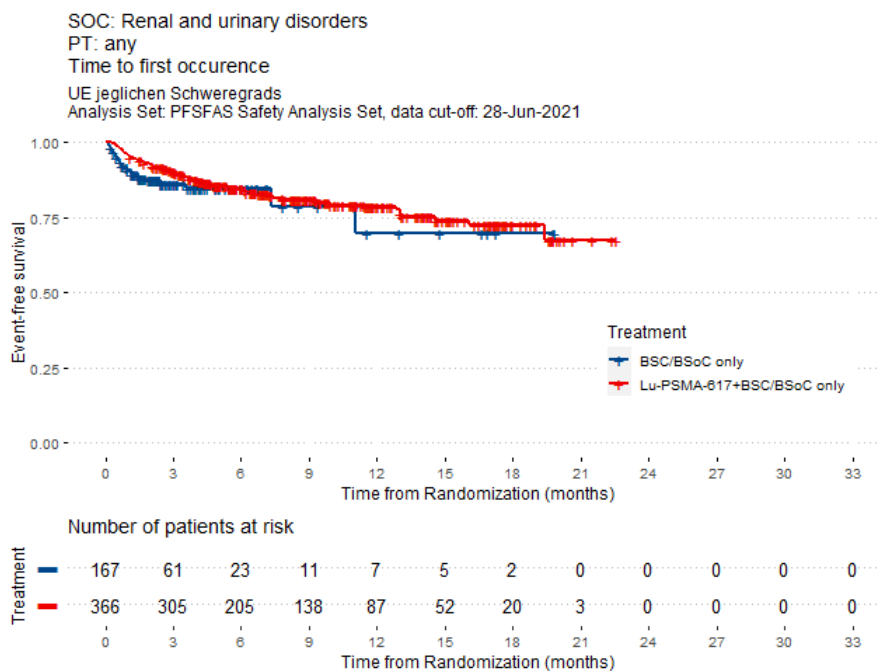


Abbildung 295: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: any

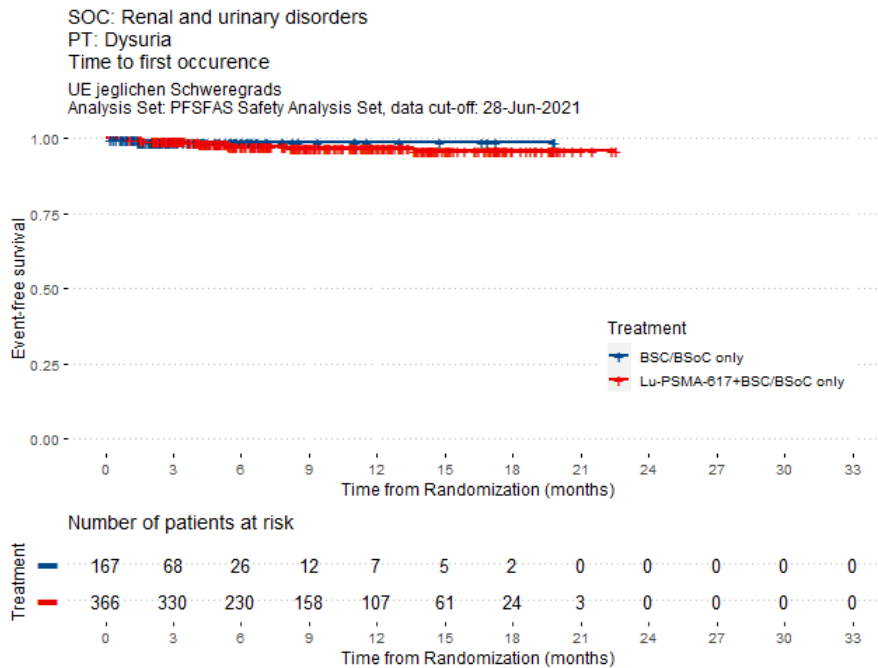


Abbildung 296: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Dysuria

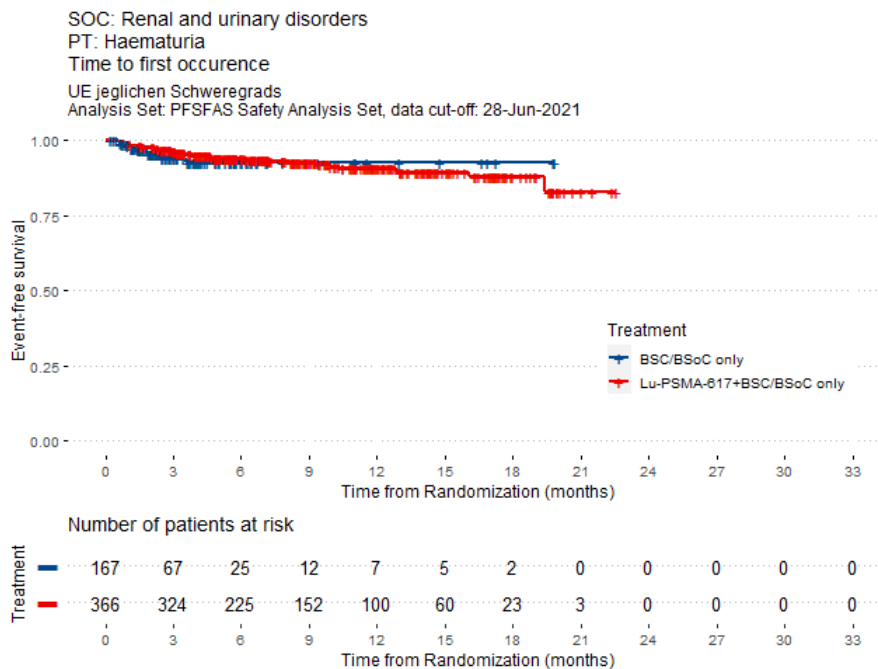


Abbildung 297: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Haematuria



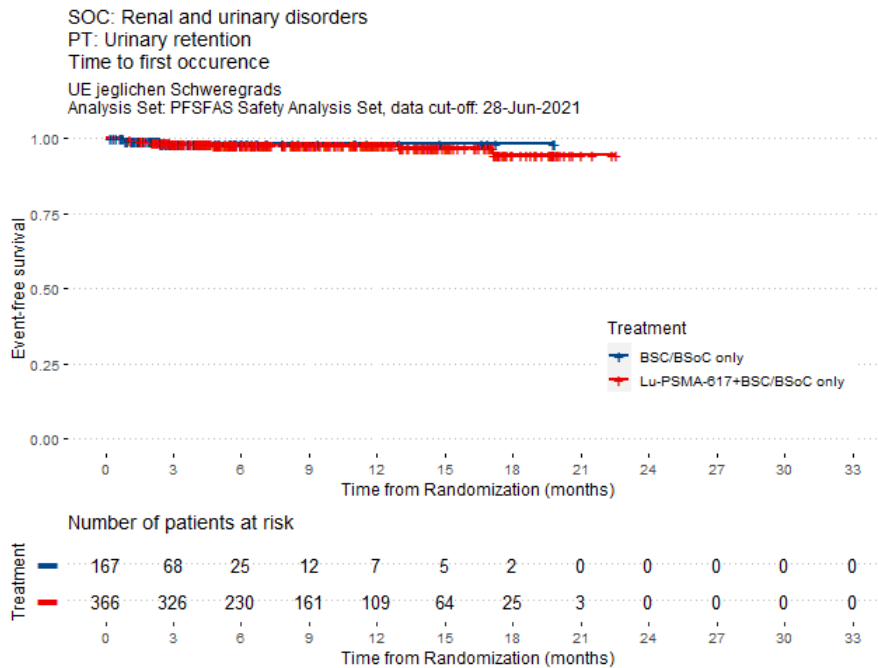


Abbildung 298: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Urinary retention

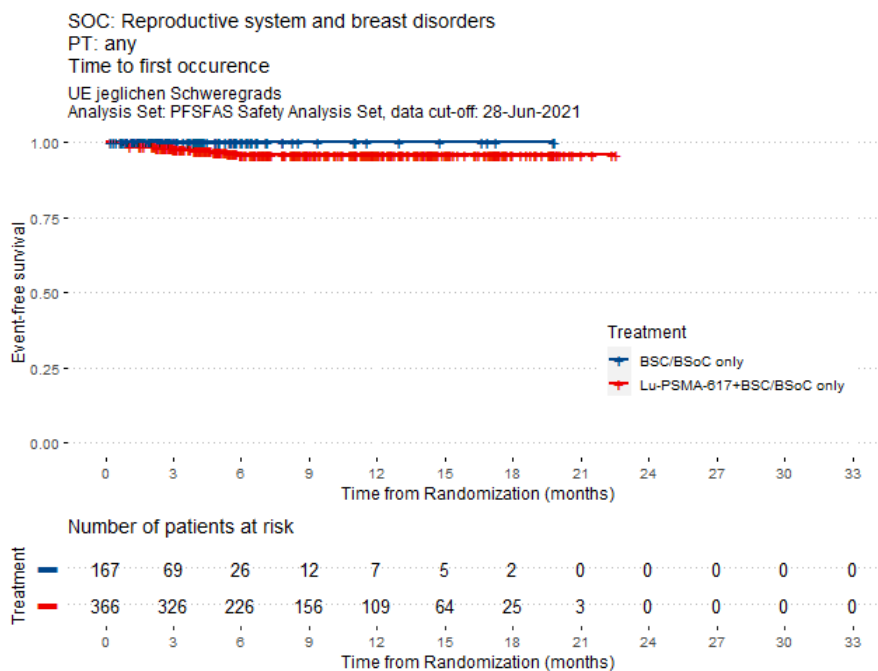


Abbildung 299: UE jeglichen Schweregrads: Time to first occurrence of SOC: Reproductive system and breast disorders; PT: any

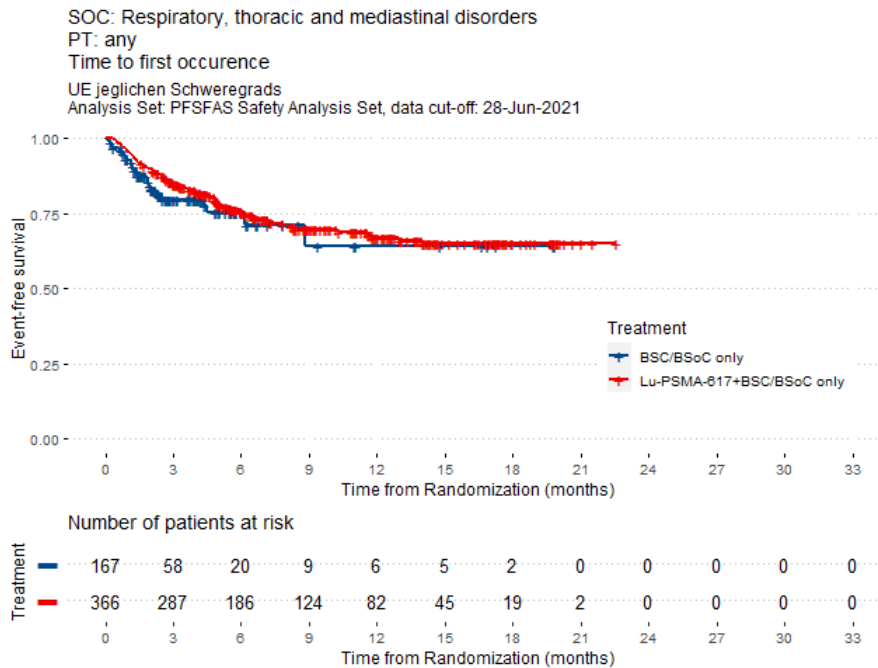


Abbildung 300: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: any

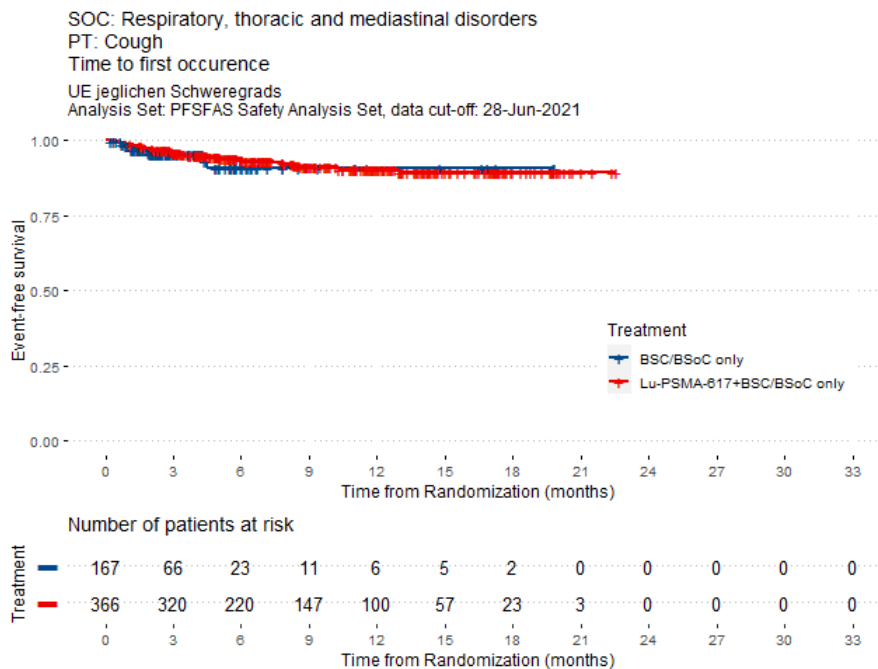


Abbildung 301: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: Cough

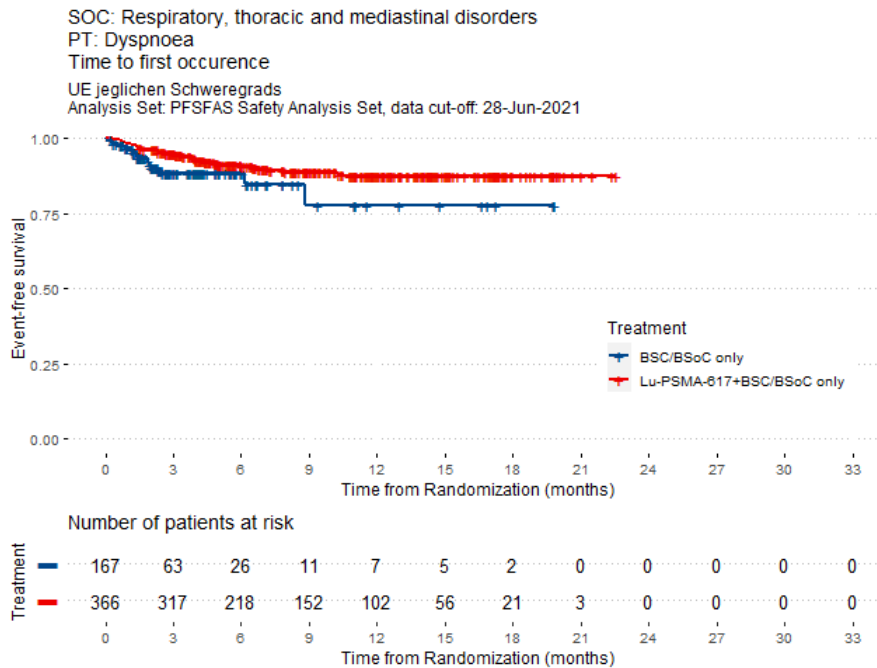


Abbildung 302: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea

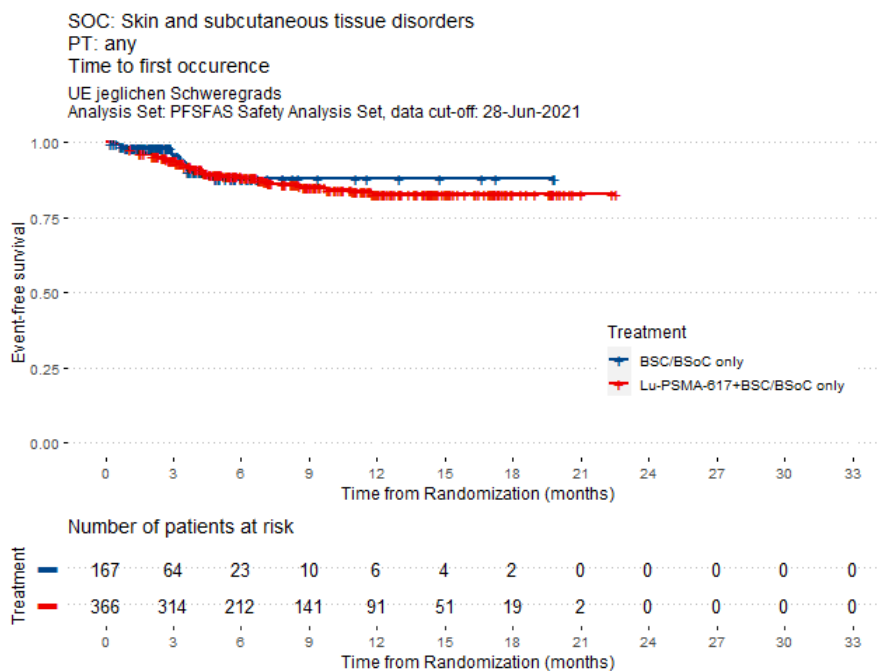


Abbildung 303: UE jeglichen Schweregrads: Time to first occurrence of SOC: Skin and subcutaneous tissue disorders; PT: any

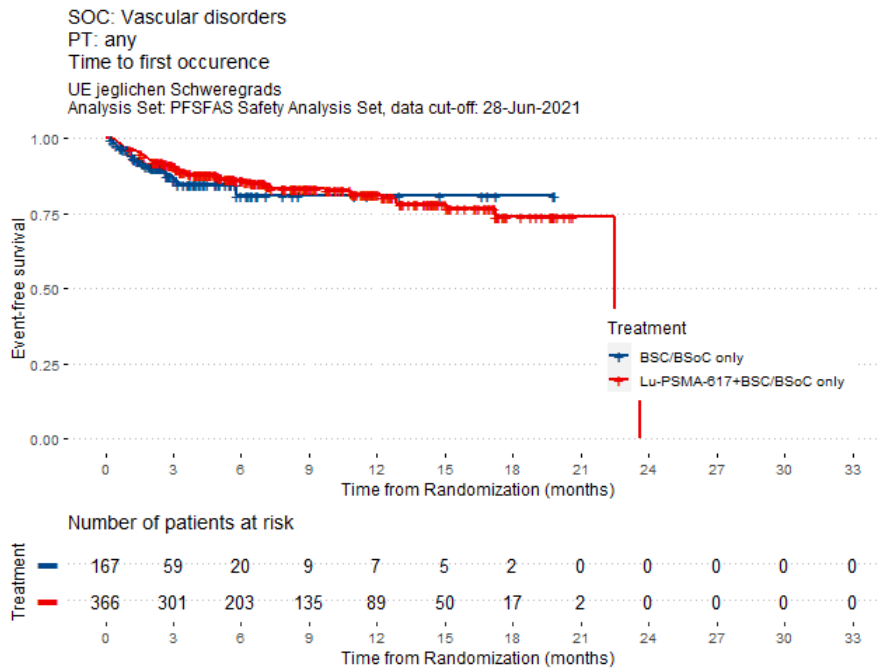


Abbildung 304: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: any

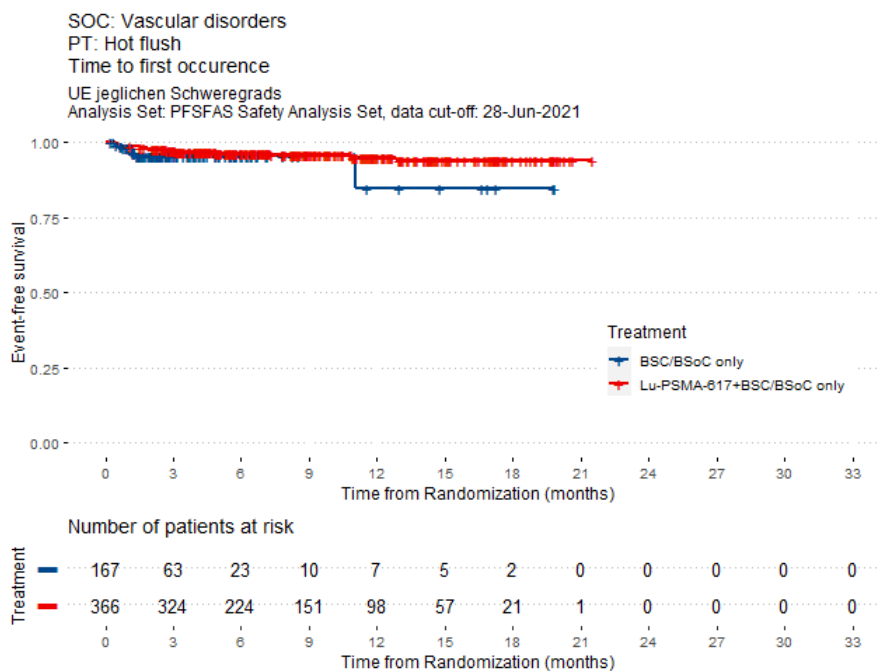


Abbildung 305: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: Hot flush

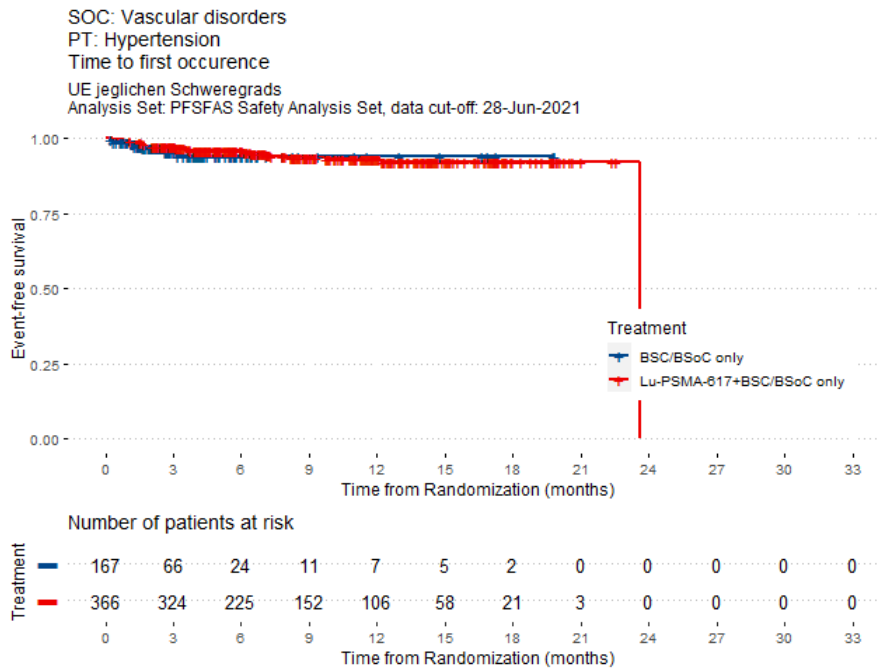


Abbildung 306: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: Hypertension

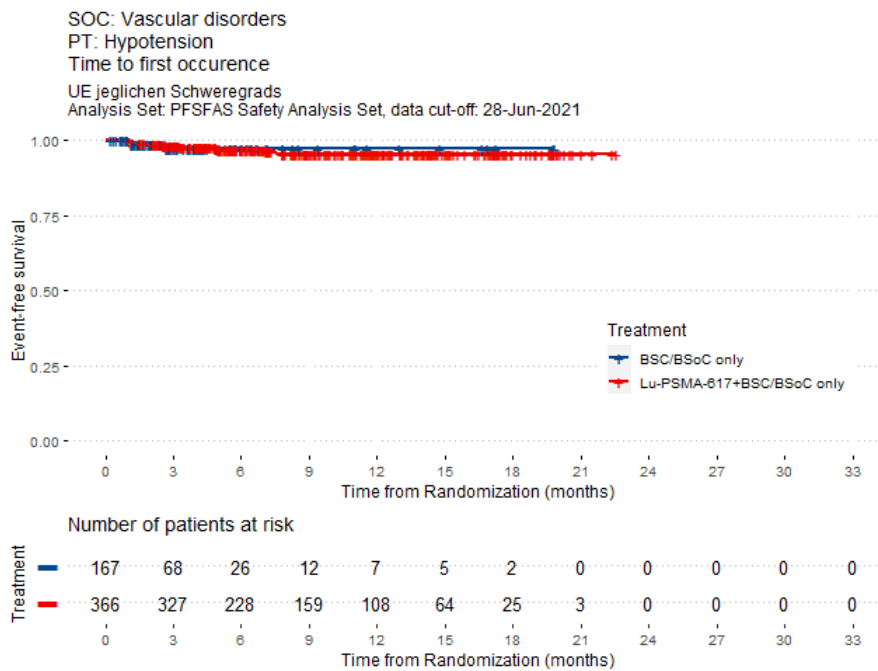


Abbildung 307: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: Hypotension

**Anhang 3.4.2: Schwere UE (CTCAE-Grad 3-5)**

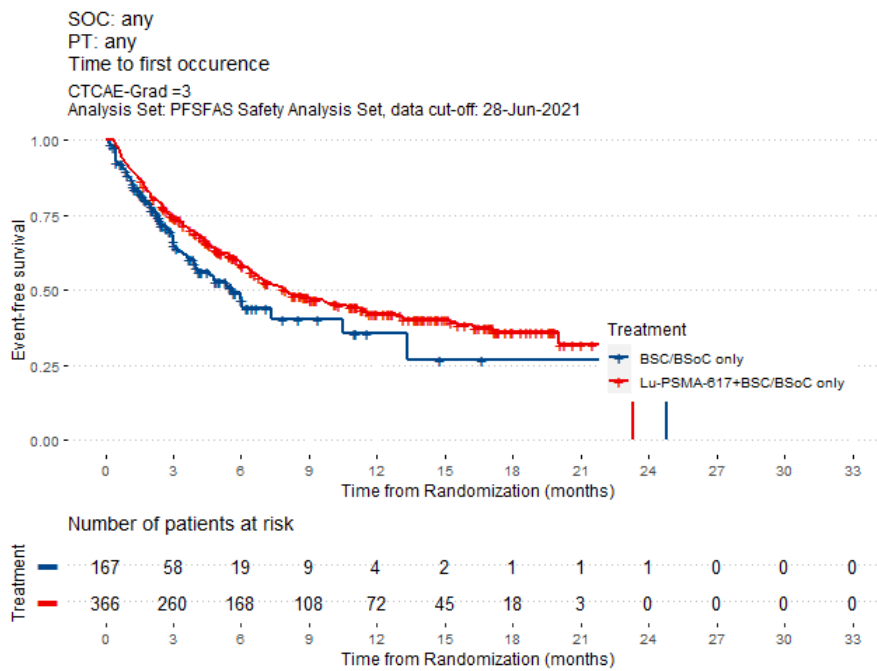


Abbildung 308: CTCAE-Grad 3-5: Time to first occurrence of SOC: any; PT: any

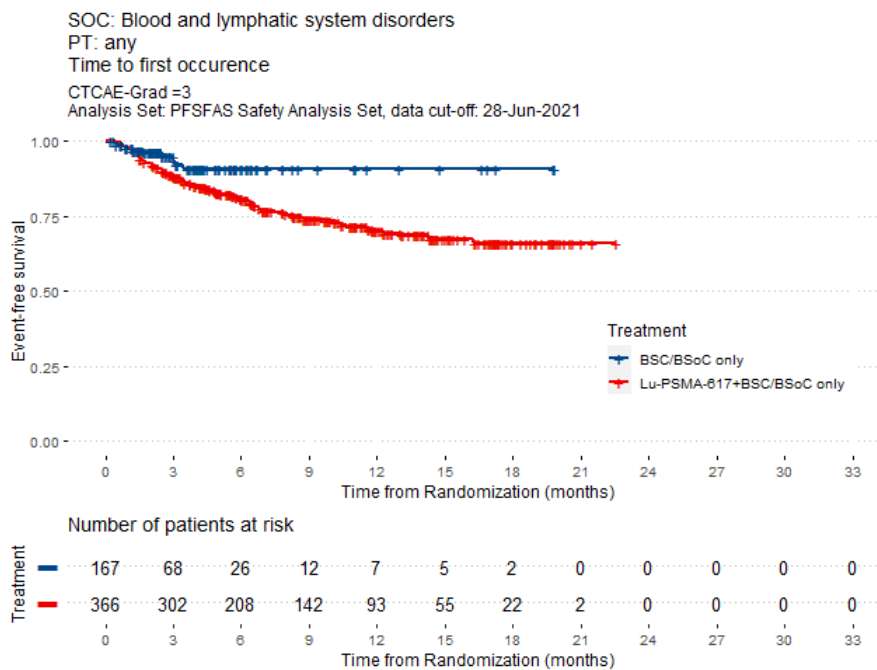


Abbildung 309: CTCAE-Grad 3-5: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: any

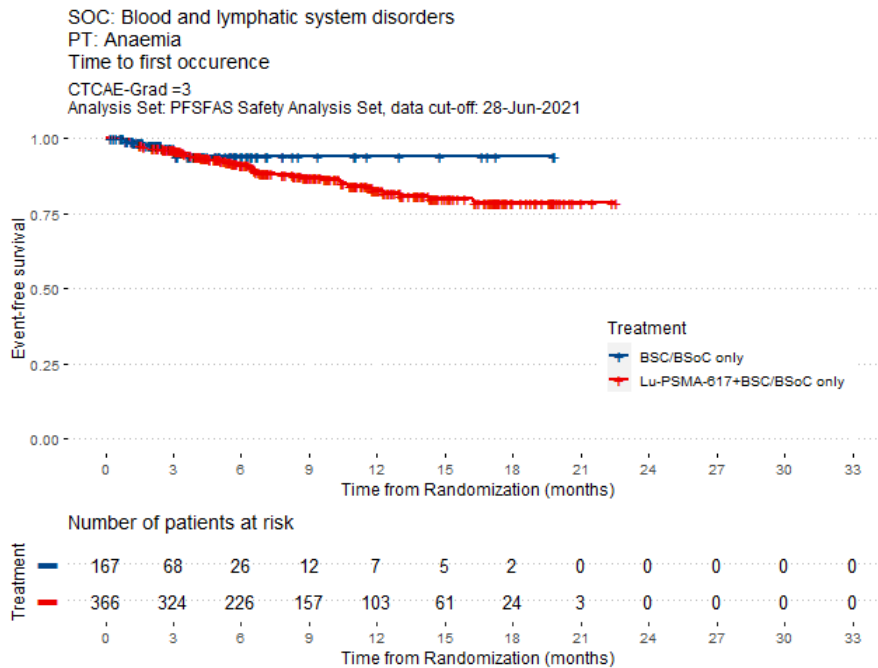


Abbildung 310: CTCAE-Grad 3-5: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Anaemia

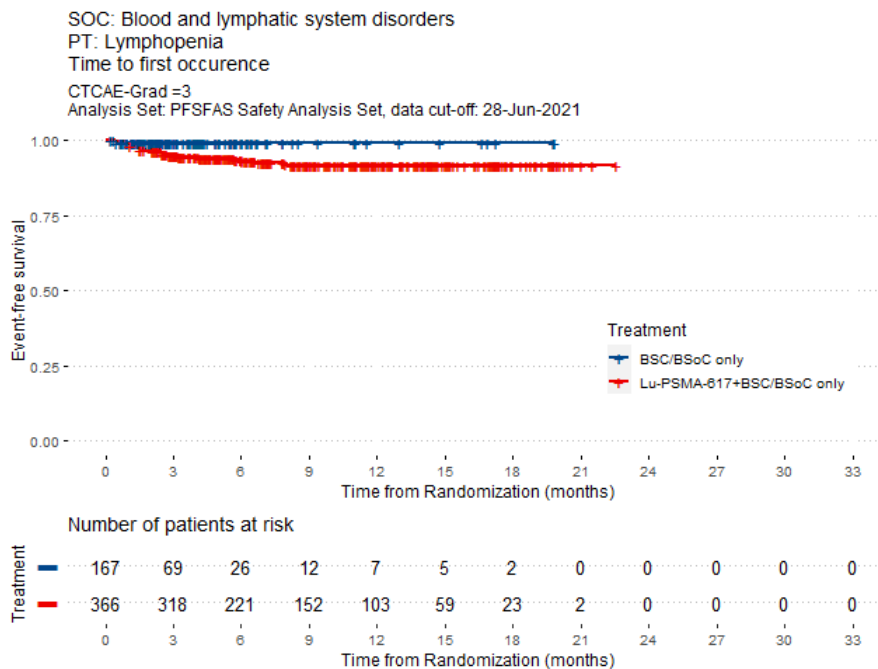


Abbildung 311: CTCAE-Grad 3-5: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Lymphopenia

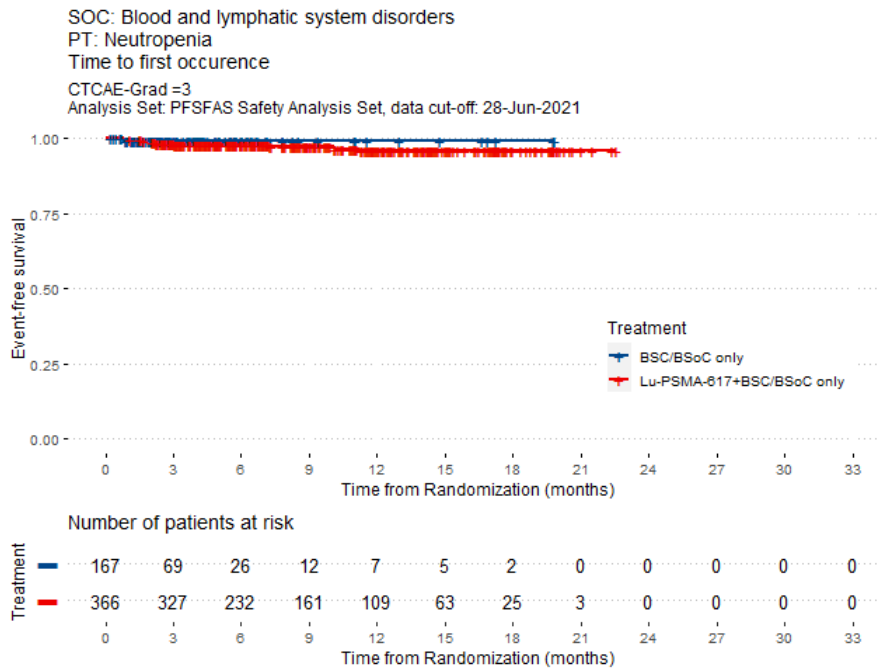


Abbildung 312: CTCAE-Grad 3-5: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Neutropenia

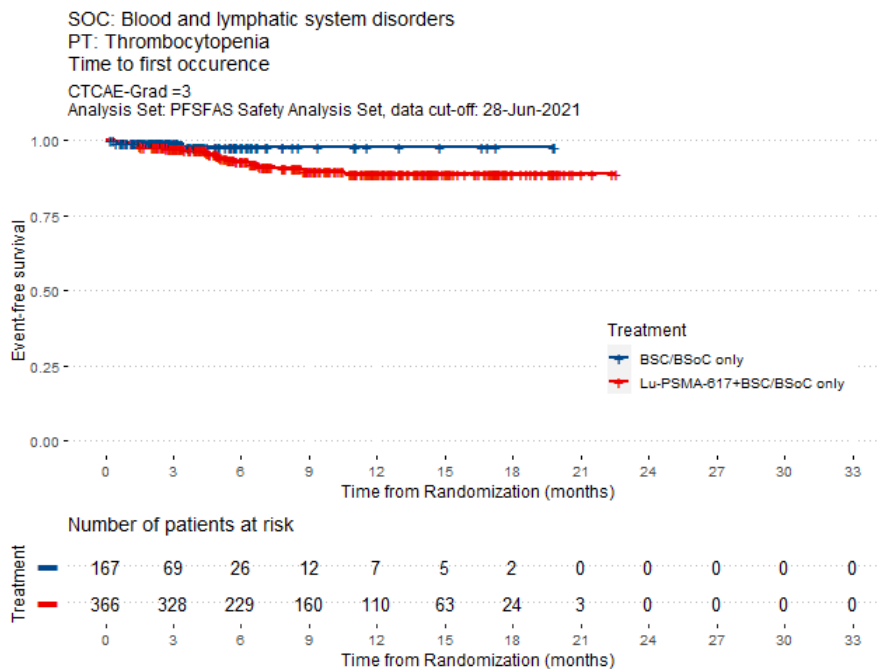


Abbildung 313: CTCAE-Grad 3-5: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Thrombocytopenia



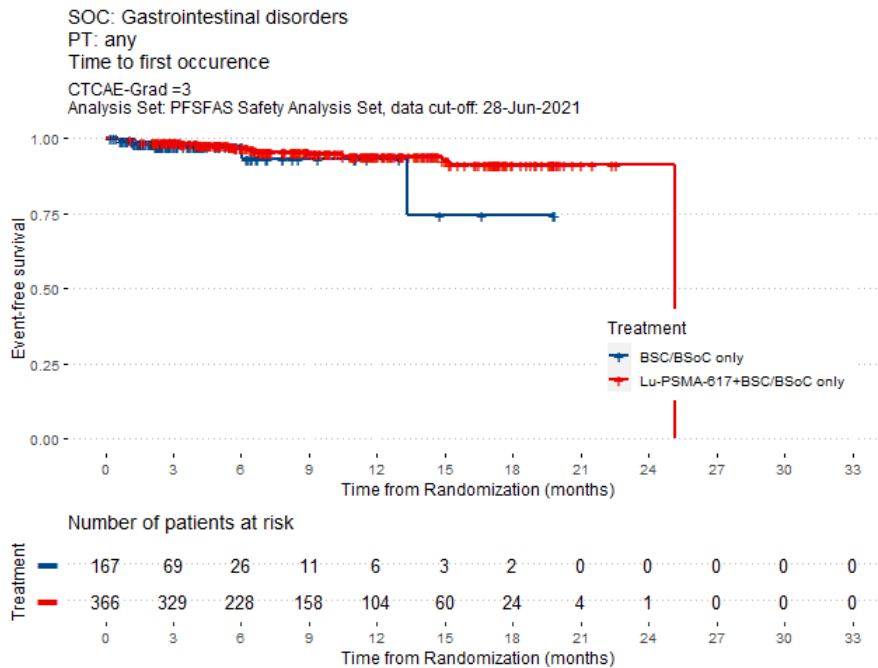


Abbildung 314: CTCAE-Grad 3-5: Time to first occurrence of SOC: Gastrointestinal disorders; PT: any

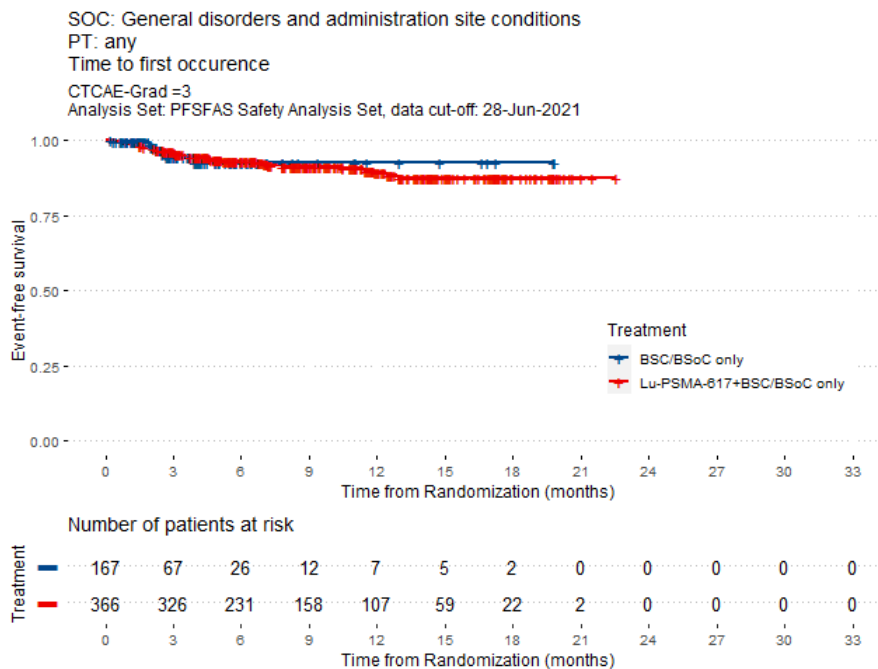


Abbildung 315: CTCAE-Grad 3-5: Time to first occurrence of SOC: General disorders and administration site conditions; PT: any

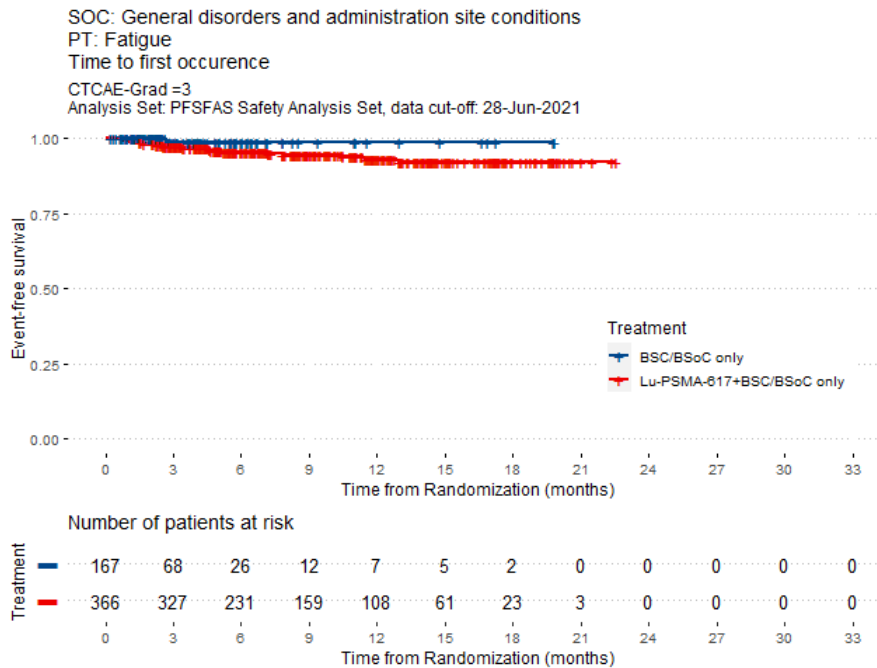


Abbildung 316: CTCAE-Grad 3-5: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Fatigue

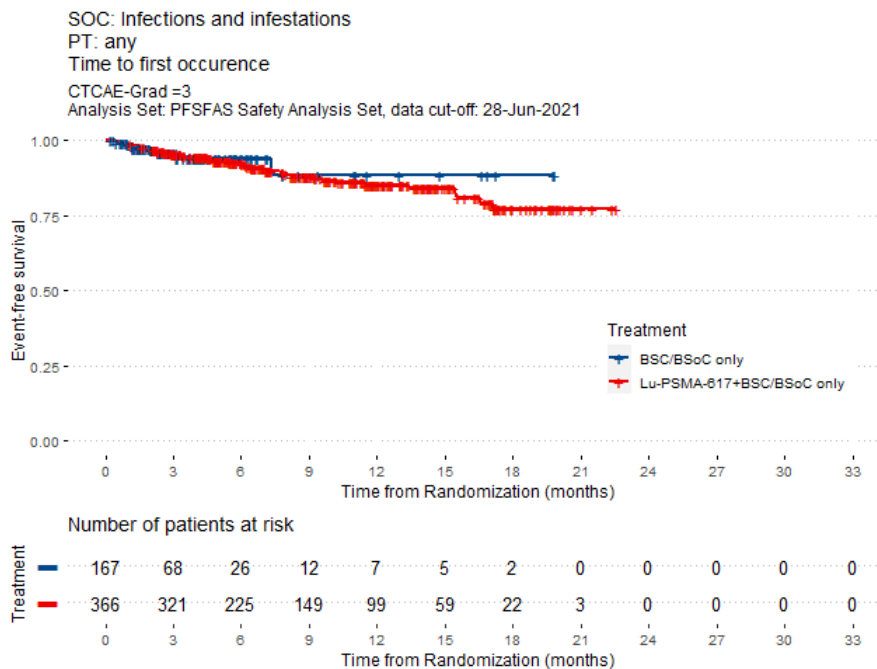


Abbildung 317: CTCAE-Grad 3-5: Time to first occurrence of SOC: Infections and infestations; PT: any

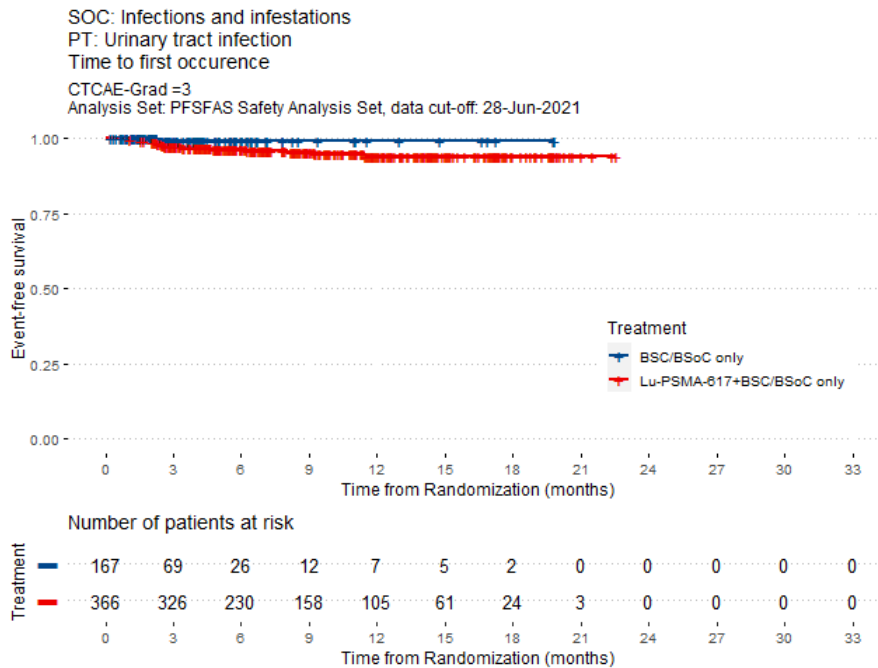


Abbildung 318: CTCAE-Grad 3-5: Time to first occurrence of SOC: Infections and infestations; PT: Urinary tract infection

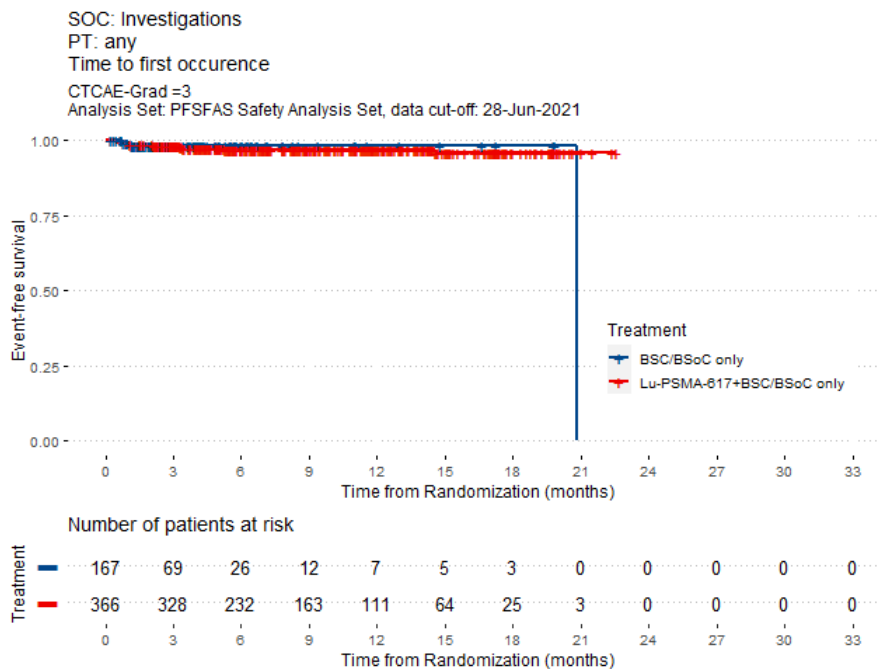


Abbildung 319: CTCAE-Grad 3-5: Time to first occurrence of SOC: Investigations; PT: any

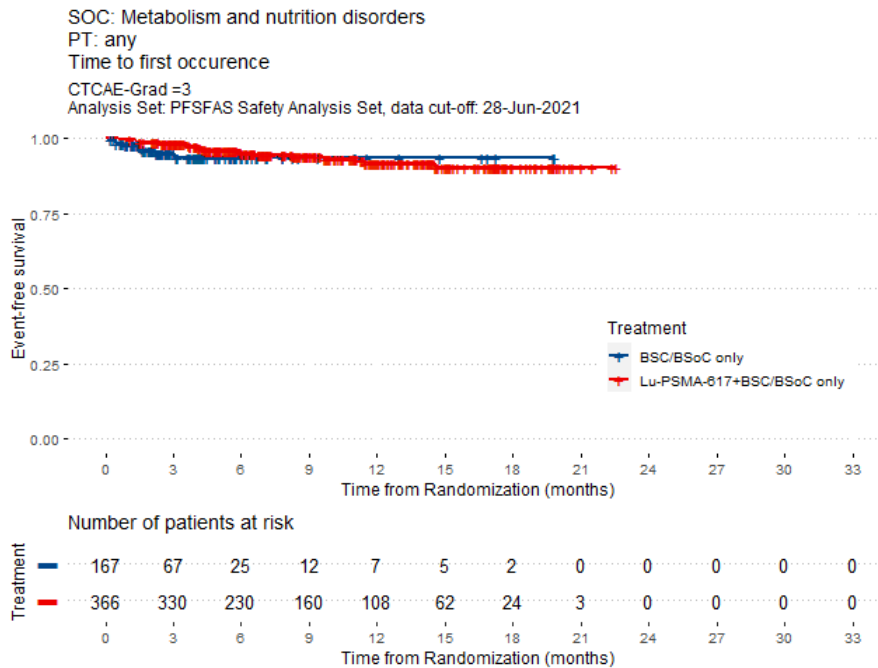


Abbildung 320: CTCAE-Grad 3-5: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: any

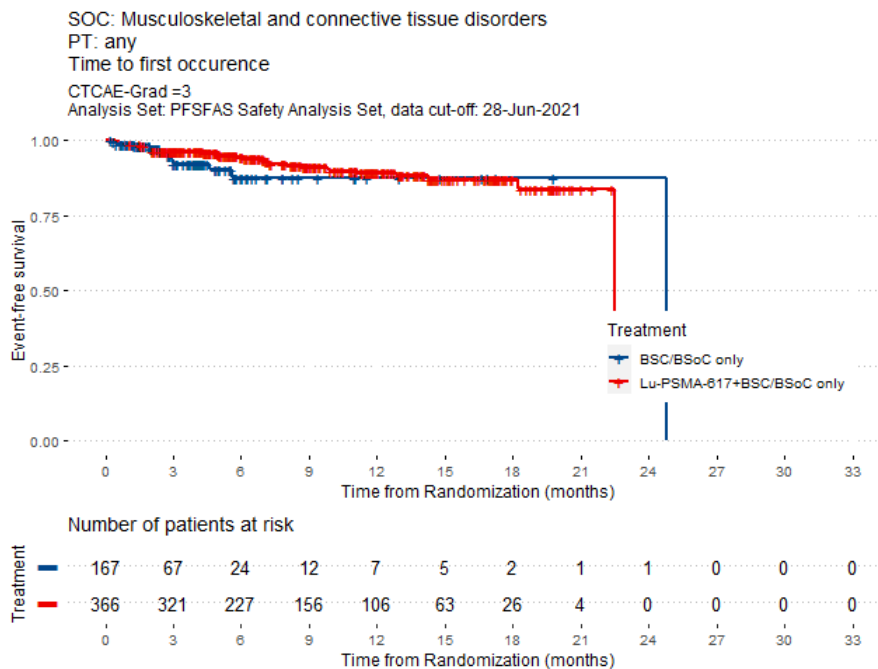


Abbildung 321: CTCAE-Grad 3-5: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: any

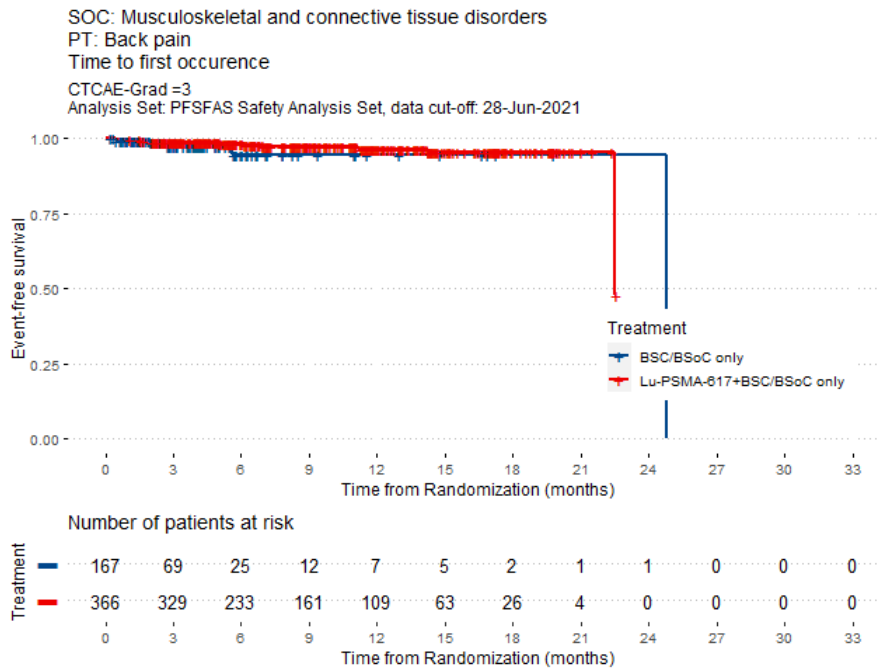


Abbildung 322: CTCAE-Grad 3-5: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Back pain

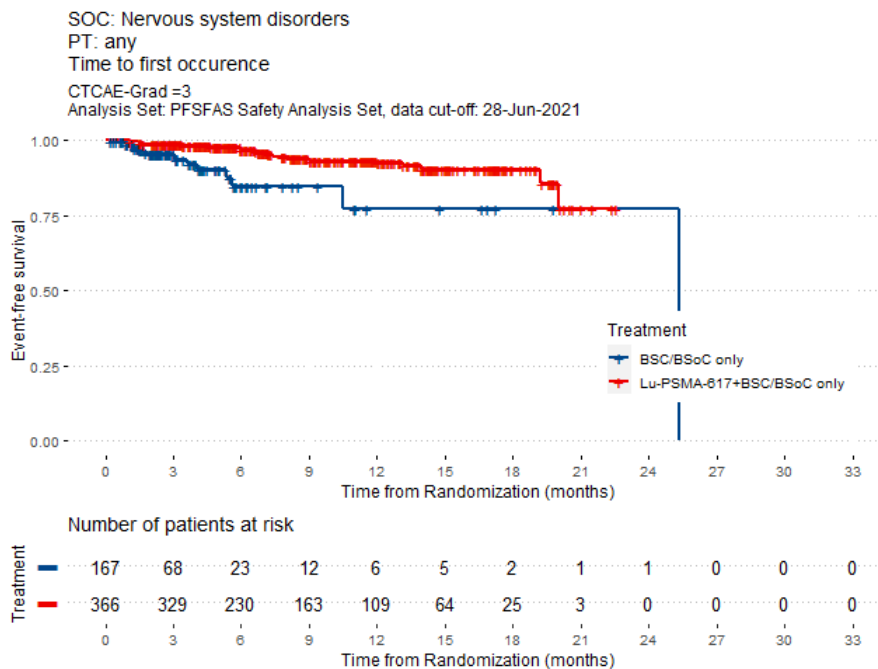


Abbildung 323: CTCAE-Grad 3-5: Time to first occurrence of SOC: Nervous system disorders; PT: any

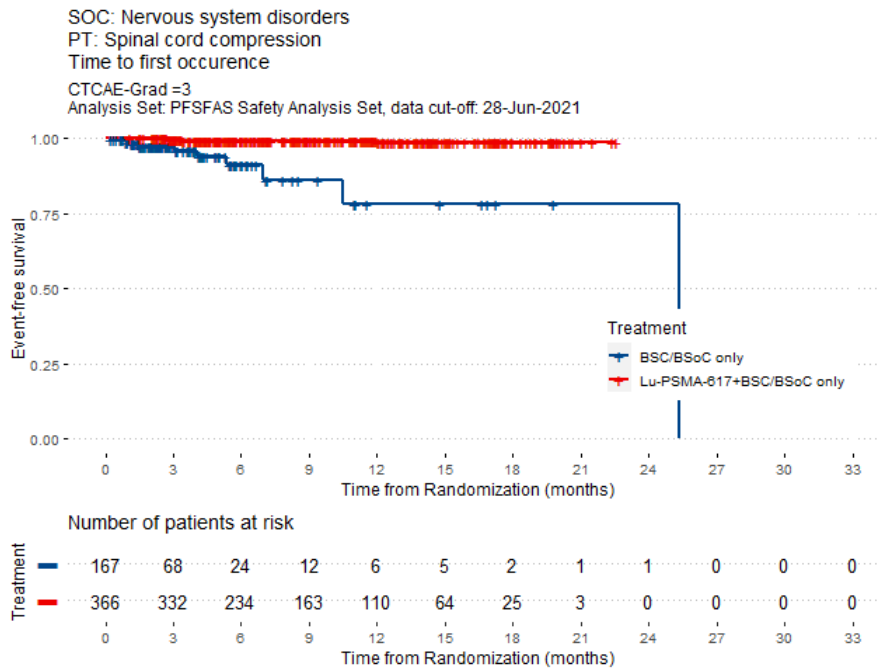


Abbildung 324: CTCAE-Grad 3-5: Time to first occurrence of SOC: Nervous system disorders; PT: Spinal cord compression

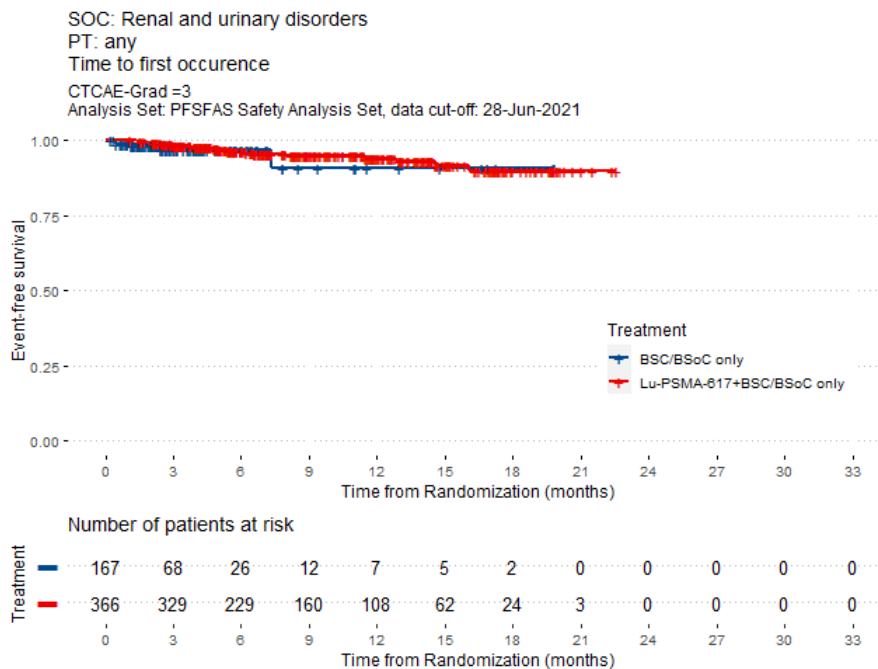


Abbildung 325: CTCAE-Grad 3-5: Time to first occurrence of SOC: Renal and urinary disorders; PT: any

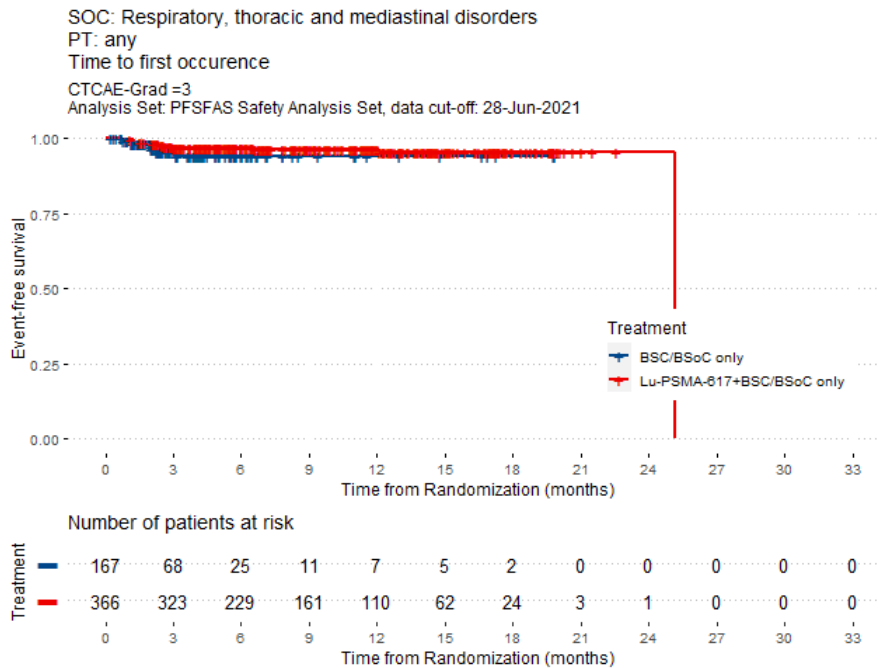


Abbildung 326: CTCAE-Grad 3-5: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: any

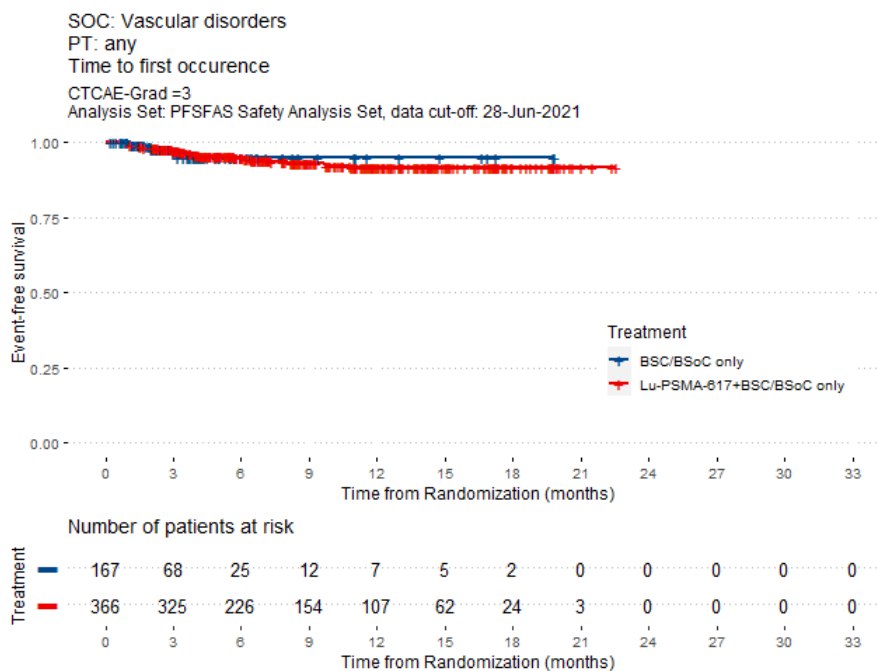


Abbildung 327: CTCAE-Grad 3-5: Time to first occurrence of SOC: Vascular disorders; PT: any

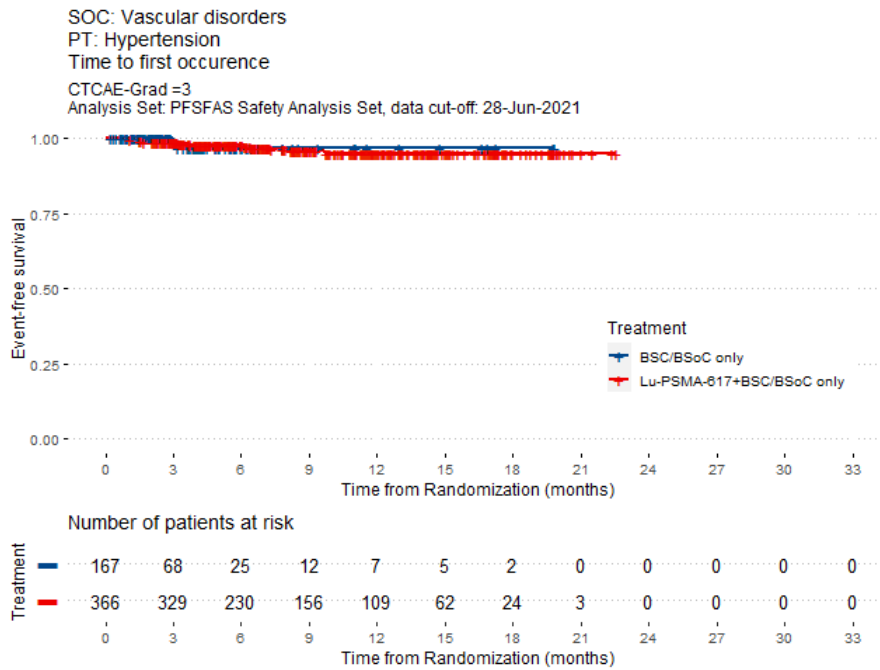


Abbildung 328: CTCAE-Grad 3-5: Time to first occurrence of SOC: Vascular disorders; PT: Hypertension



**Anhang 3.4.3: Schwerwiegende UE**

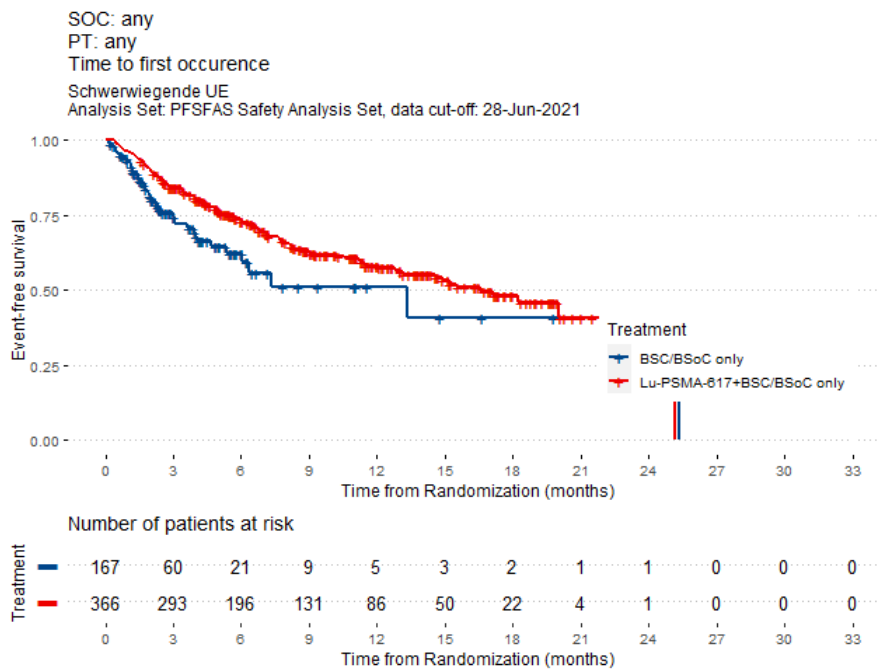


Abbildung 329: Schwerwiegende UE: Time to first occurrence of SOC: any; PT: any

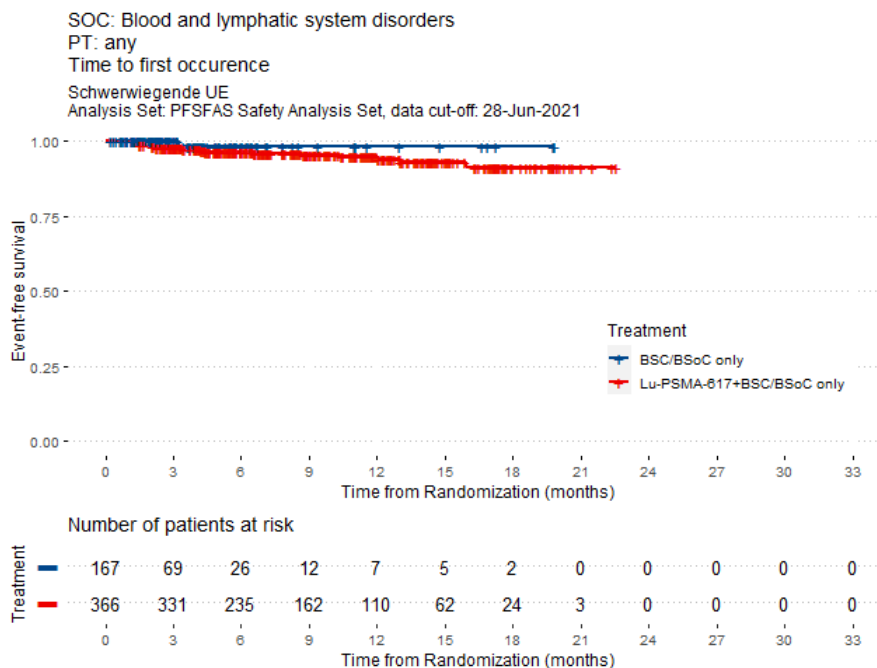


Abbildung 330: Schwerwiegende UE: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: any

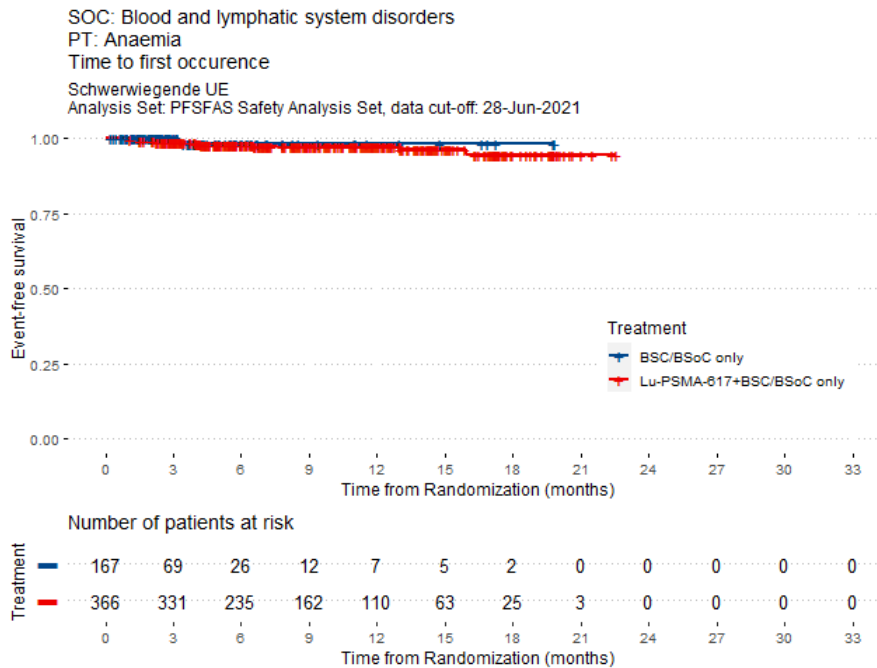


Abbildung 331: Schwerwiegende UE: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Anaemia

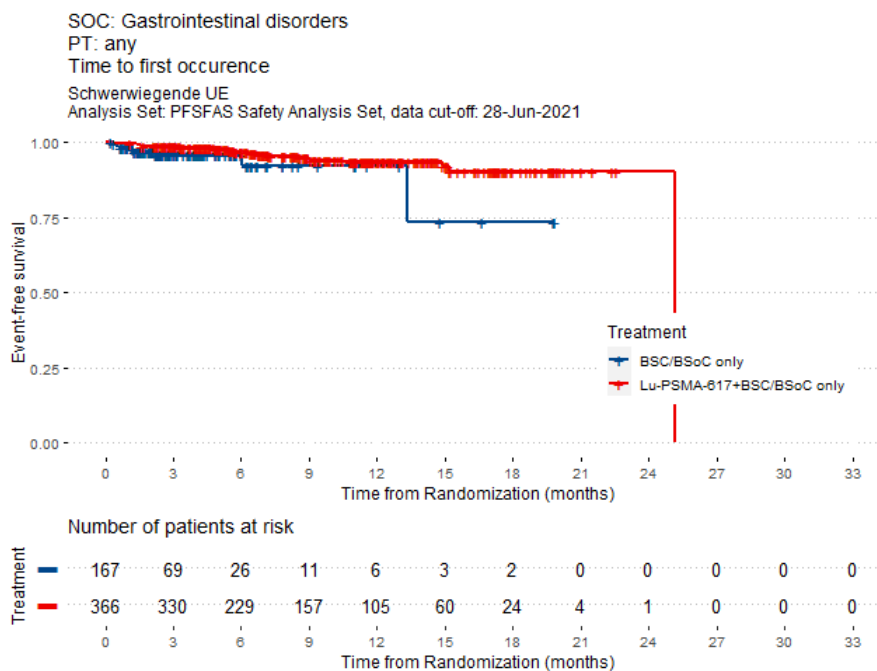


Abbildung 332: Schwerwiegende UE: Time to first occurrence of SOC: Gastrointestinal disorders; PT: any

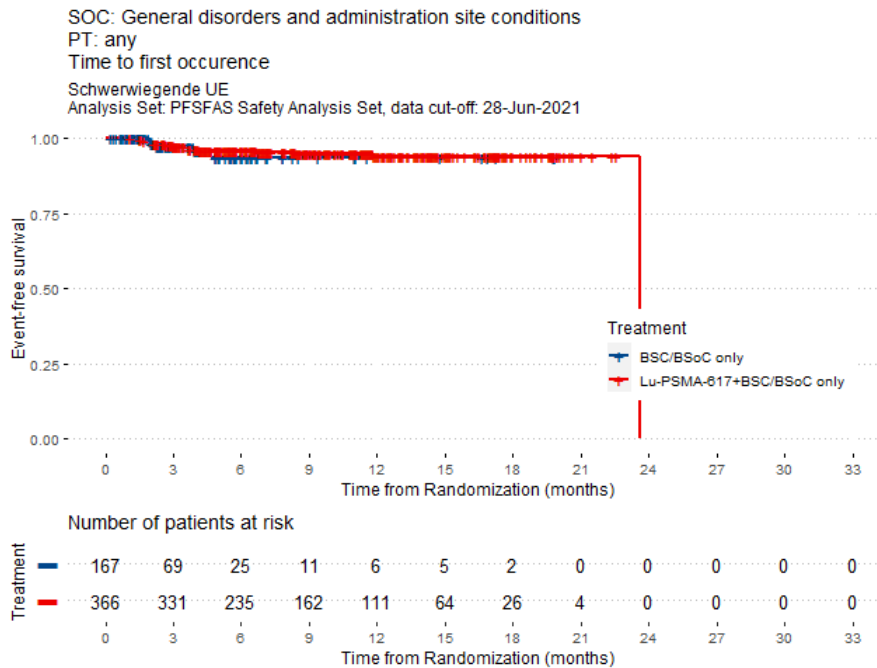


Abbildung 333: Schwerwiegende UE: Time to first occurrence of SOC: General disorders and administration site conditions; PT: any

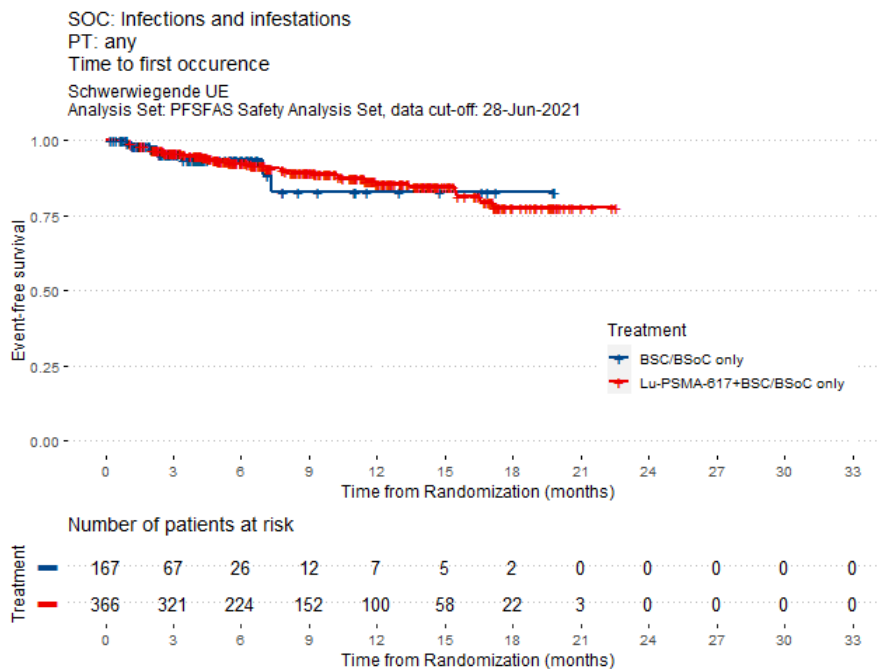


Abbildung 334: Schwerwiegende UE: Time to first occurrence of SOC: Infections and infestations; PT: any

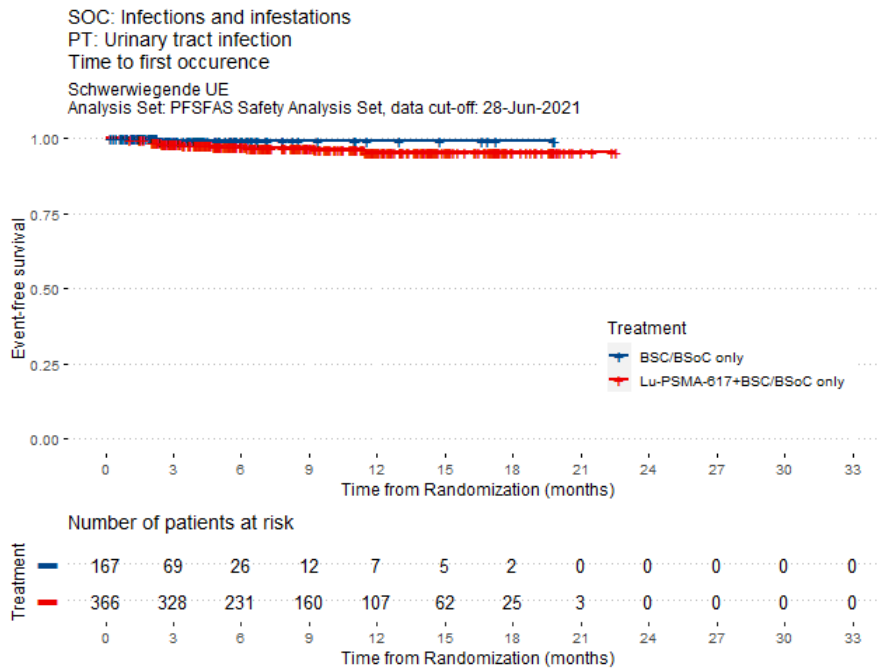


Abbildung 335: Schwerwiegende UE: Time to first occurrence of SOC: Infections and infestations; PT: Urinary tract infection

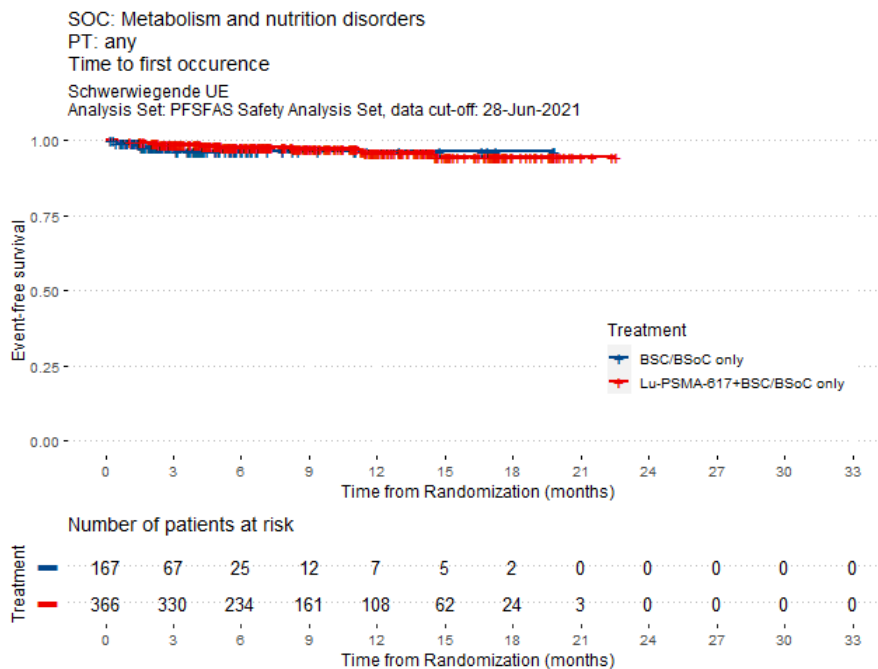


Abbildung 336: Schwerwiegende UE: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: any

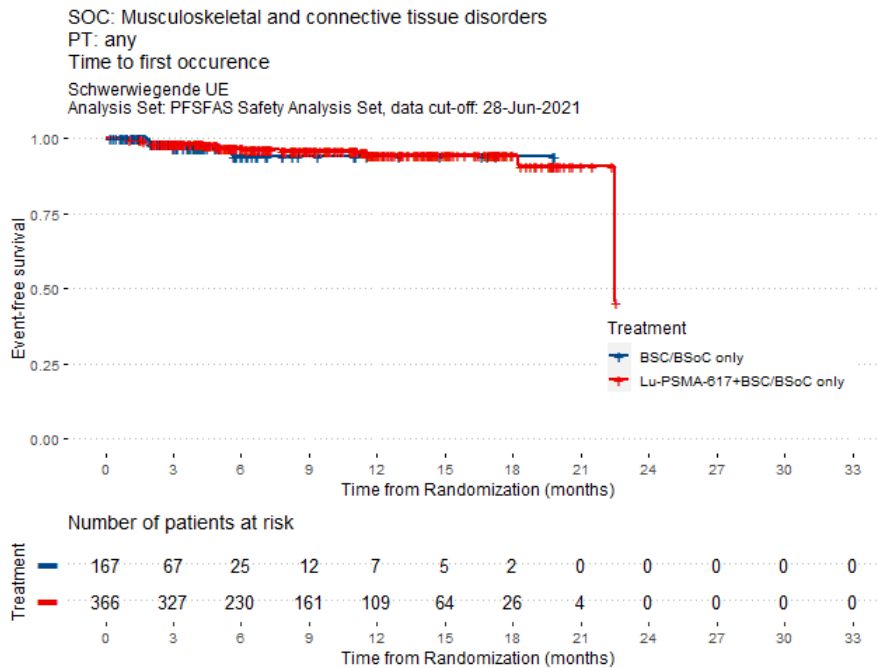


Abbildung 337: Schwerwiegende UE: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: any

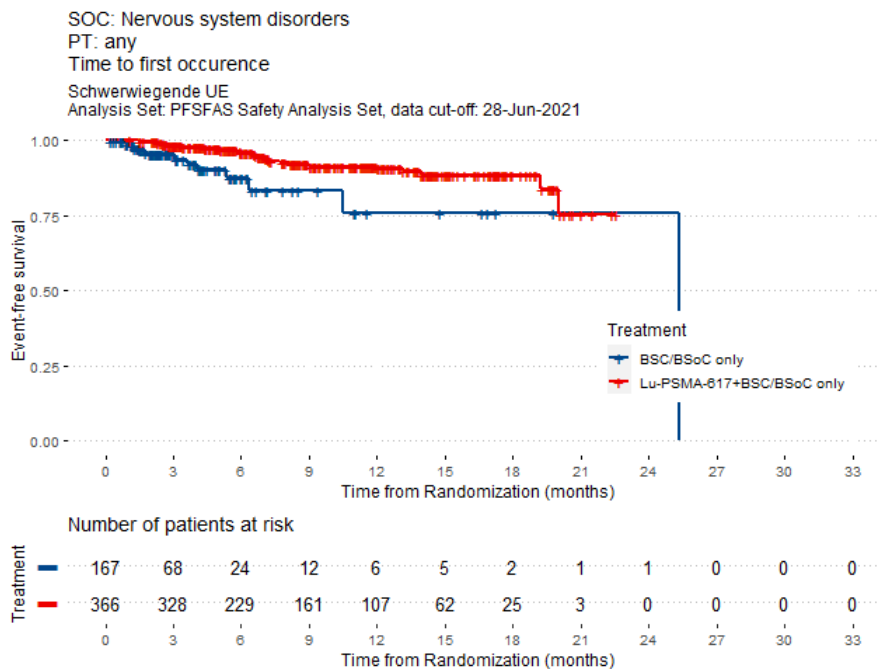


Abbildung 338: Schwerwiegende UE: Time to first occurrence of SOC: Nervous system disorders; PT: any

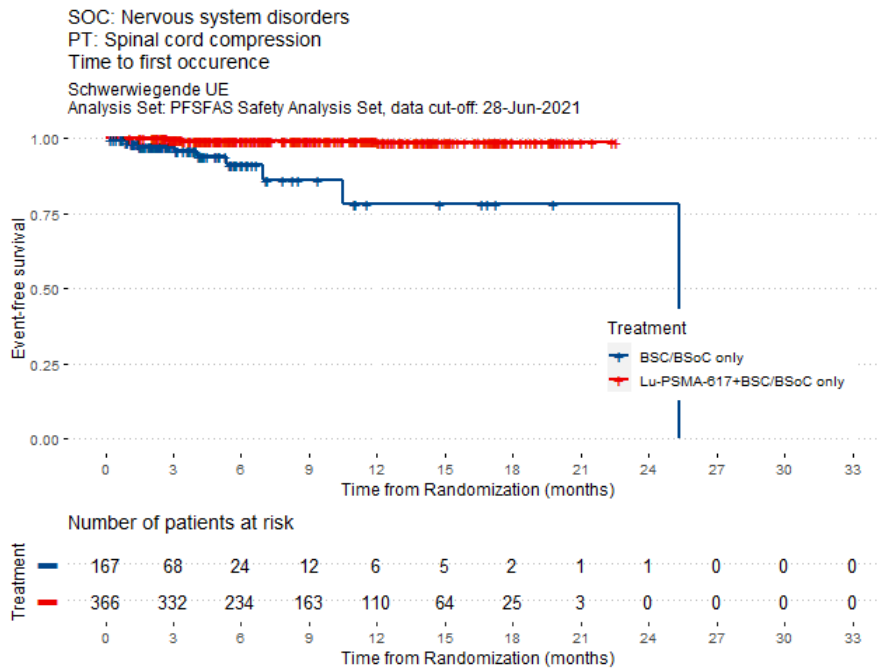


Abbildung 339: Schwerwiegende UE: Time to first occurrence of SOC: Nervous system disorders; PT: Spinal cord compression

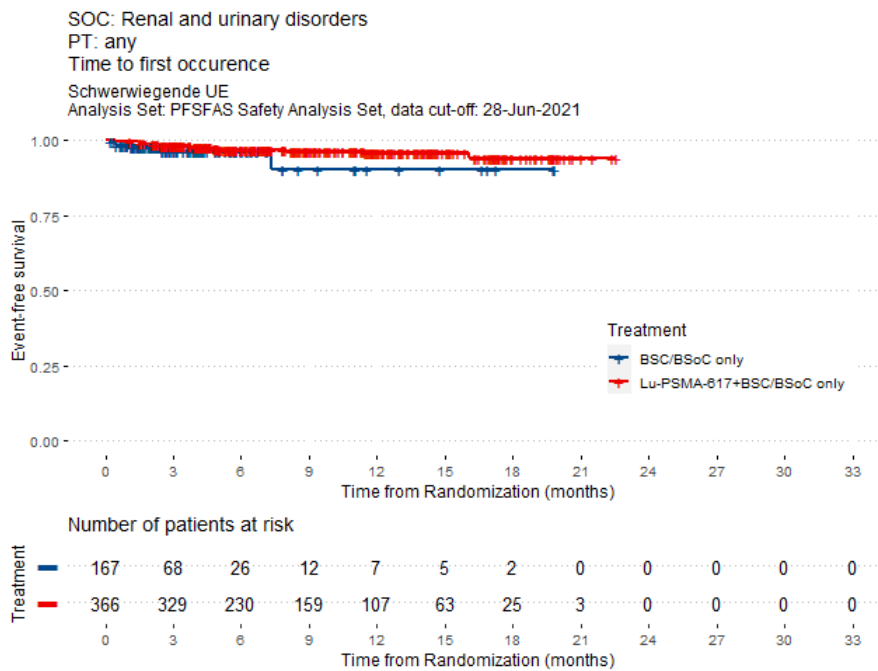


Abbildung 340: Schwerwiegende UE: Time to first occurrence of SOC: Renal and urinary disorders; PT: any

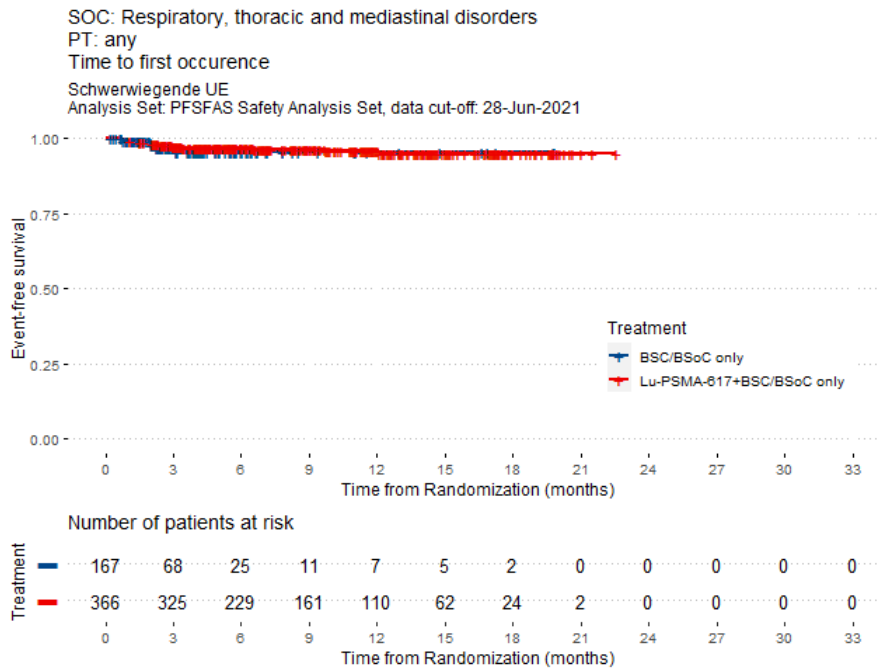


Abbildung 341: Schwerwiegende UE: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: any