

Dossier zur Nutzenbewertung gemäß § 35a SGB V

(¹⁷⁷Lu)Lutetiumvipivotidtetraxetan (Pluvicto®)

Novartis Radiopharmaceuticals GmbH

Modul 4 A

Behandlung von erwachsenen Patienten mit progredientem Prostata-spezifischen-Membranantigen-(PSMA-)positivem, metastasiertem, kastrationsresistentem Prostatakarzinom (mCRPC), die zuvor mittels Inhibition des AR-Signalwegs und taxanbasierter Chemotherapie behandelt wurden

Anhang 4-H Kaplan-Meier-Kurven

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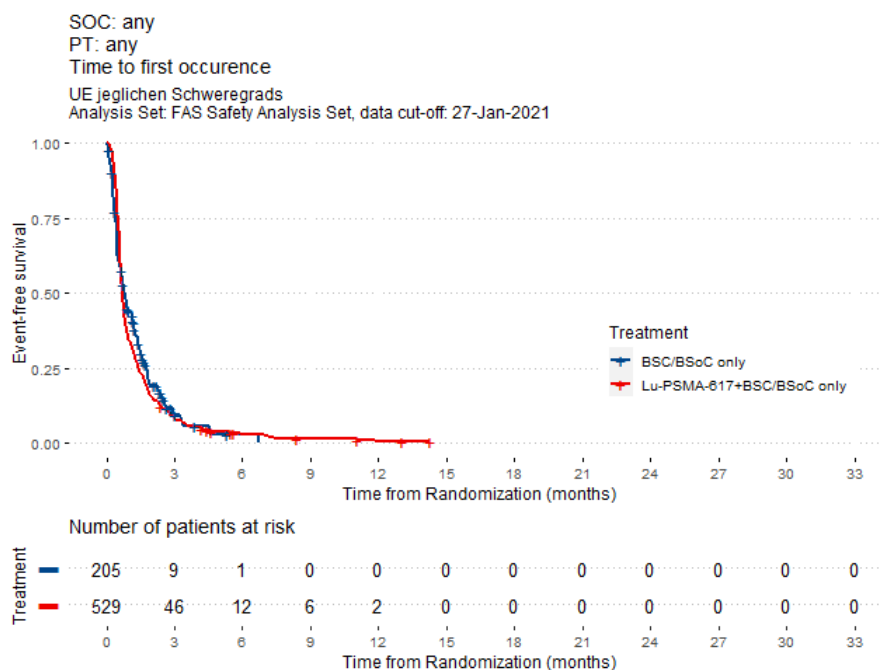
Anhang 4-H: Kaplan-Meier-Kurven**Anhang 4-H.1: Unerwünschte Ereignisse nach System Organ Class und Preferred Term****Anhang 4-H.1.1: UE jeglichen Schweregrads**

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

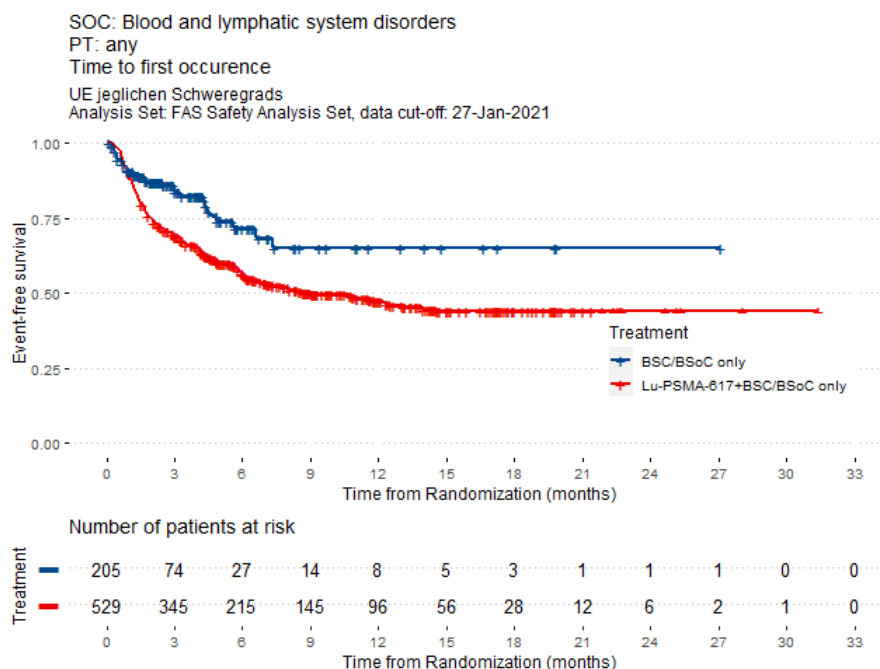


Abbildung 2: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: any

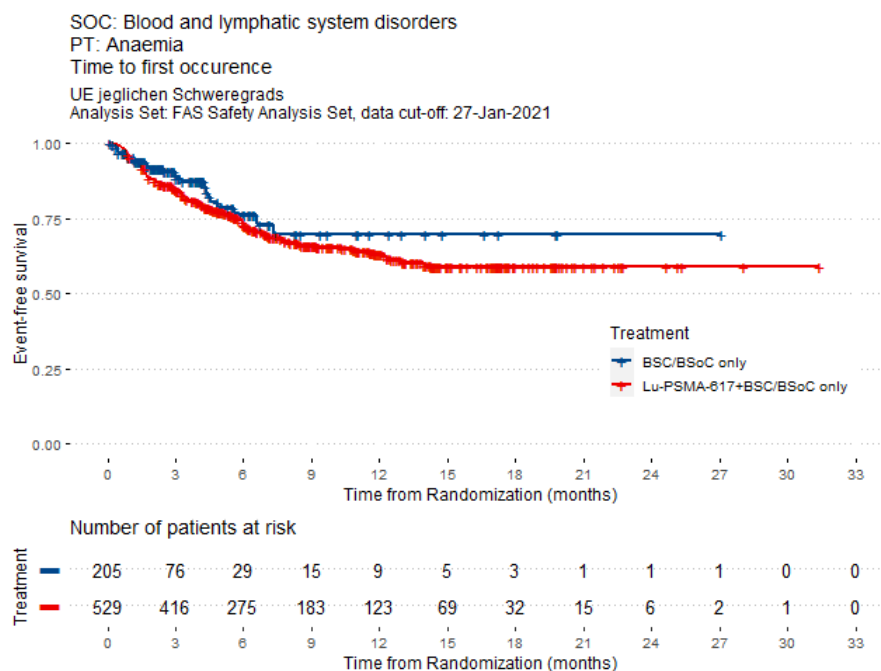


Abbildung 3: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Anaemia

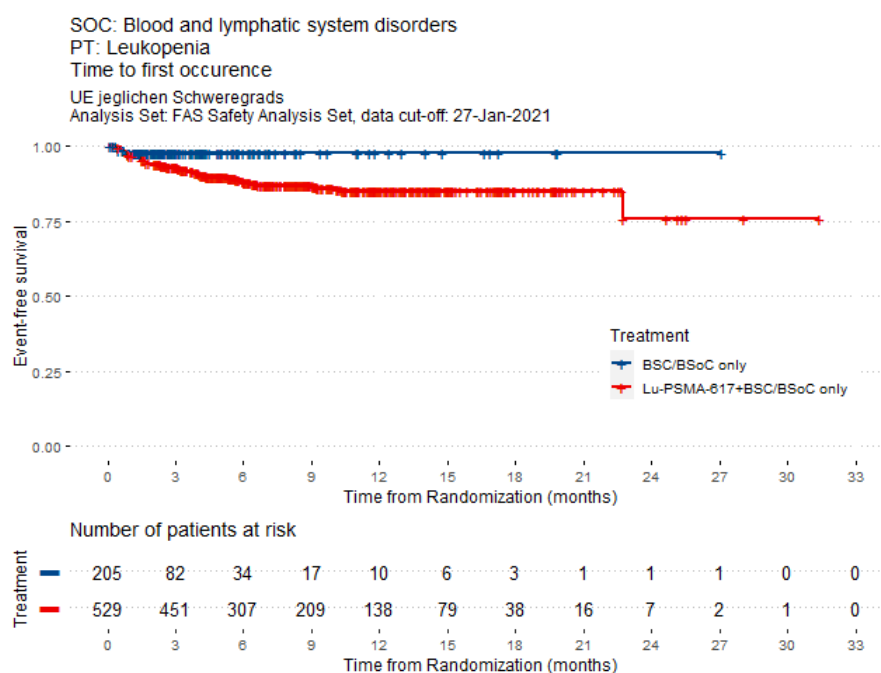


Abbildung 4: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Leukopenia

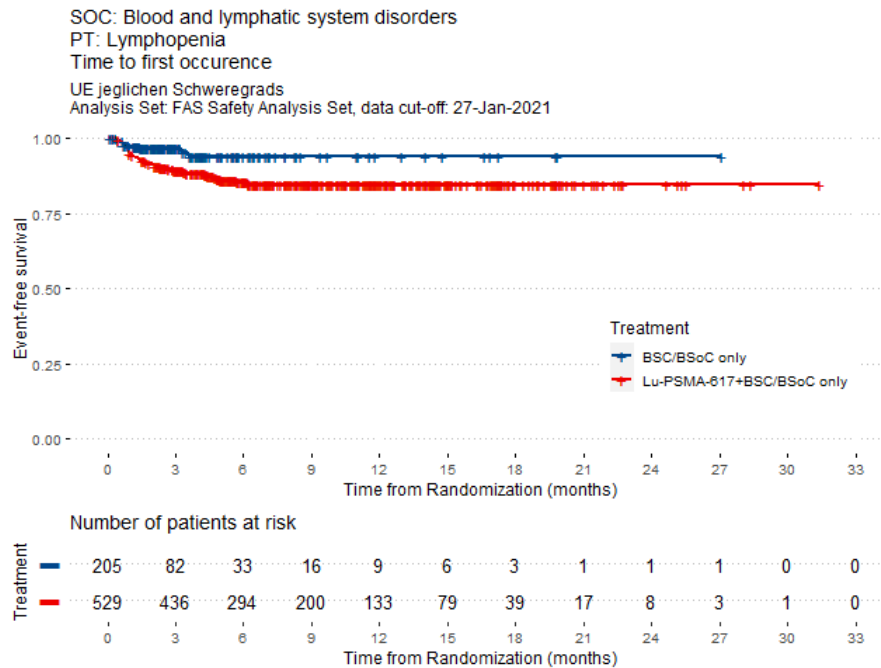


Abbildung 5: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Lymphopenia

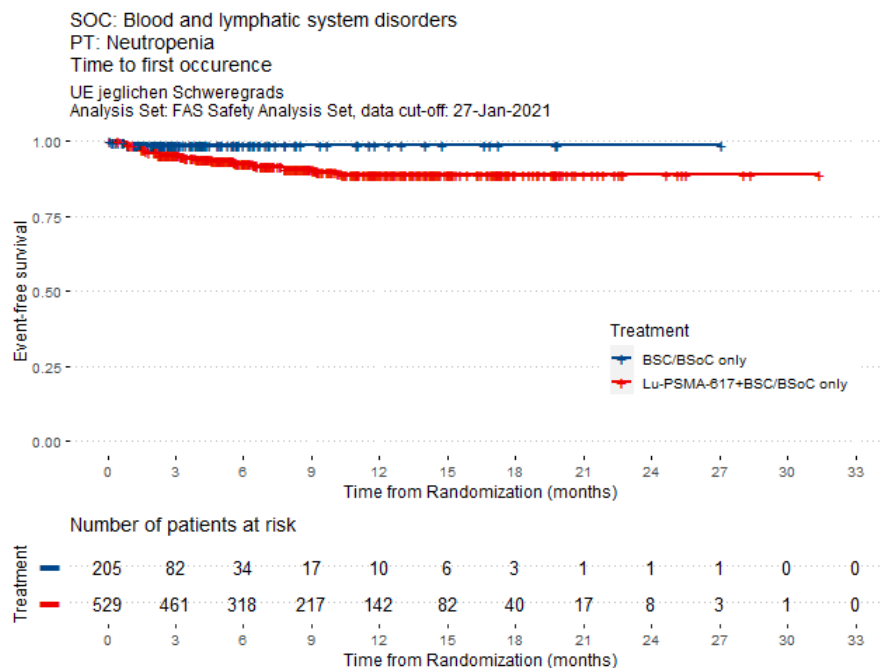


Abbildung 6: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Neutropenia

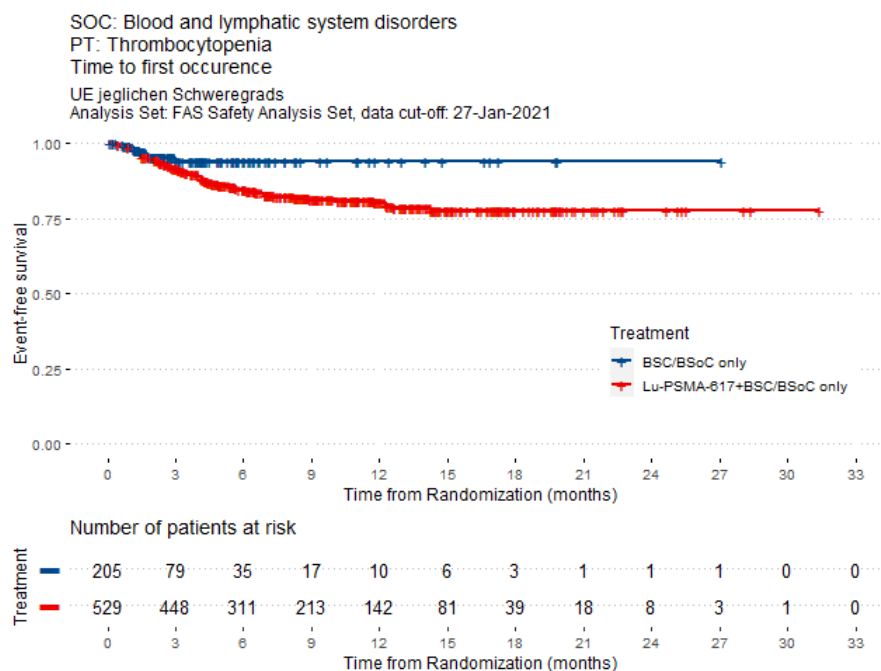


Abbildung 7: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Thrombocytopenia

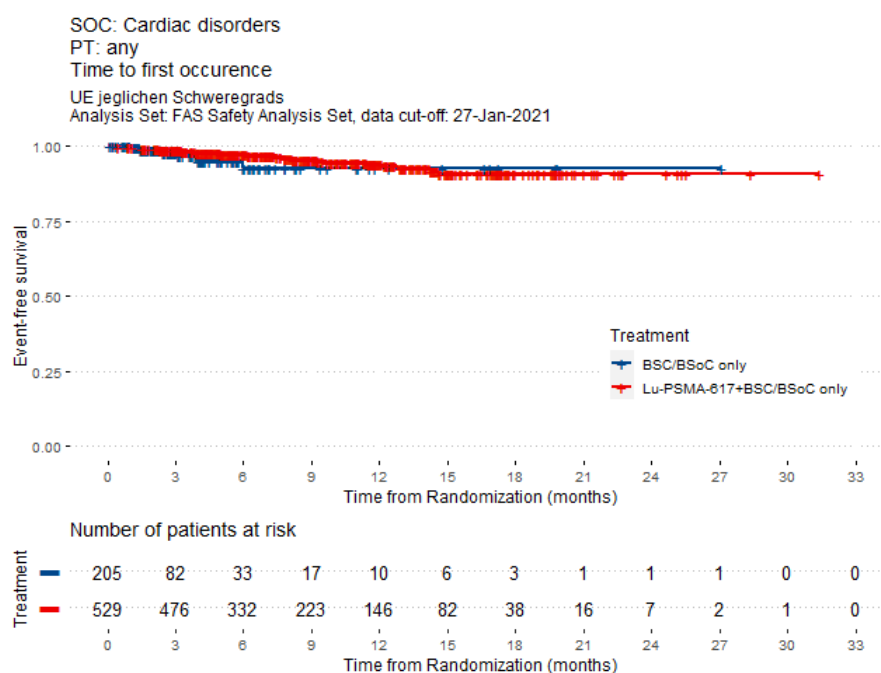


Abbildung 8: UE jeglichen Schweregrads: Time to first occurrence of SOC: Cardiac disorders; PT: any

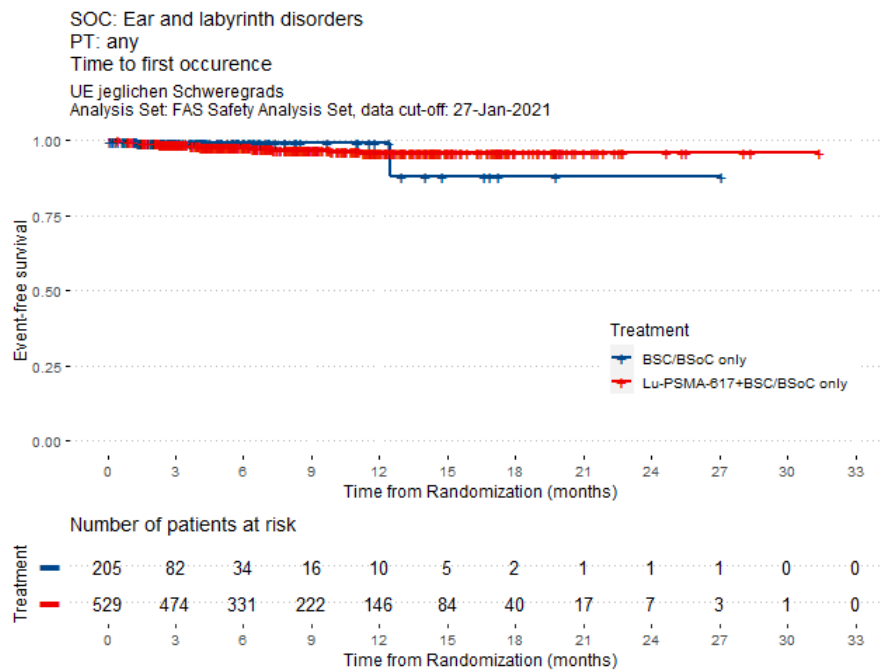


Abbildung 9: UE jeglichen Schweregrads: Time to first occurrence of SOC: Ear and labyrinth disorders; PT: any

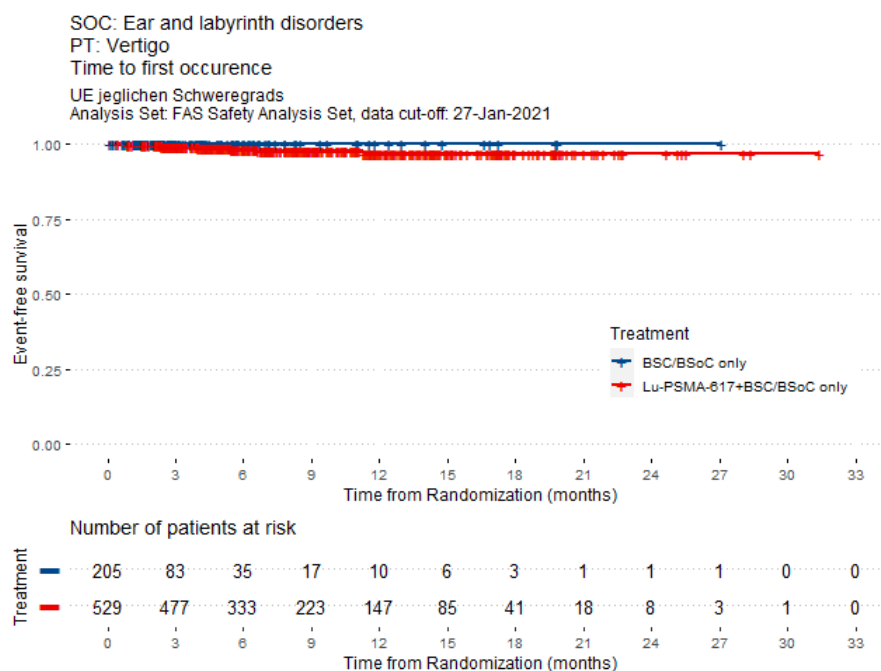


Abbildung 10: UE jeglichen Schweregrads: Time to first occurrence of SOC: Ear and labyrinth disorders; PT: Vertigo

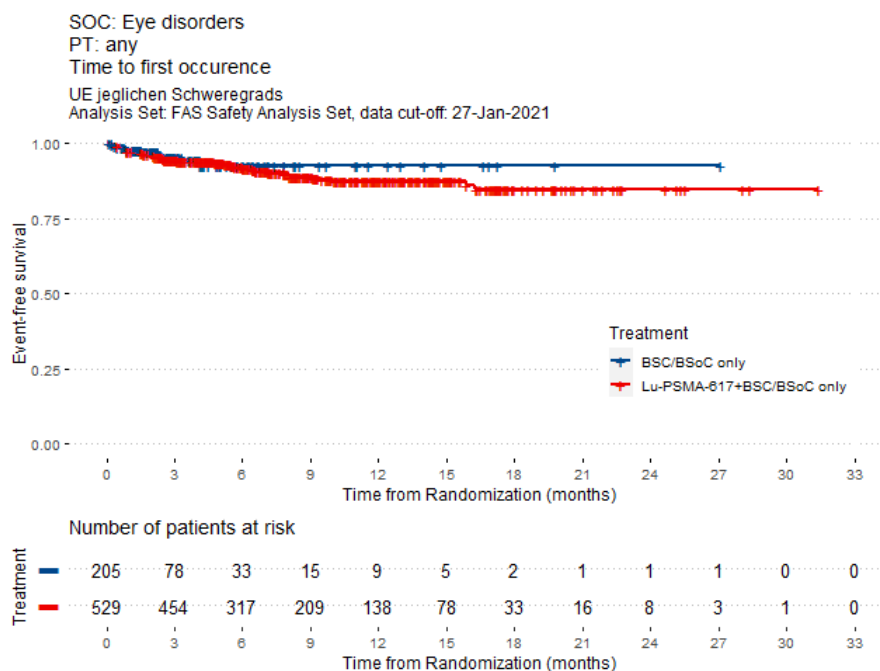


Abbildung 11: UE jeglichen Schweregrads: Time to first occurrence of SOC: Eye disorders;
PT: any

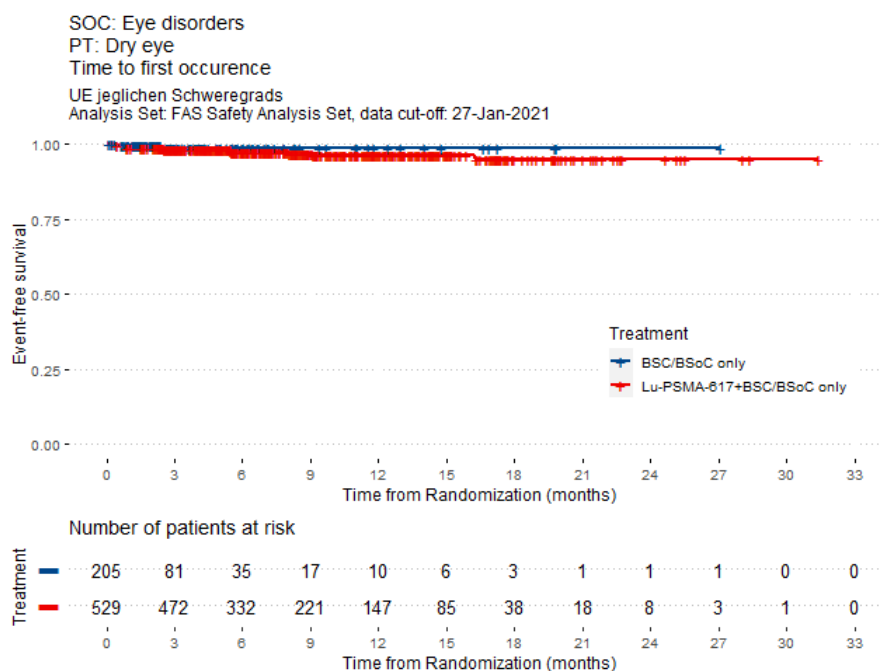


Abbildung 12: UE jeglichen Schweregrads: Time to first occurrence of SOC: Eye disorders;
PT: Dry eye

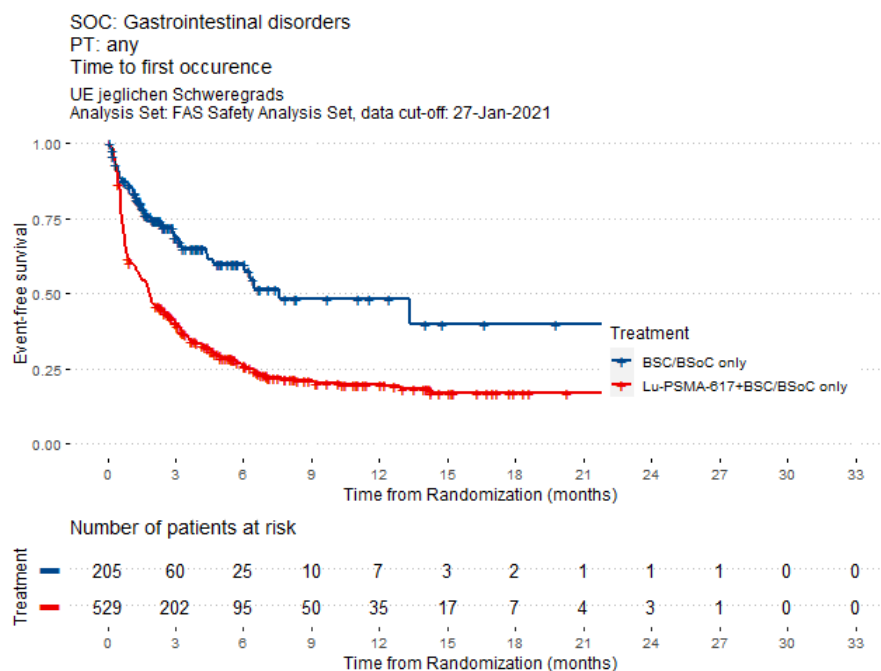


Abbildung 13: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: any

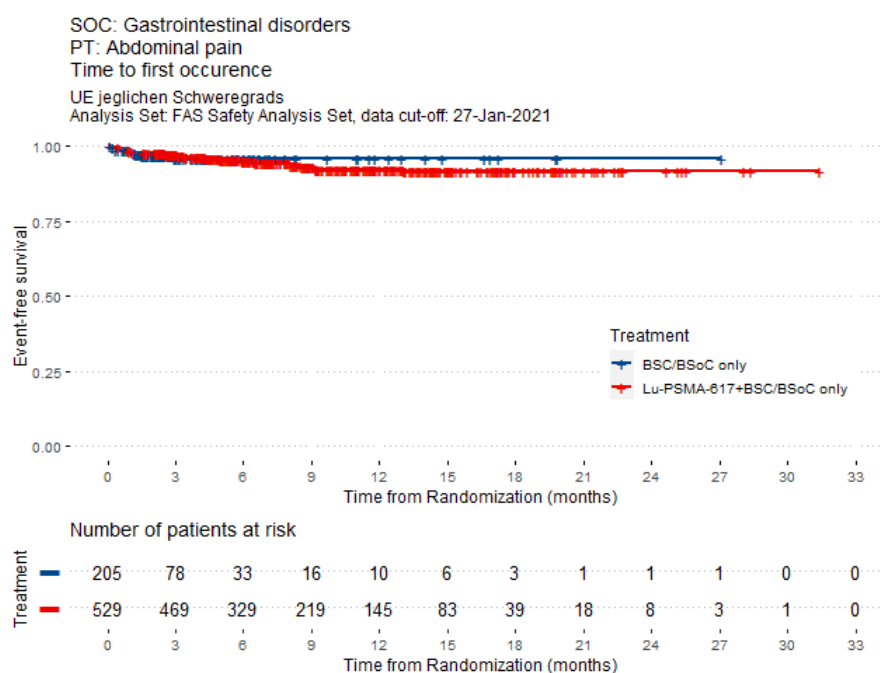


Abbildung 14: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Abdominal pain

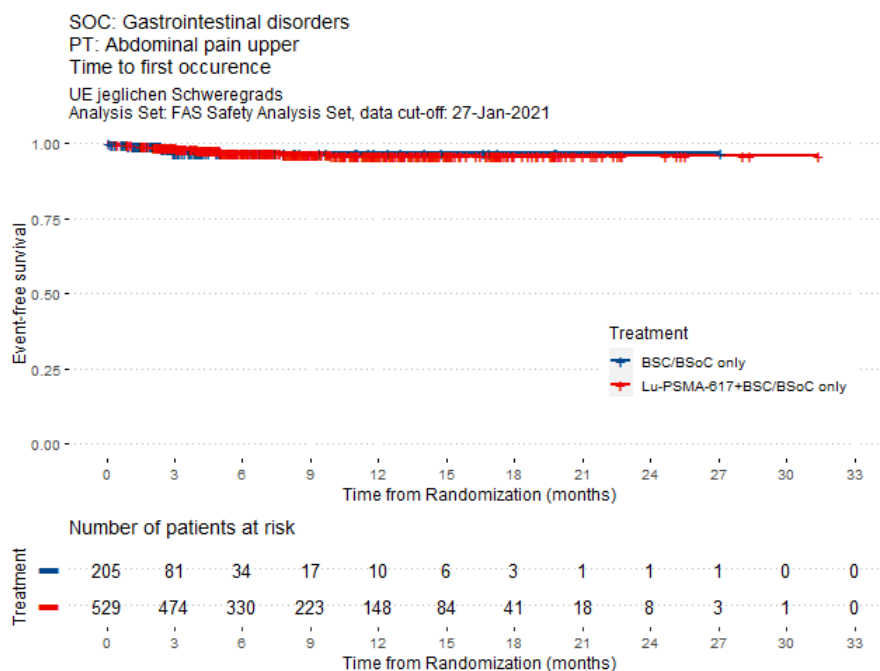


Abbildung 15: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Abdominal pain upper

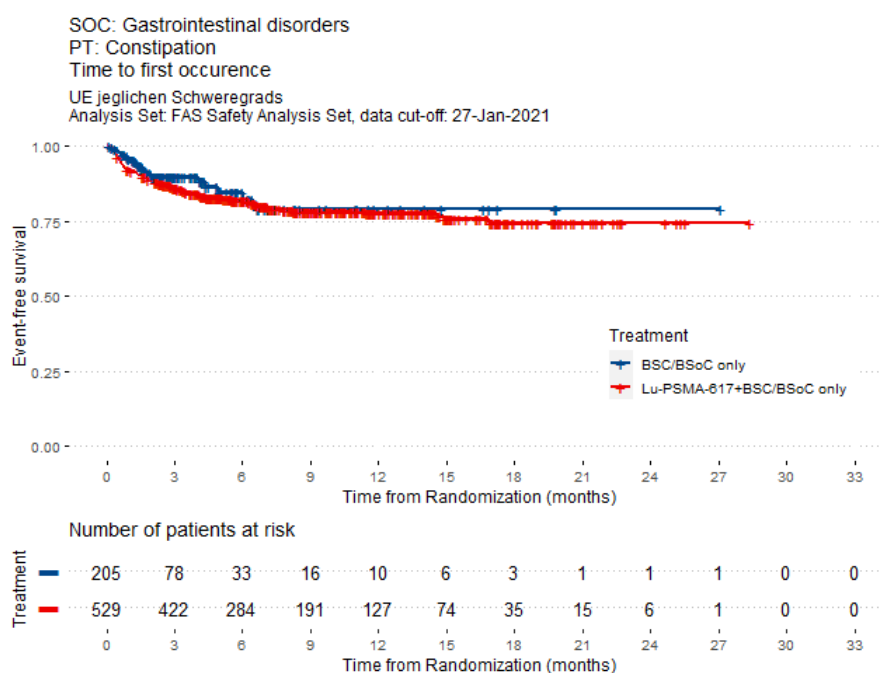


Abbildung 16: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Constipation

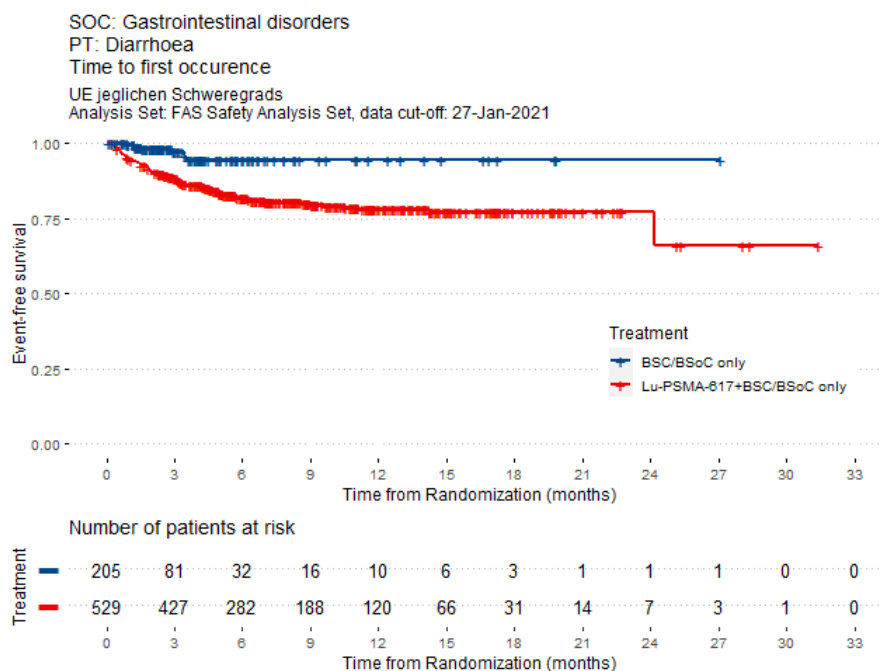


Abbildung 17: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Diarrhoea

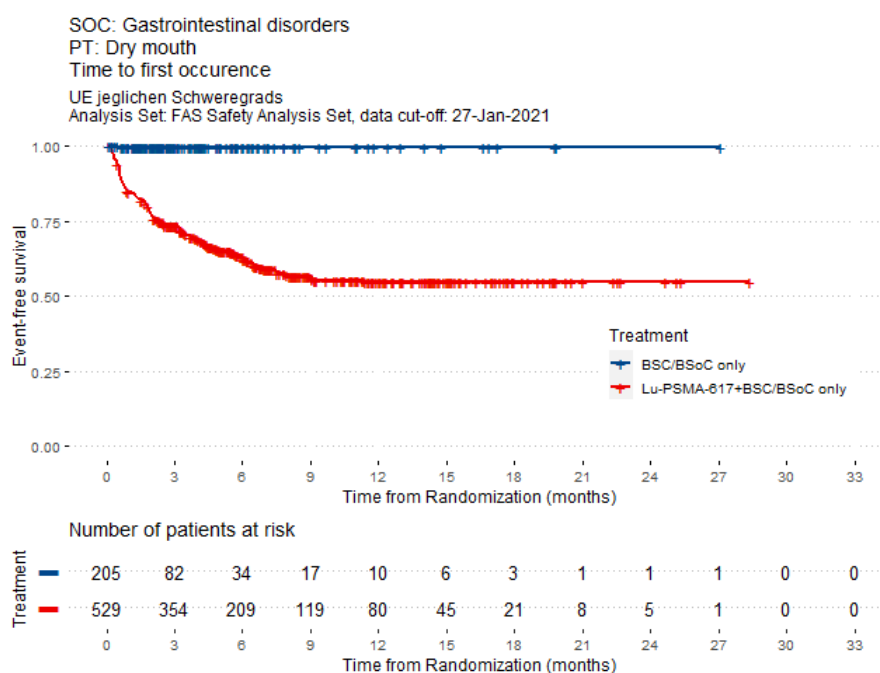


Abbildung 18: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Dry mouth

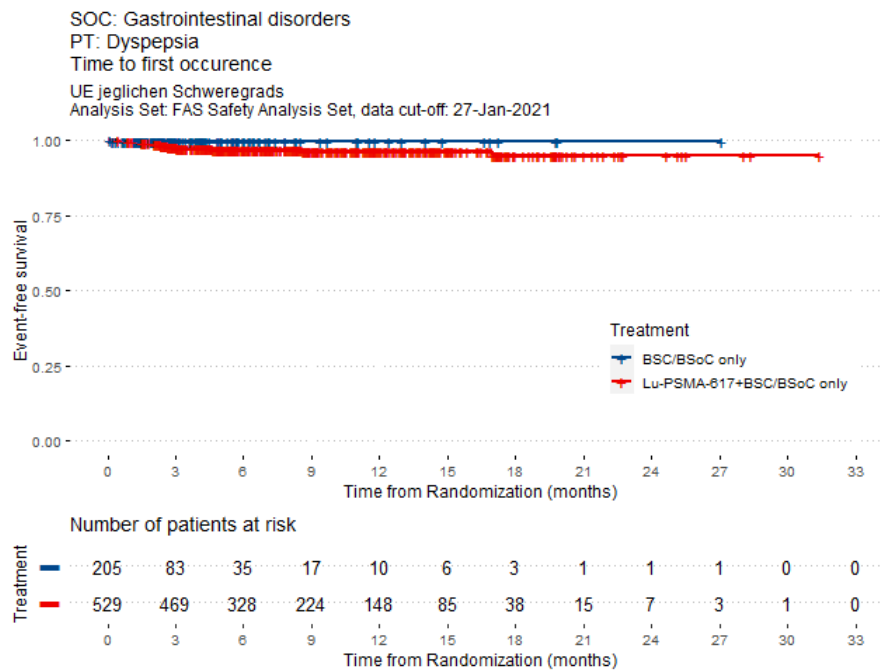


Abbildung 19: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Dyspepsia

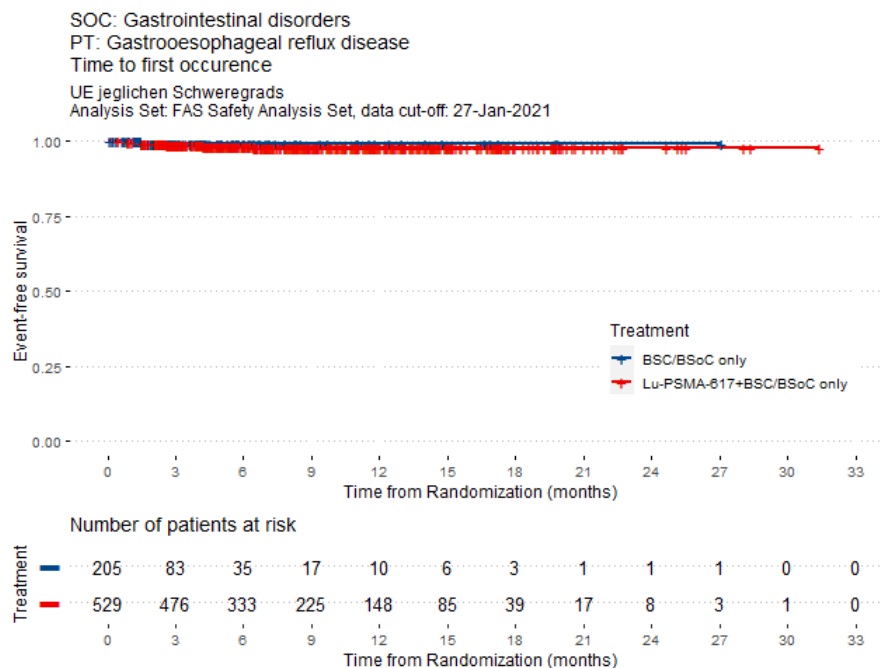


Abbildung 20: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Gastroesophageal reflux disease

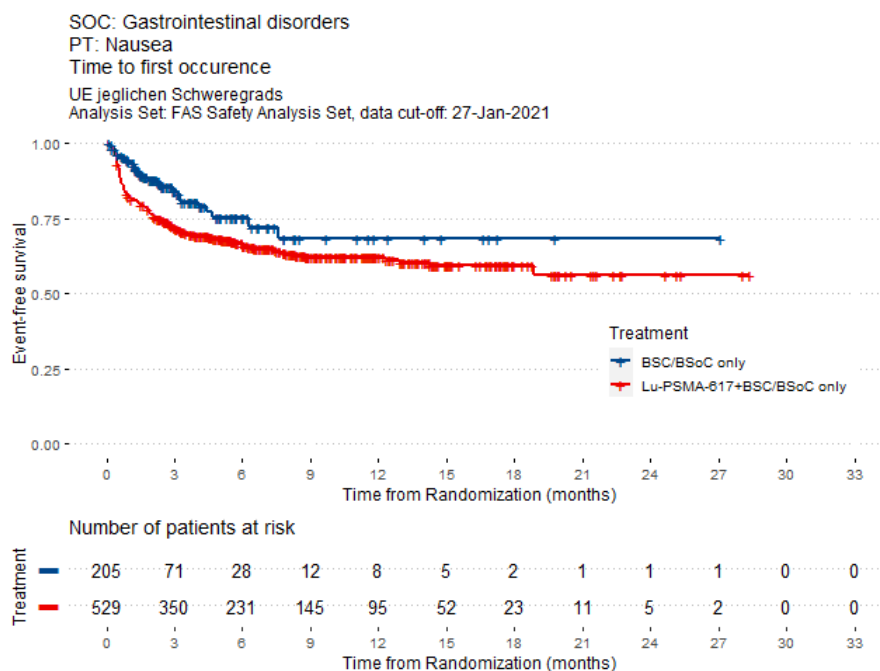


Abbildung 21: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Nausea

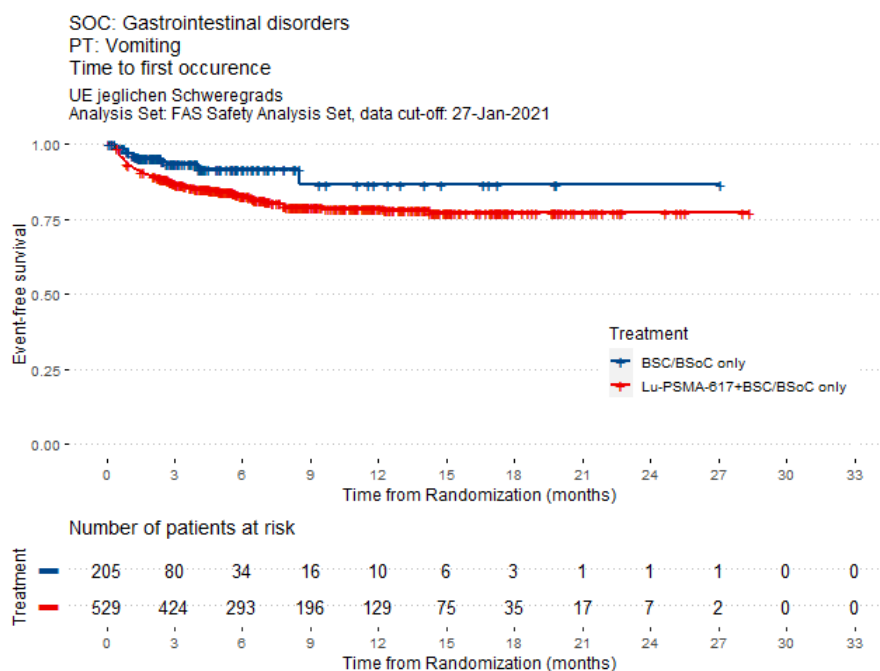


Abbildung 22: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Vomiting

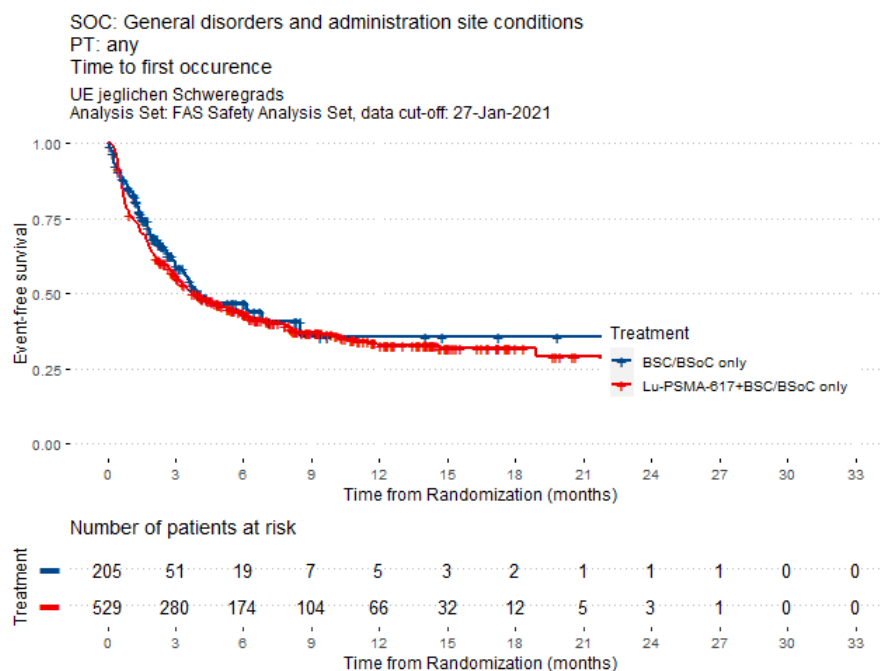


Abbildung 23: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: any

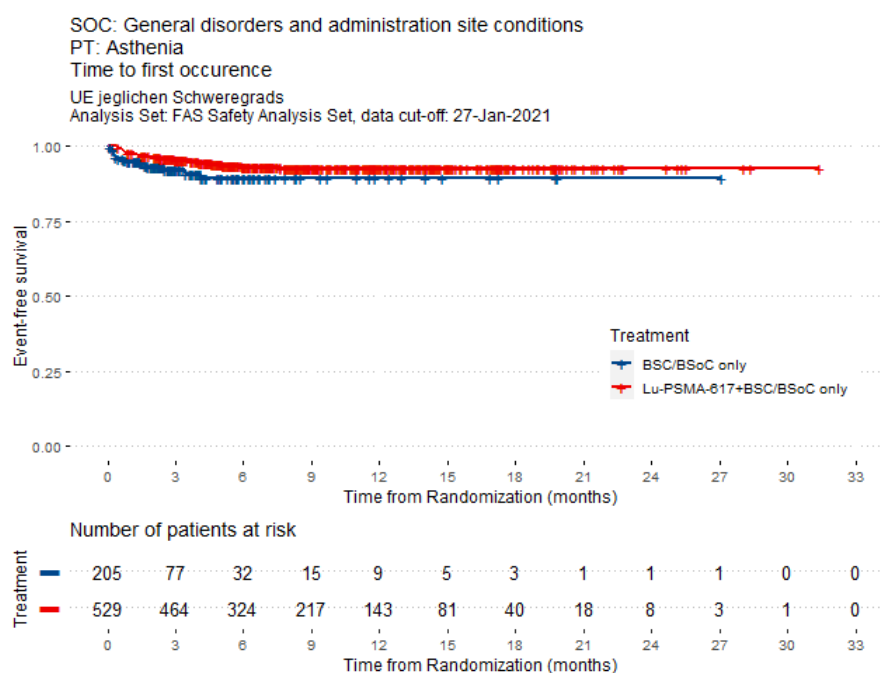


Abbildung 24: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Asthenia

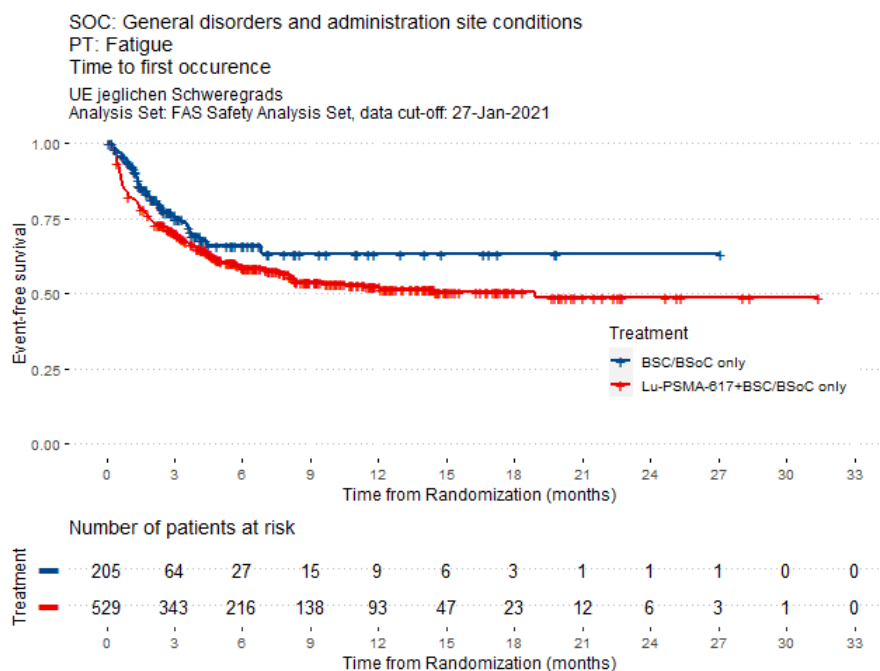


Abbildung 25: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Fatigue

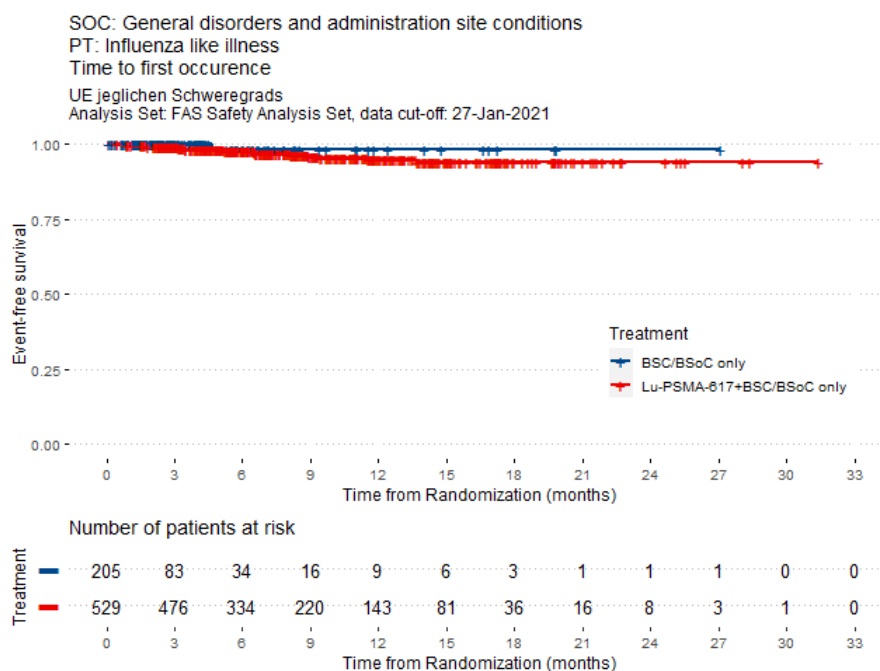


Abbildung 26: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Influenza like illness

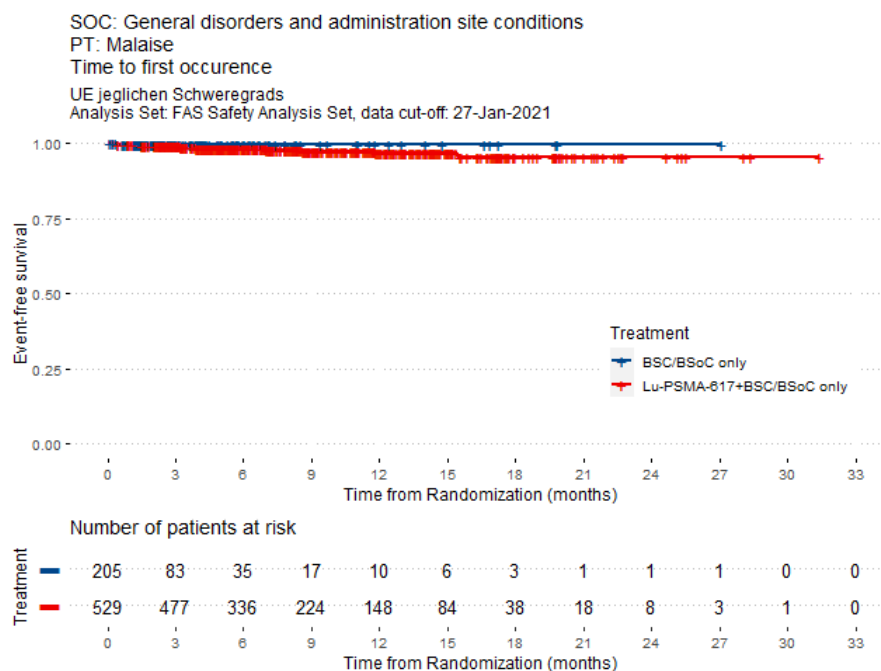


Abbildung 27: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Malaise

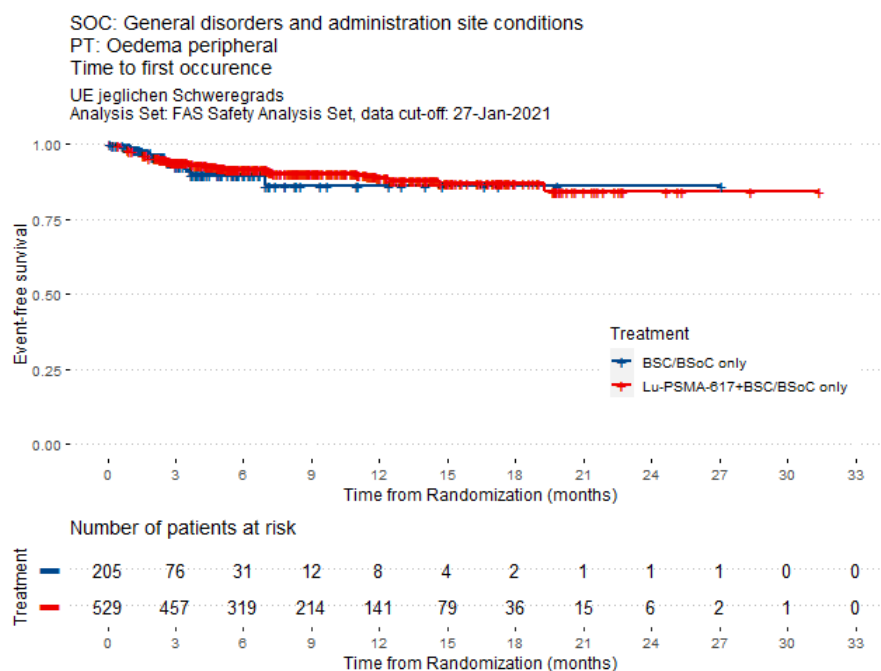


Abbildung 28: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Oedema peripheral

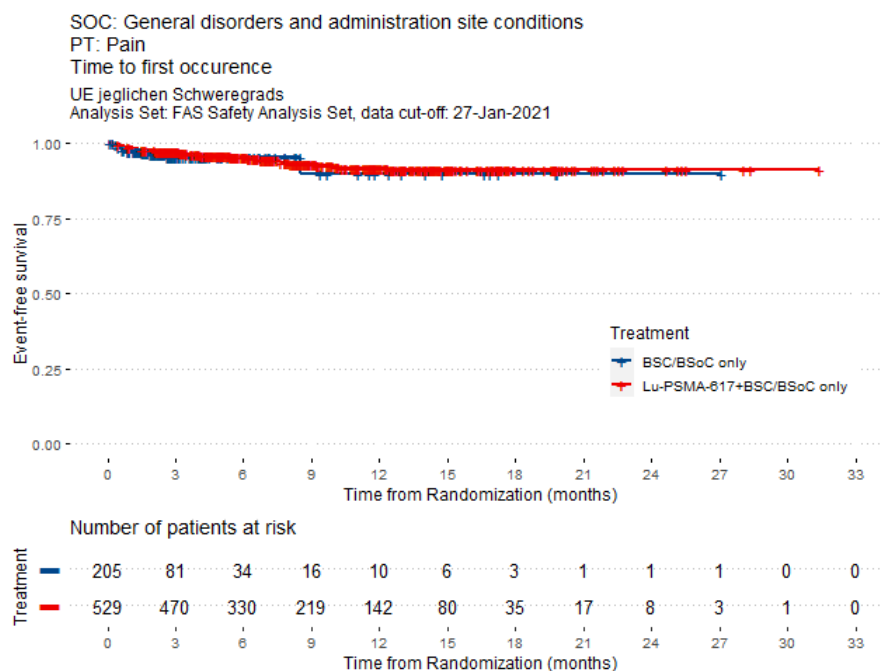


Abbildung 29: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Pain

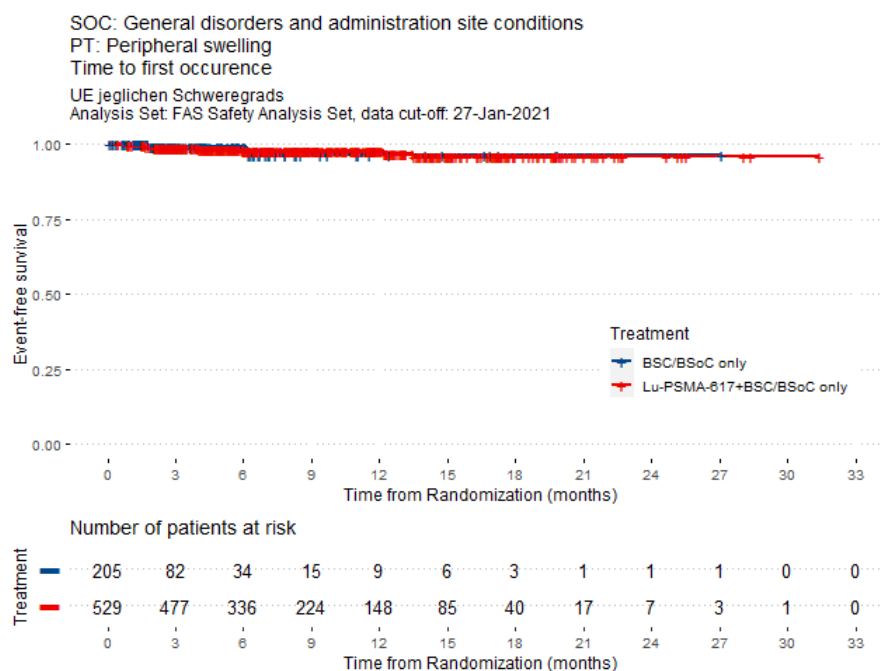


Abbildung 30: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Peripheral swelling

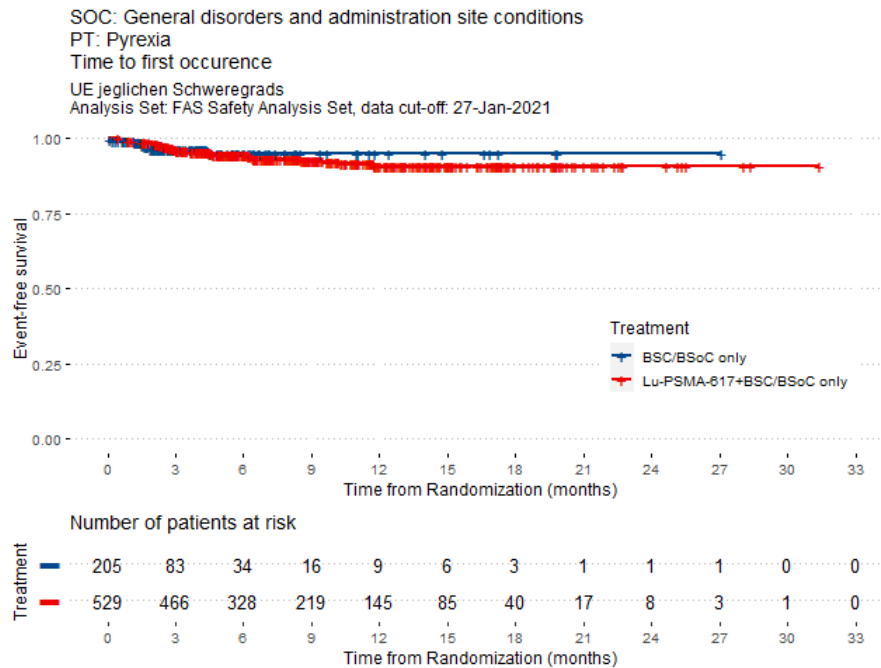


Abbildung 31: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Pyrexia

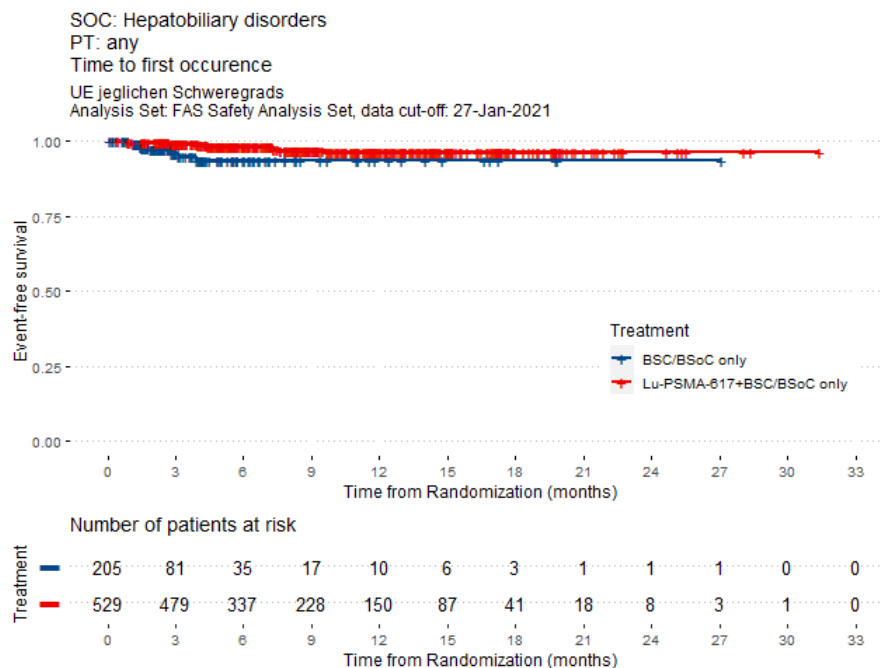


Abbildung 32: UE jeglichen Schweregrads: Time to first occurrence of SOC: Hepatobiliary disorders; PT: any

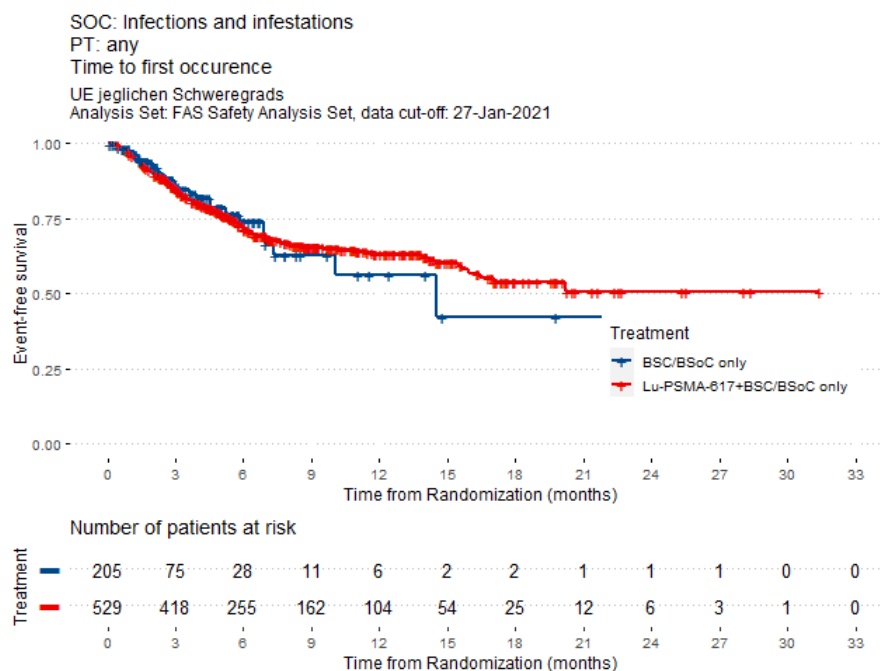


Abbildung 33: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: any

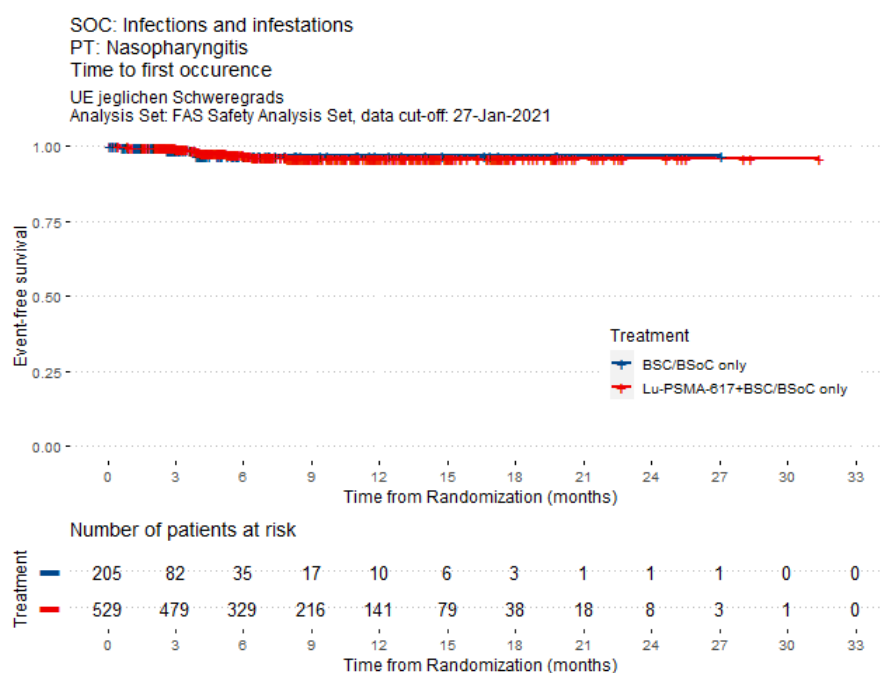


Abbildung 34: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Nasopharyngitis

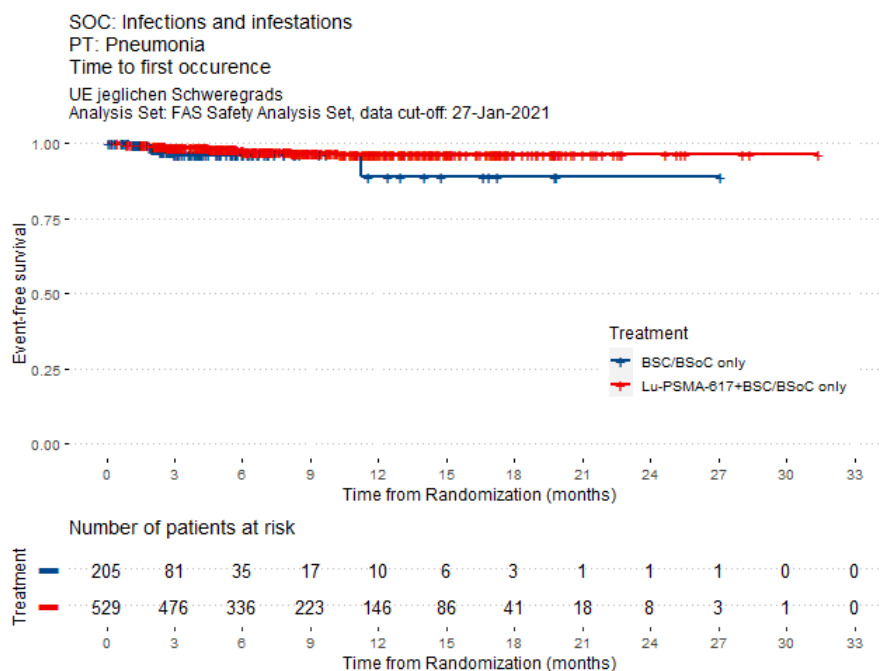


Abbildung 35: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Pneumonia

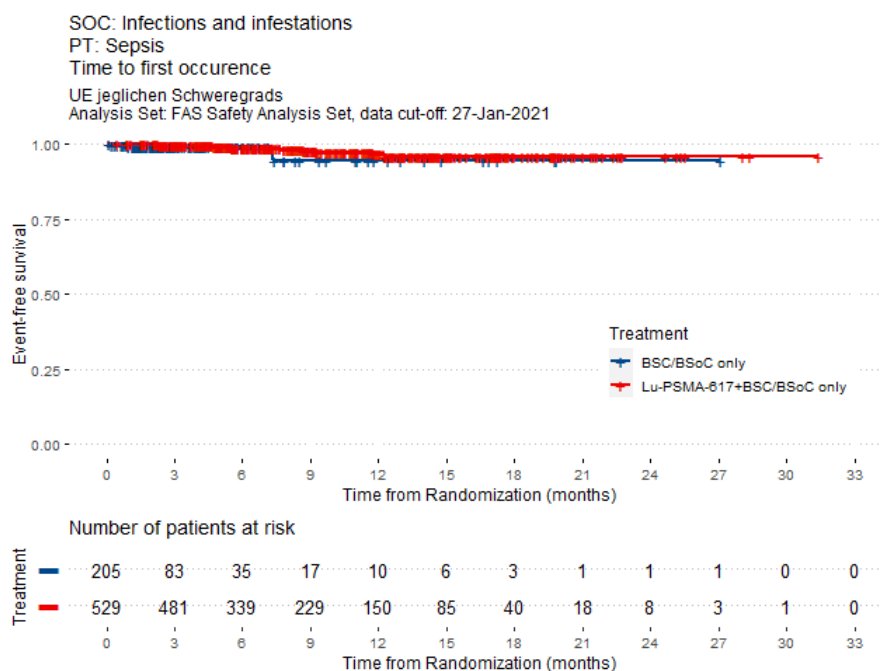


Abbildung 36: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Sepsis

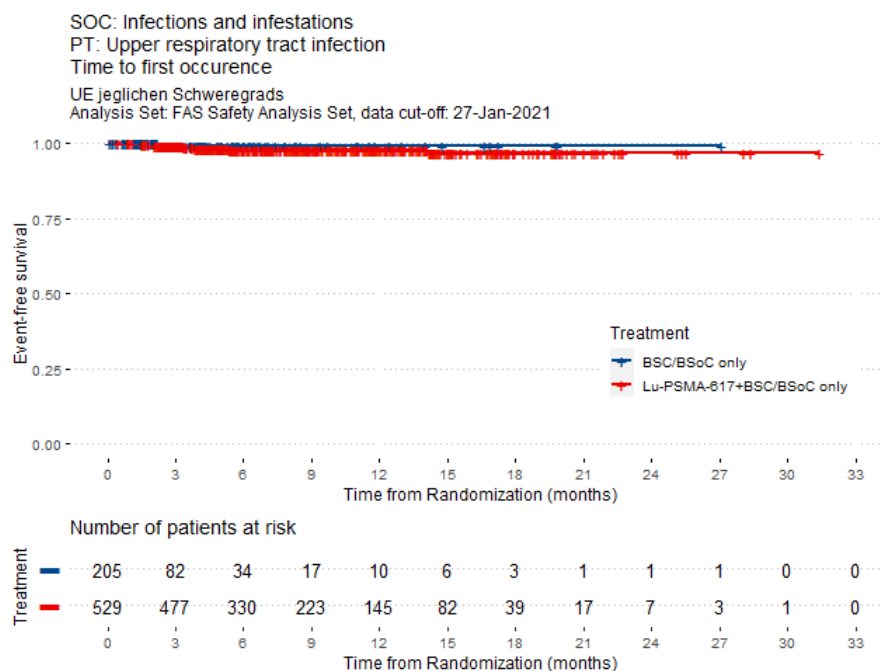


Abbildung 37: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Upper respiratory tract infection

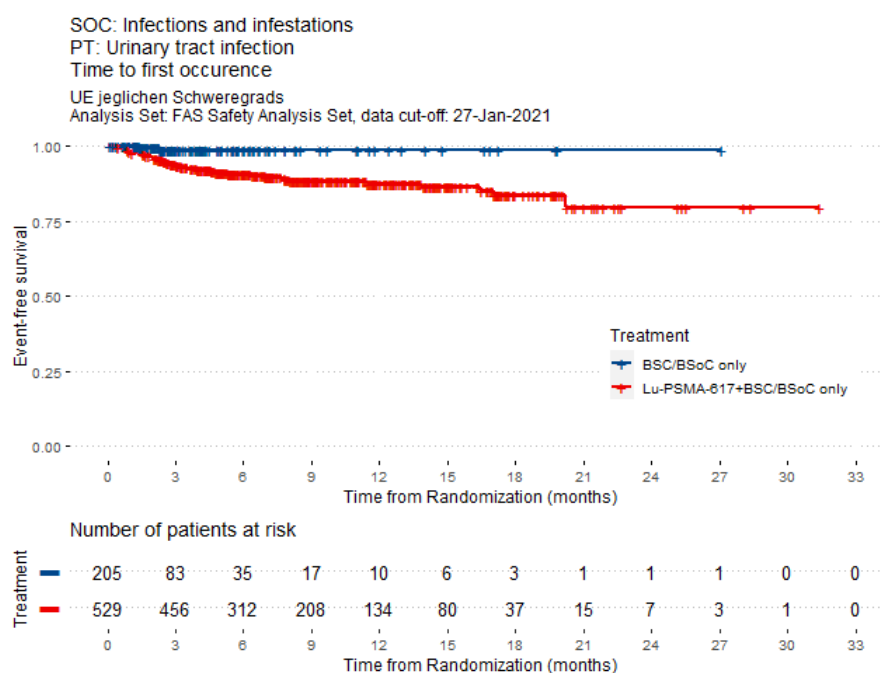


Abbildung 38: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Urinary tract infection

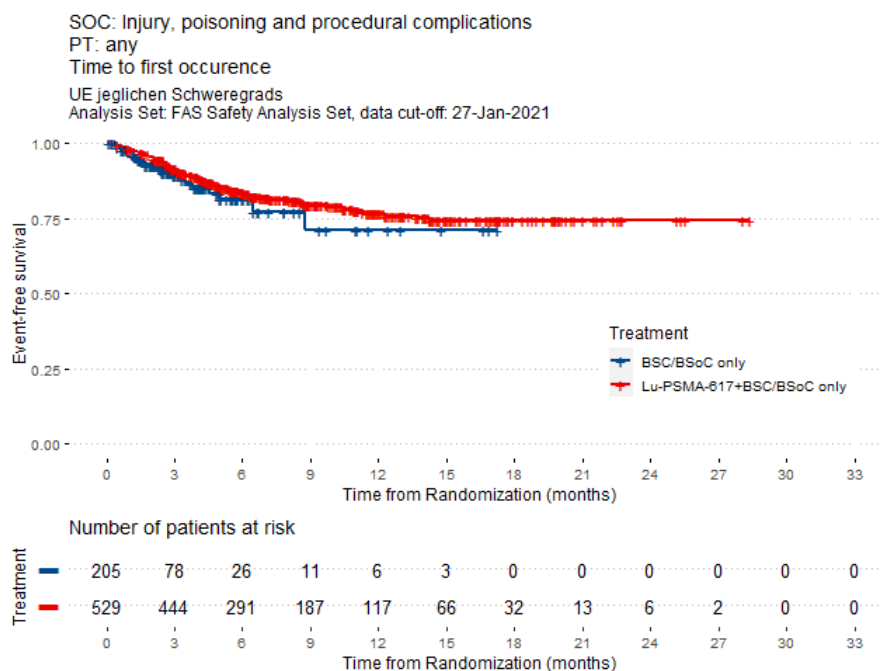


Abbildung 39: UE jeglichen Schweregrads: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: any

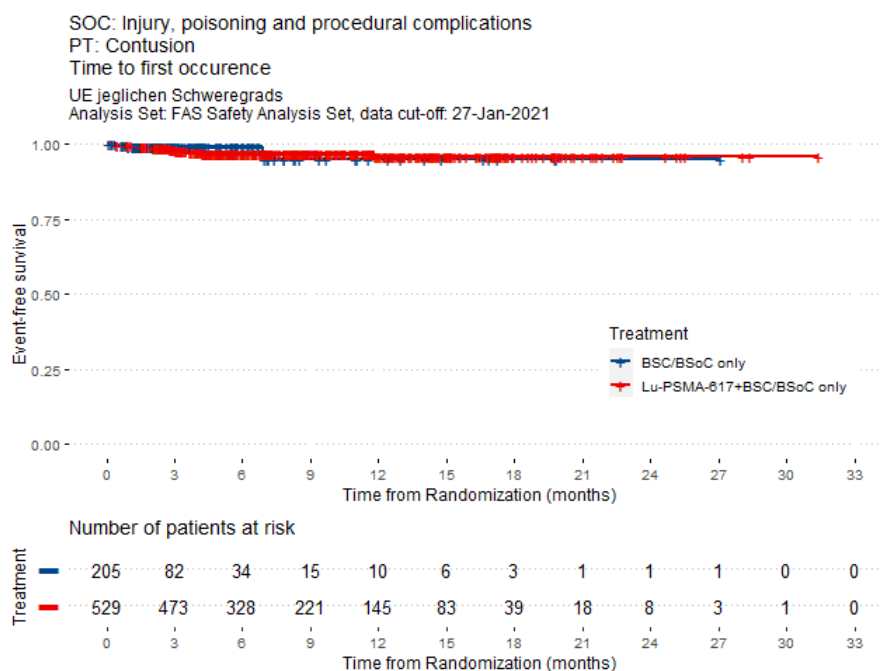


Abbildung 40: UE jeglichen Schweregrads: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: Contusion

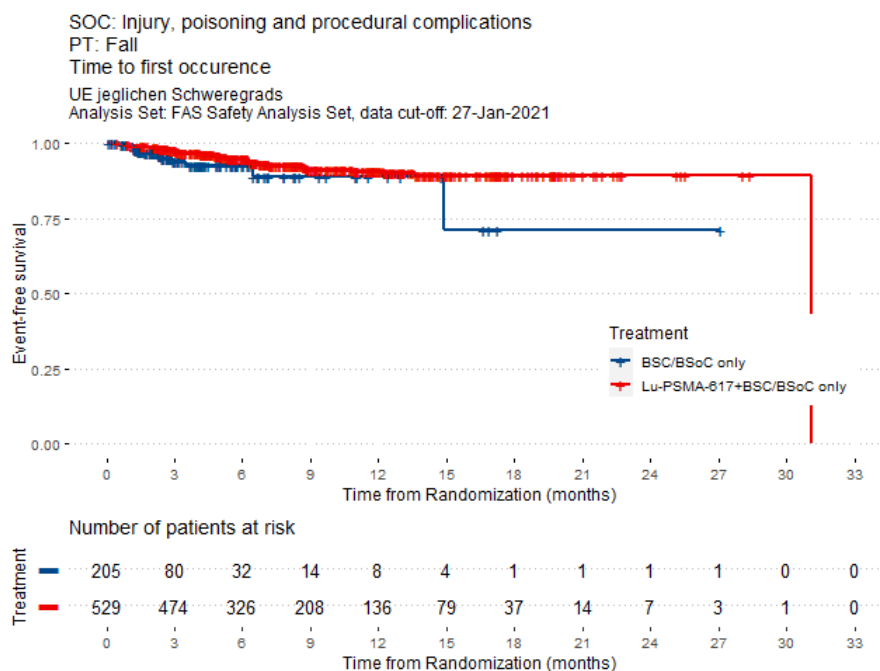


Abbildung 41: UE jeglichen Schweregrads: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: Fall

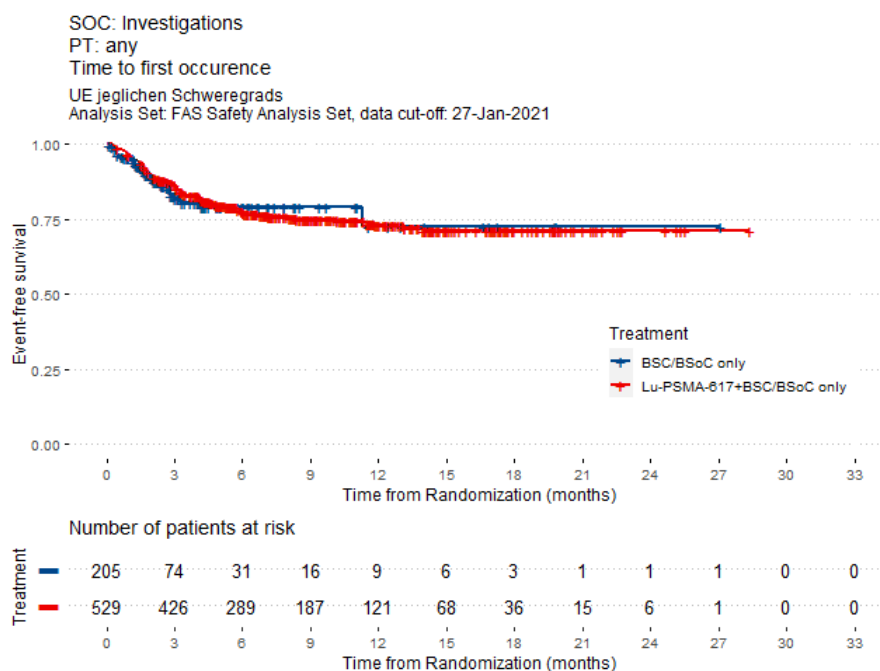


Abbildung 42: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: any

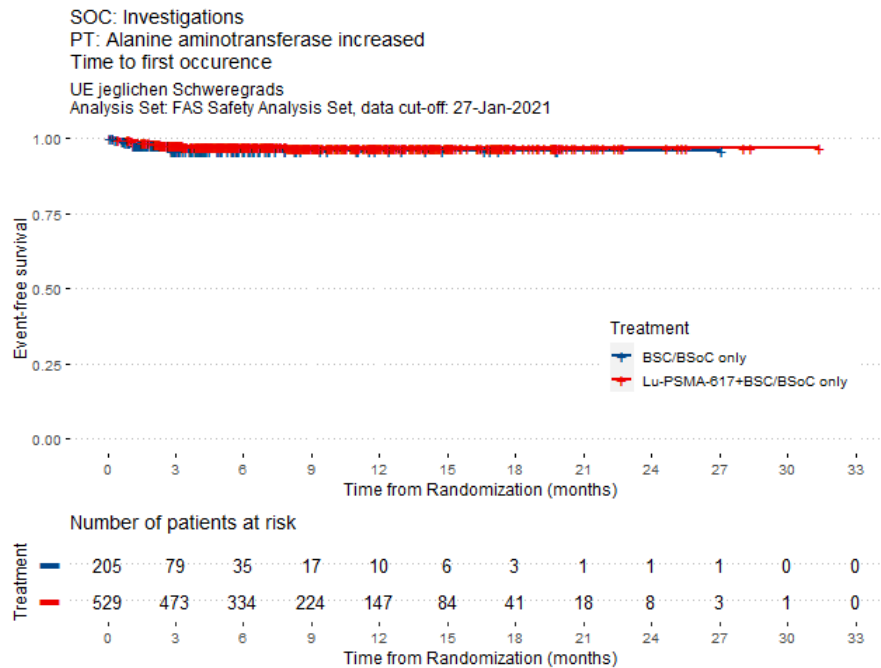


Abbildung 43: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations;
PT: Alanine aminotransferase increased

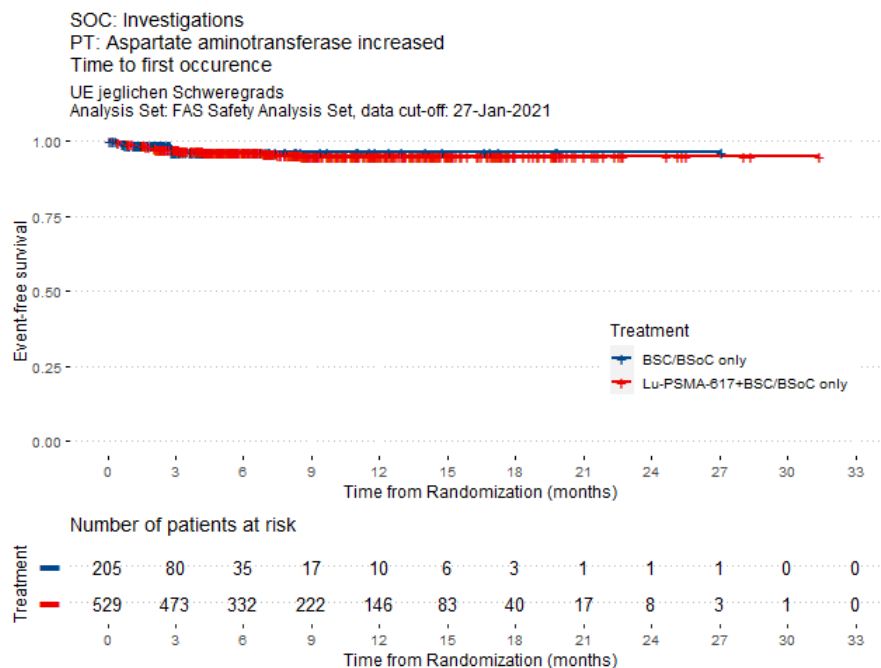


Abbildung 44: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations;
PT: Aspartate aminotransferase increased

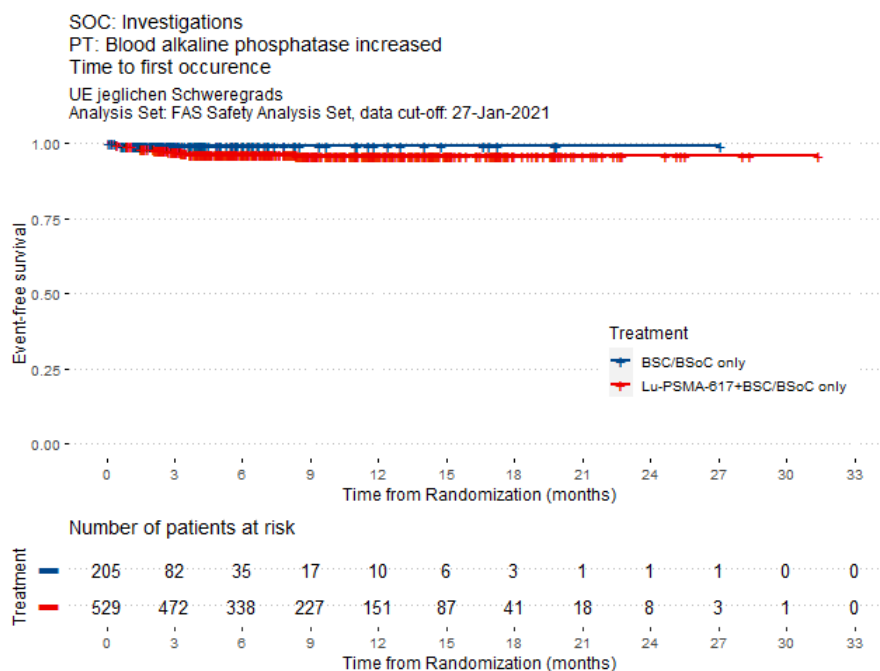


Abbildung 45: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations;
PT: Blood alkaline phosphatase increased

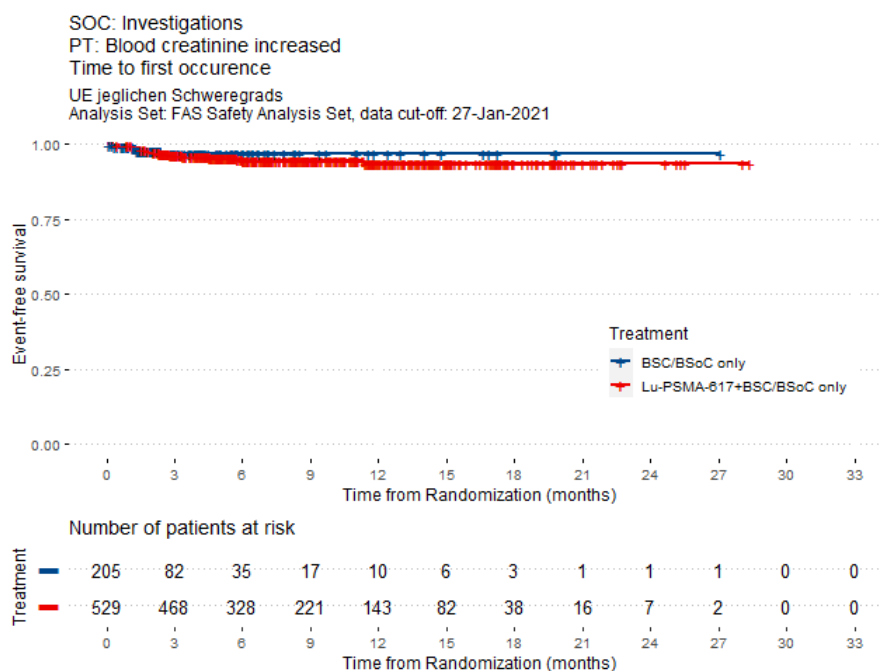


Abbildung 46: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations;
PT: Blood creatinine increased

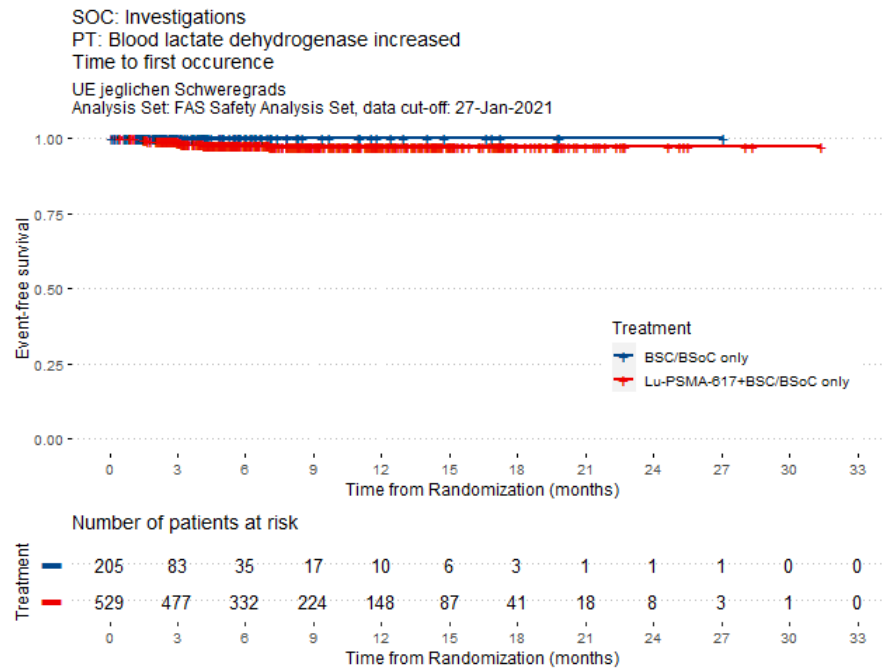


Abbildung 47: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations;
PT: Blood lactate dehydrogenase increased

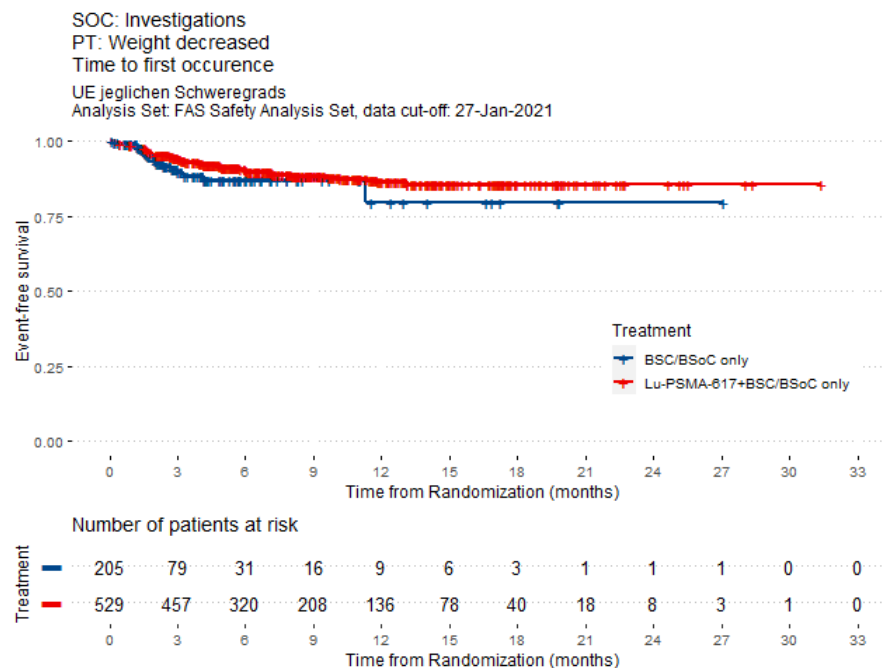


Abbildung 48: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations;
PT: Weight decreased

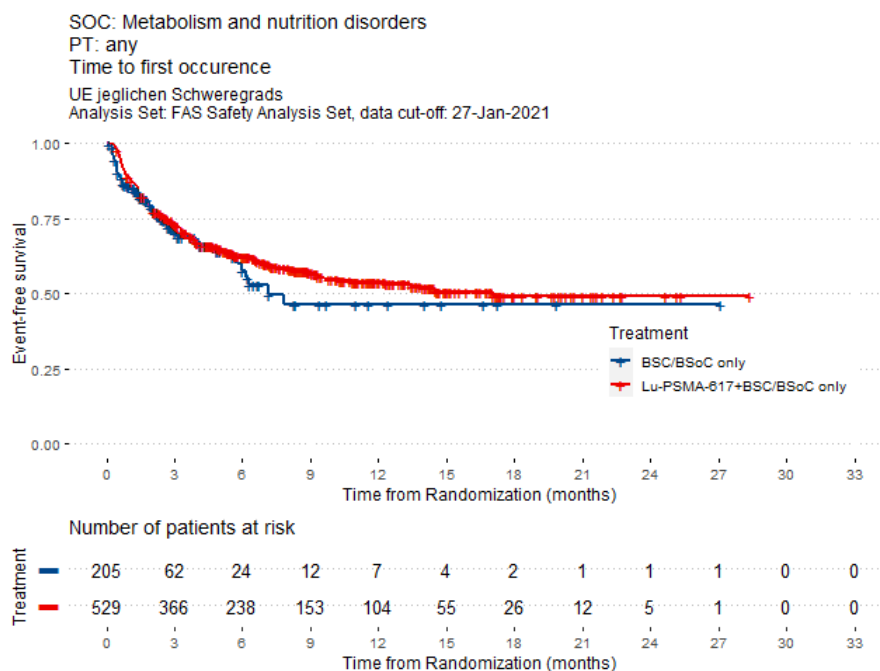


Abbildung 49: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: any

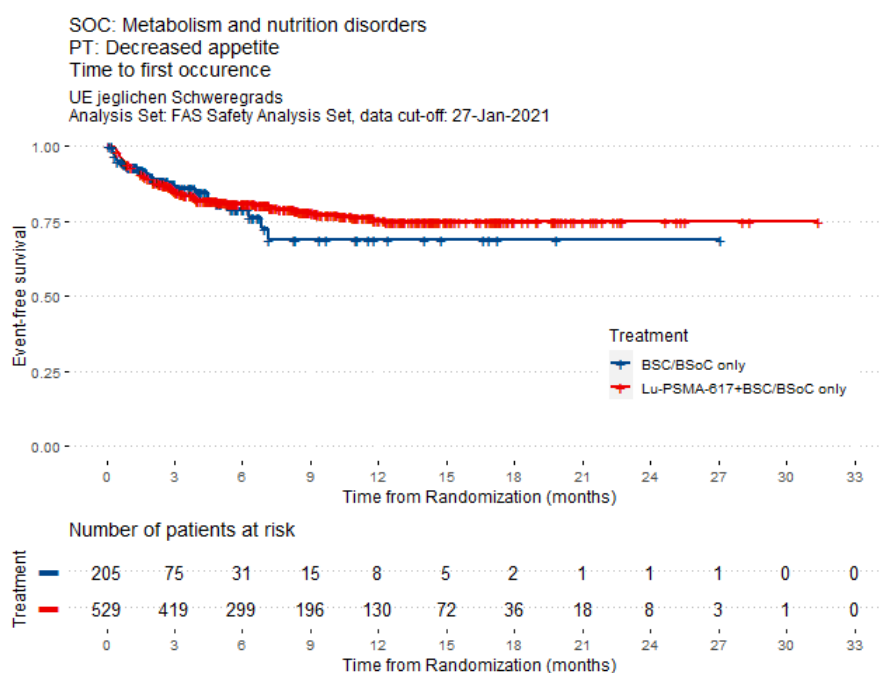


Abbildung 50: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Decreased appetite

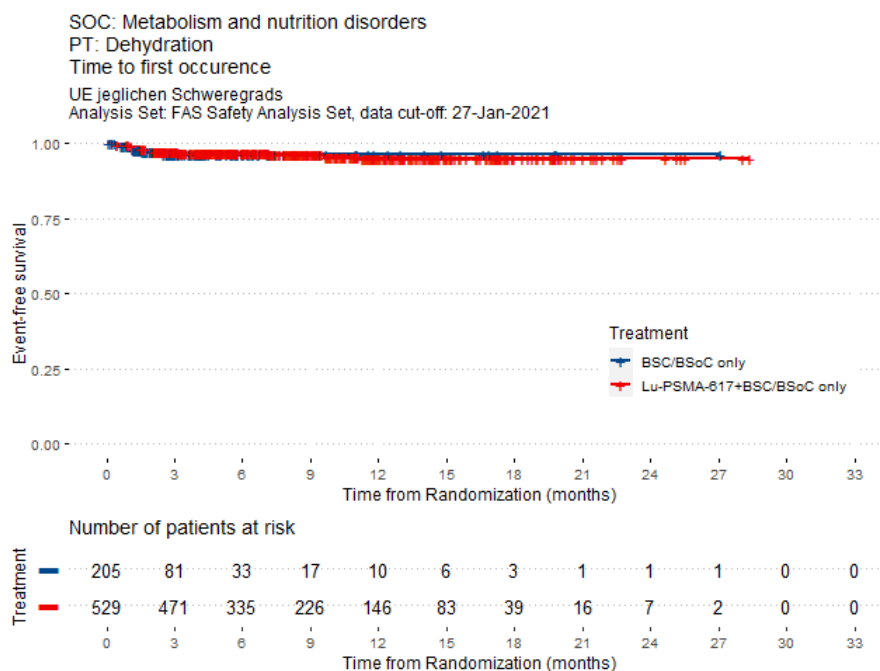


Abbildung 51: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Dehydration

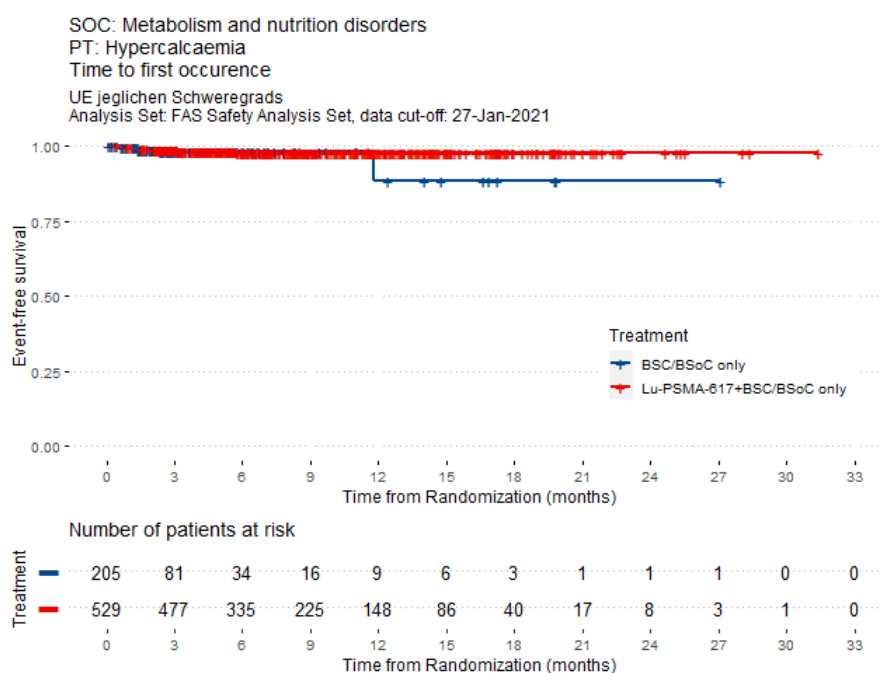


Abbildung 52: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypercalcaemia

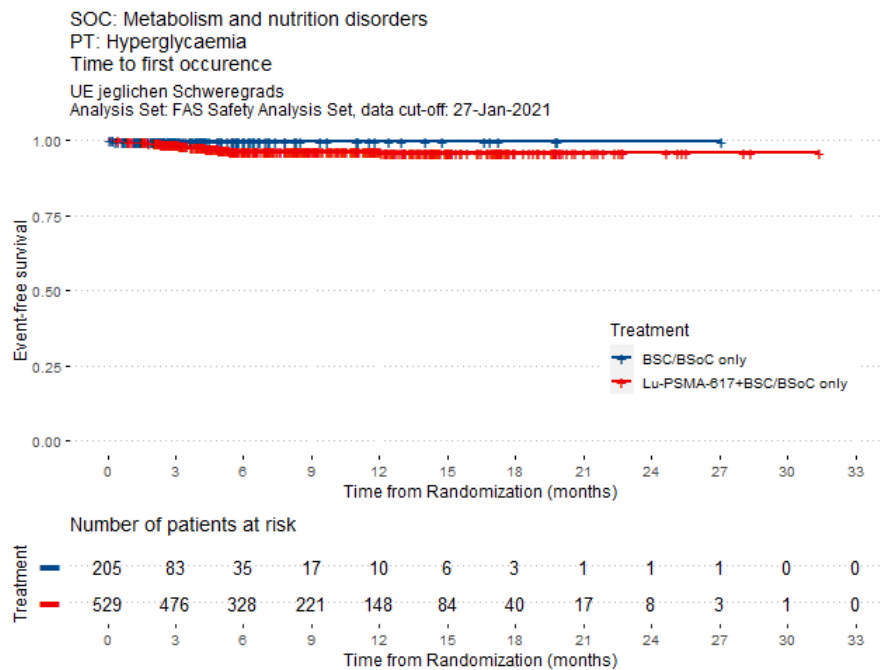


Abbildung 53: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hyperglycaemia

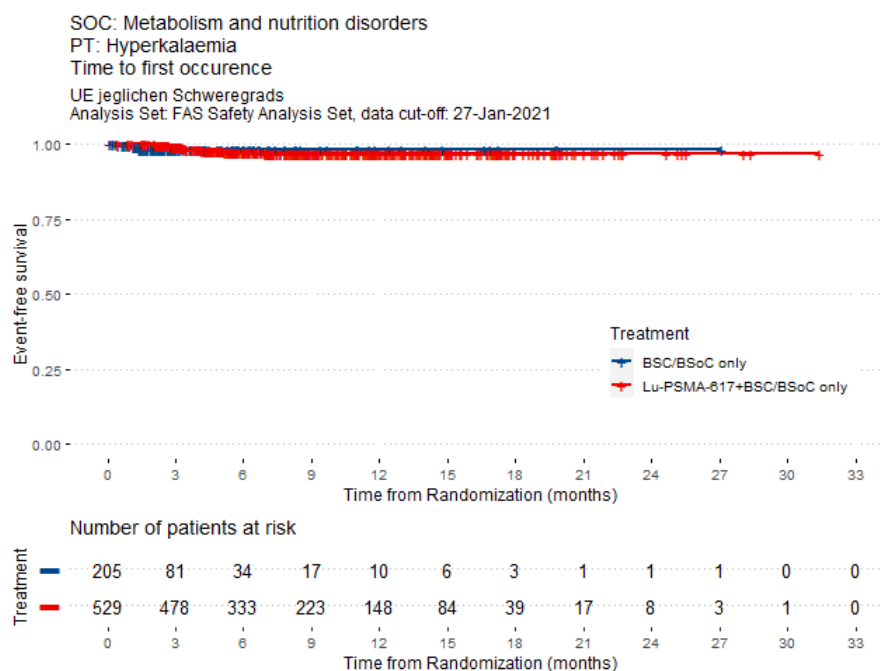


Abbildung 54: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hyperkalaemia

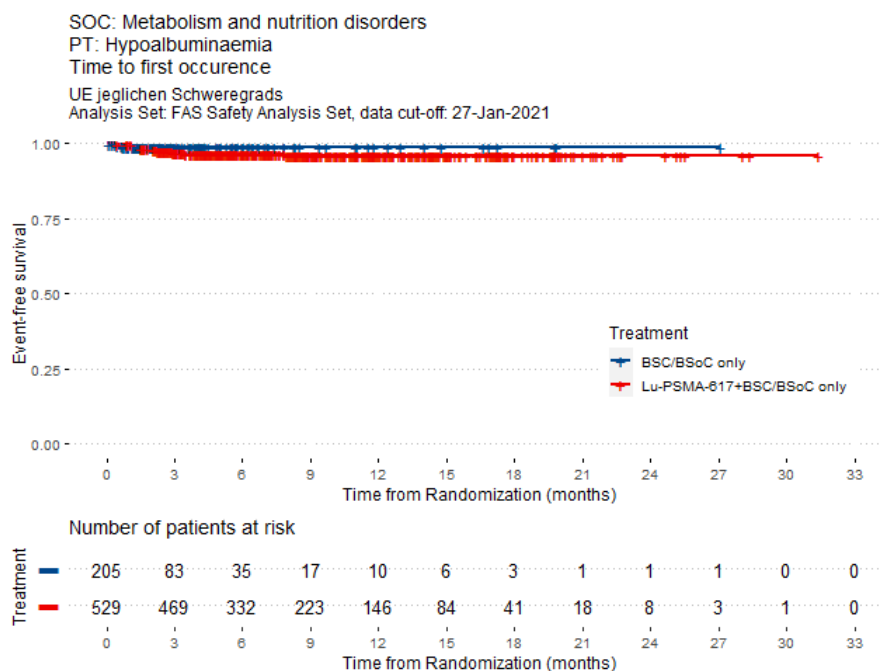


Abbildung 55: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypoalbuminaemia

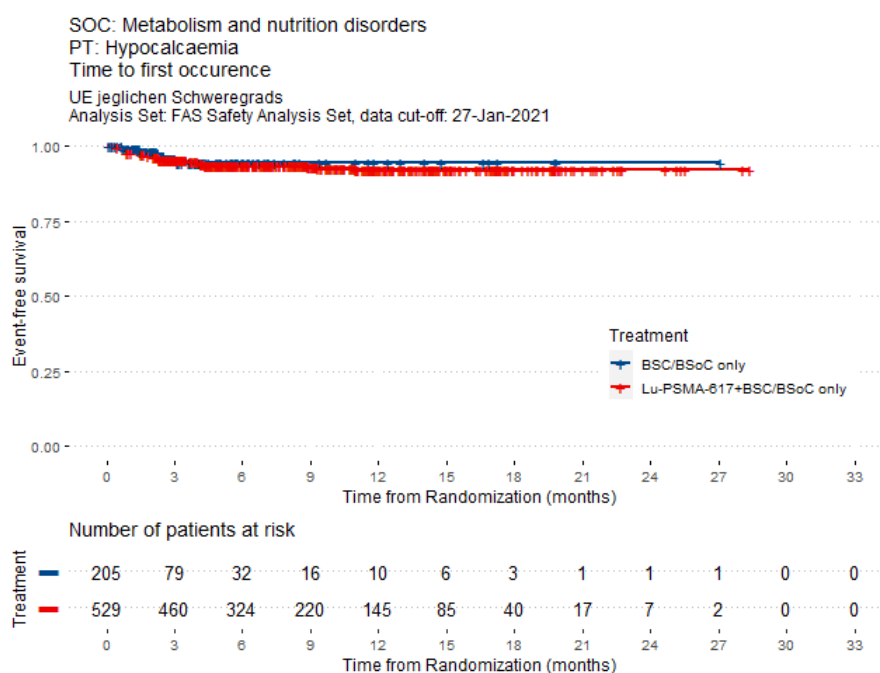


Abbildung 56: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypocalcaemia

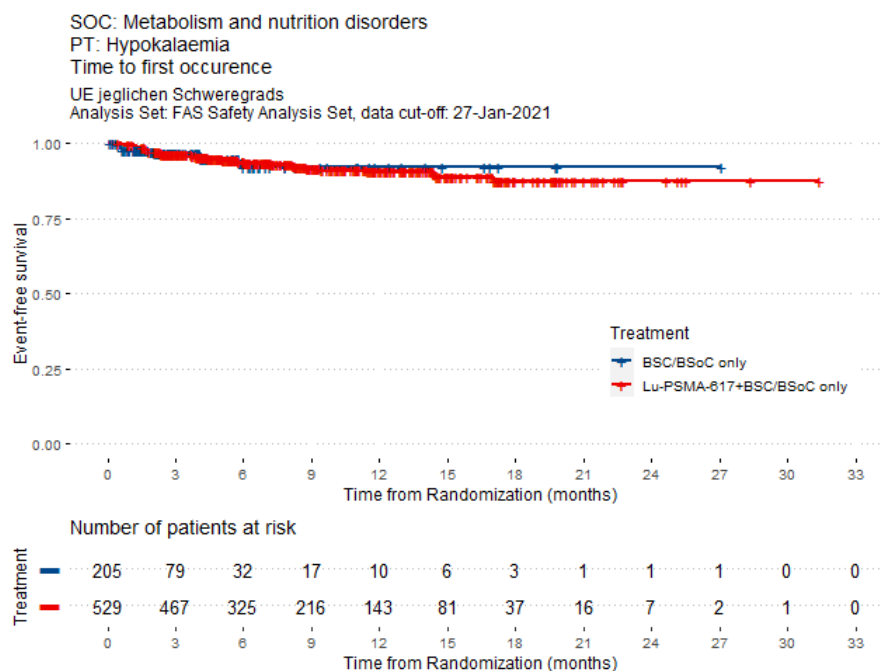


Abbildung 57: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

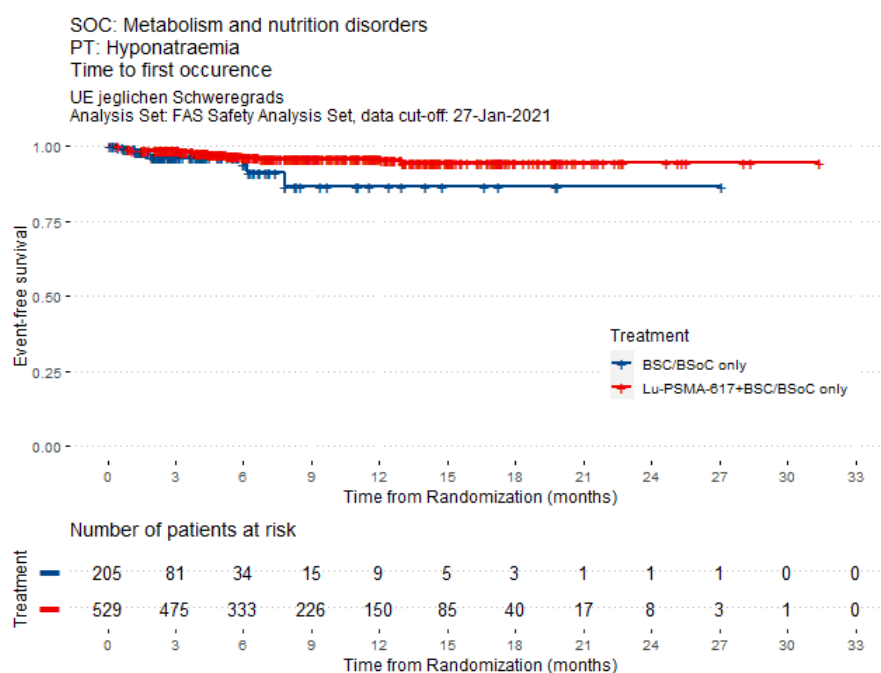


Abbildung 58: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hyponatraemia

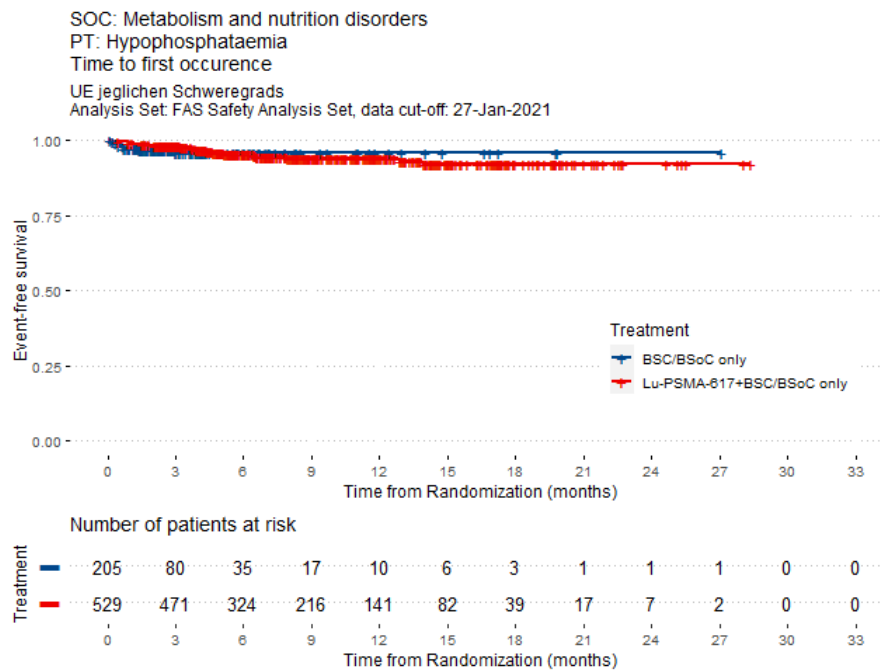


Abbildung 59: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypophosphataemia

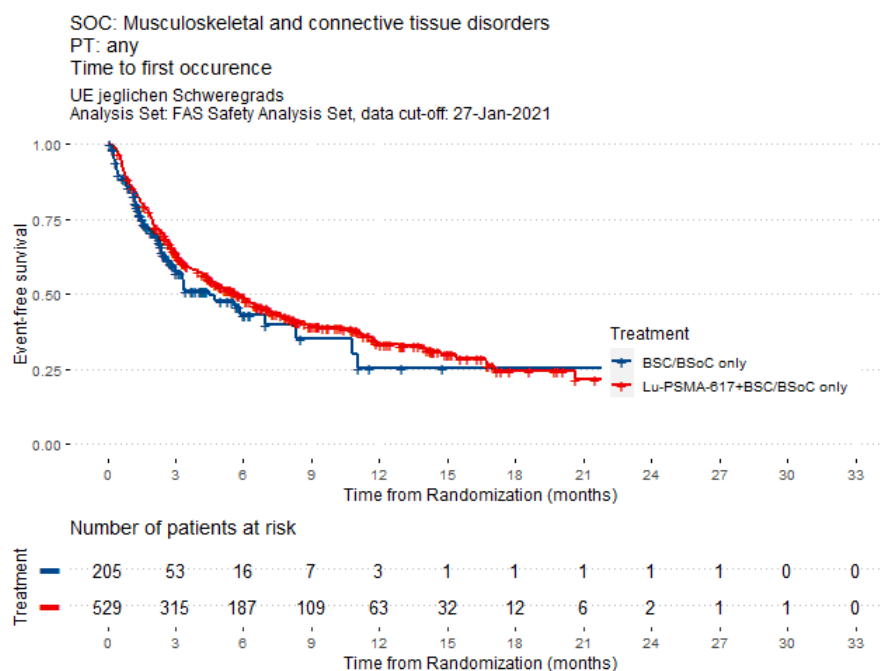


Abbildung 60: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: any

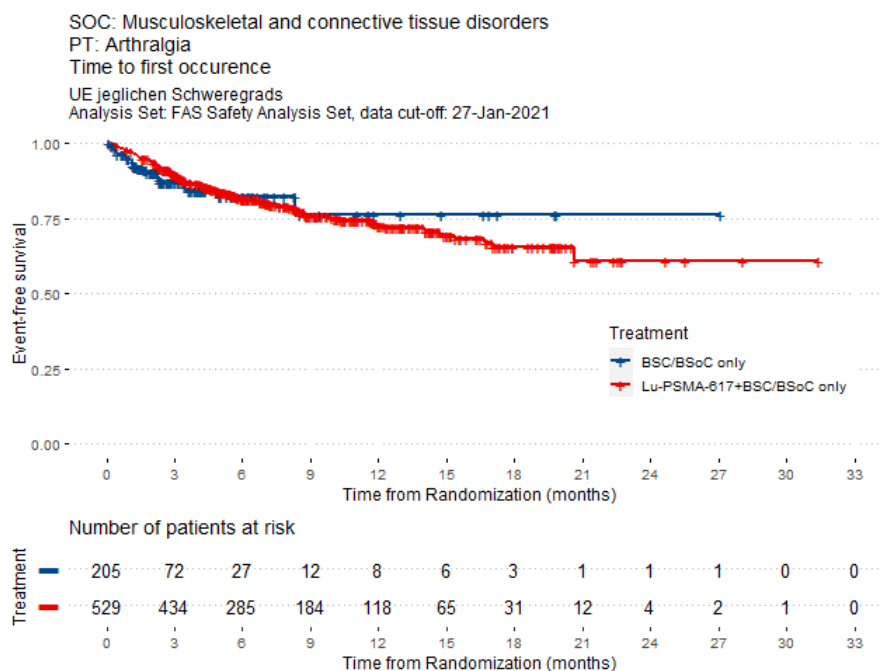


Abbildung 61: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Arthralgia

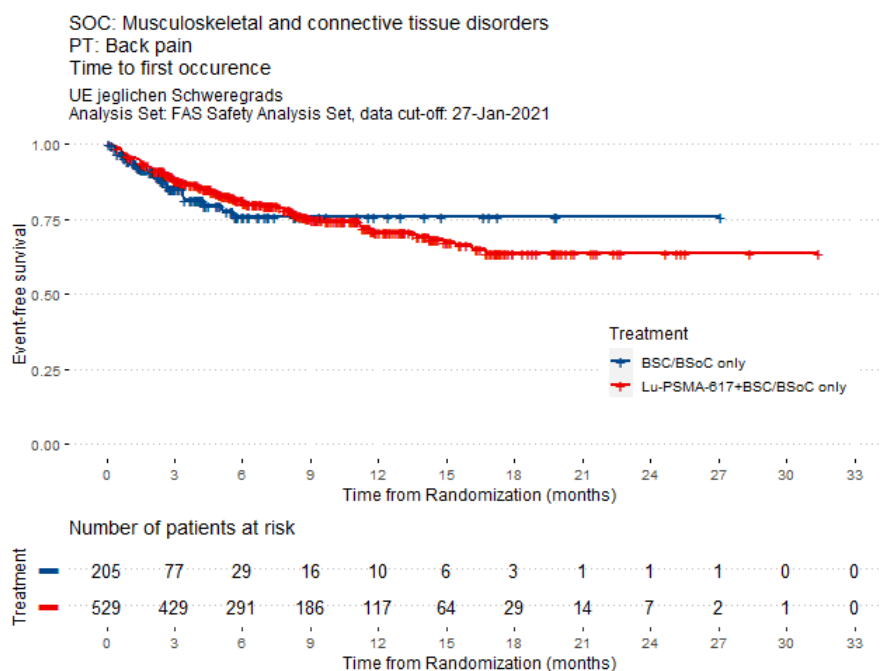


Abbildung 62: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Back pain

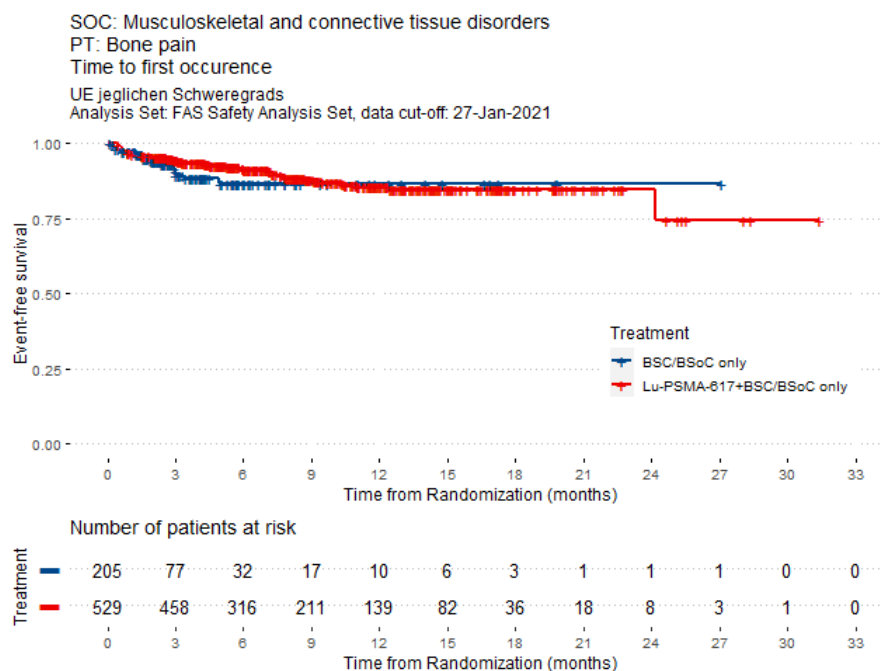


Abbildung 63: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Bone pain

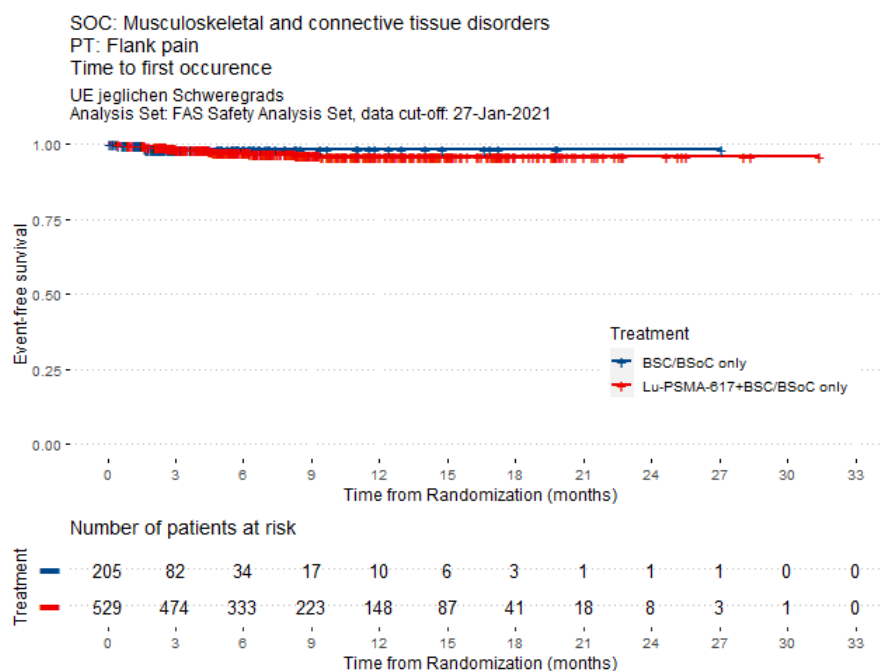


Abbildung 64: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Flank pain

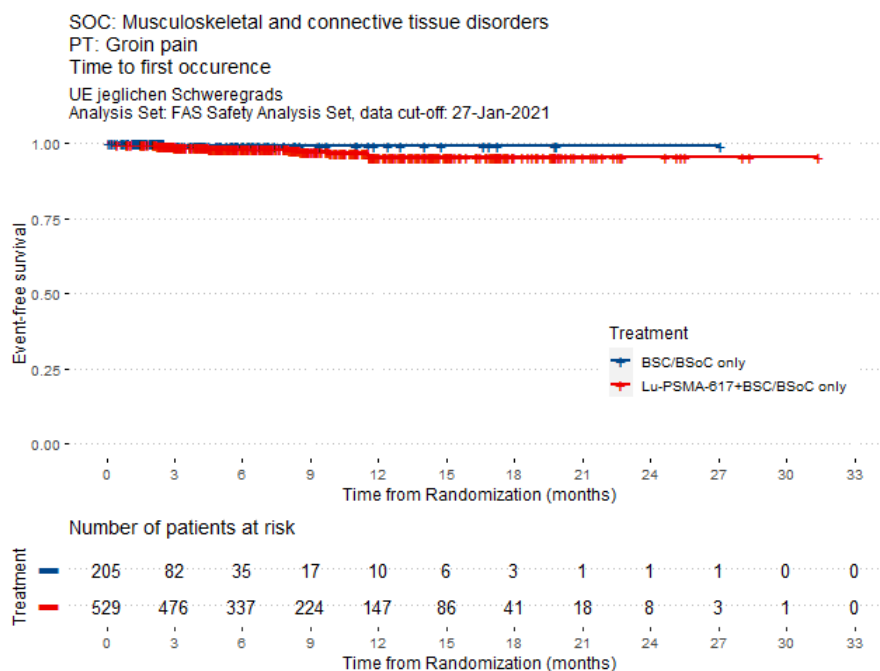


Abbildung 65: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Groin pain

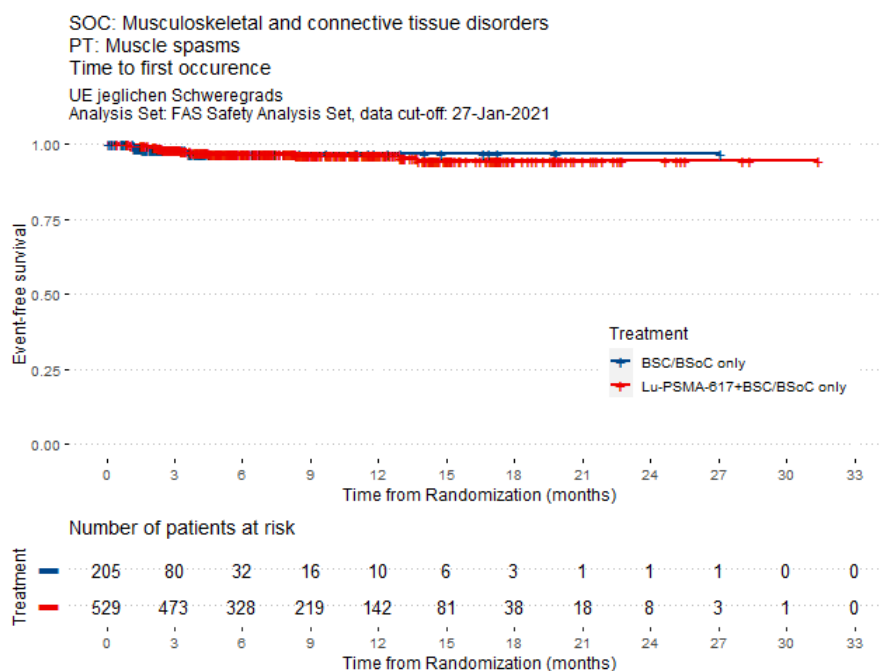


Abbildung 66: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Muscle spasms

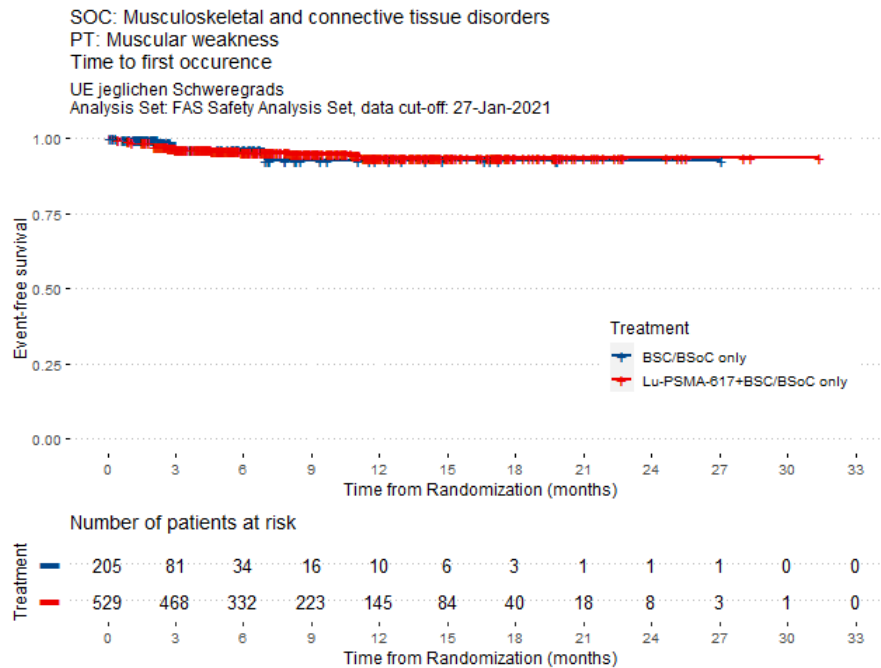


Abbildung 67: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Muscular weakness

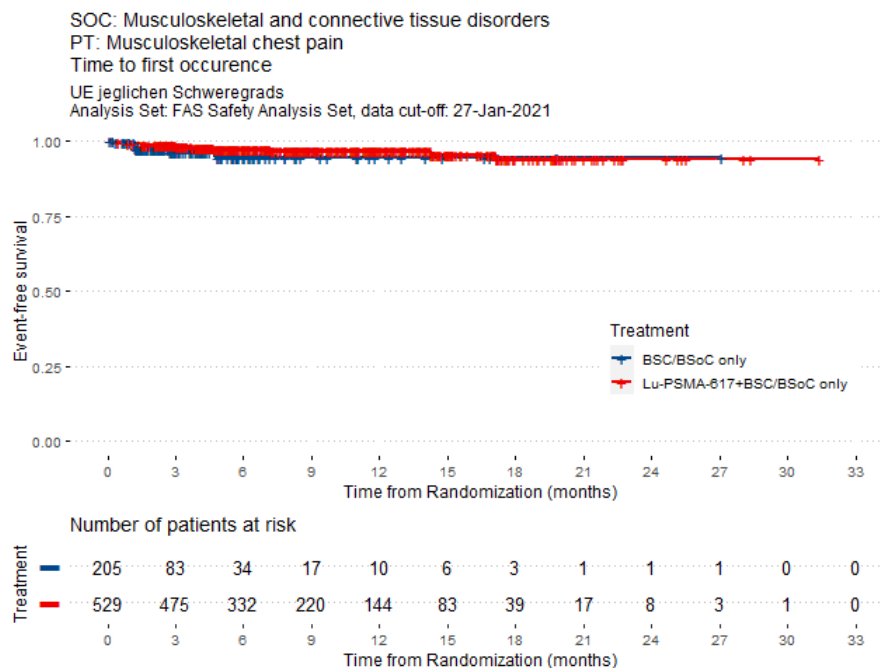


Abbildung 68: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Musculoskeletal chest pain

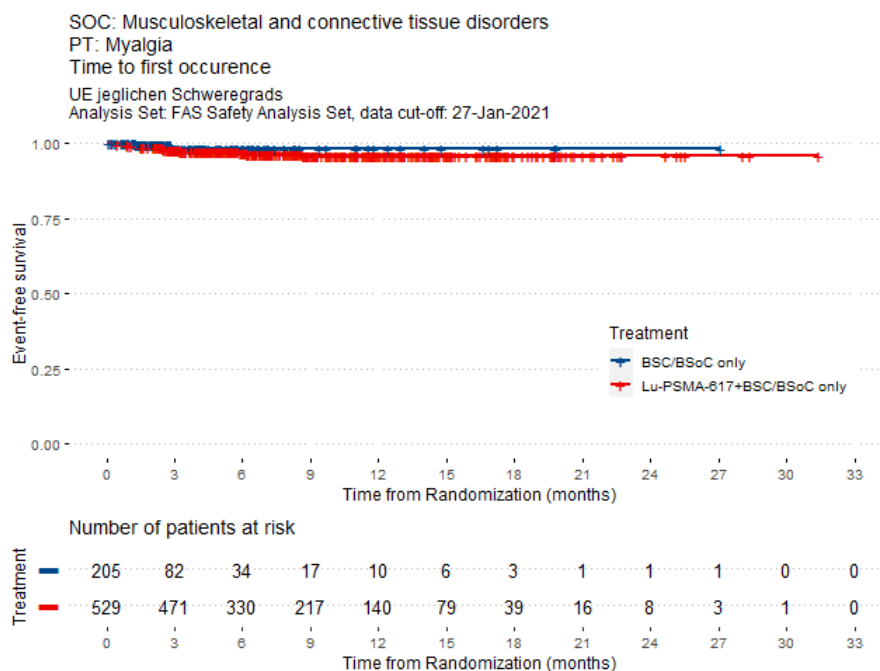


Abbildung 69: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Myalgia

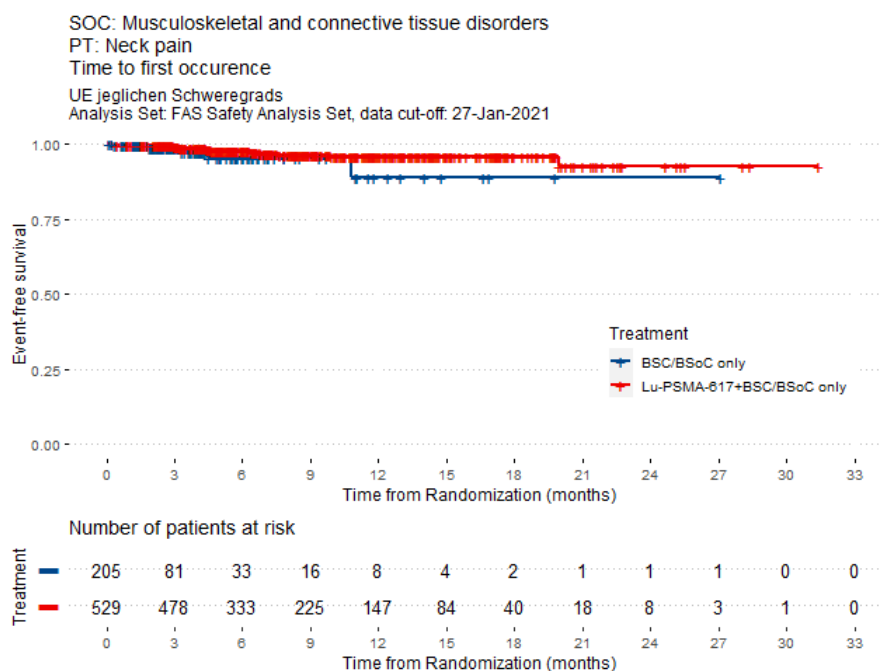


Abbildung 70: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Neck pain

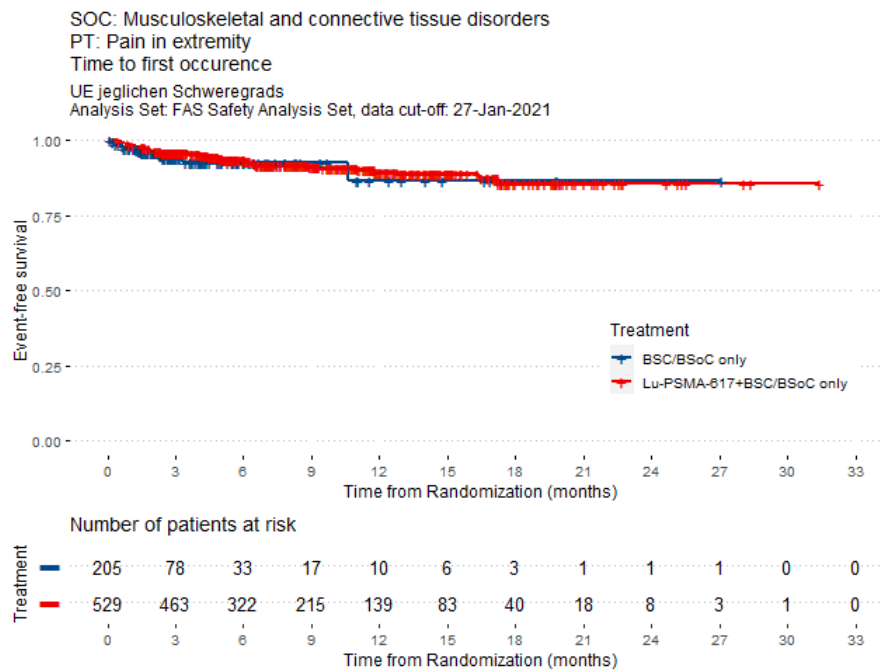


Abbildung 71: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Pain in extremity

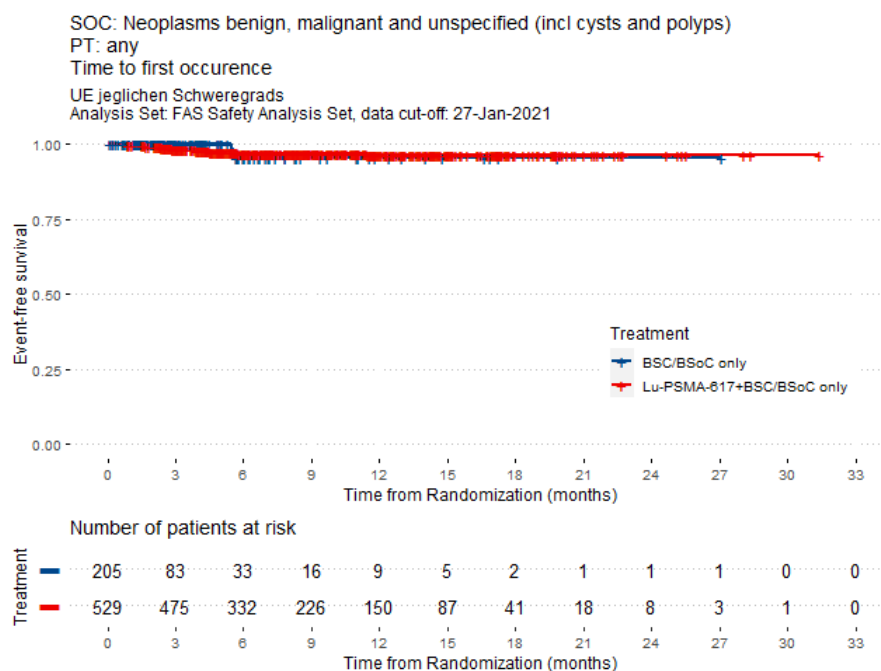


Abbildung 72: UE jeglichen Schweregrads: Time to first occurrence of SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: any

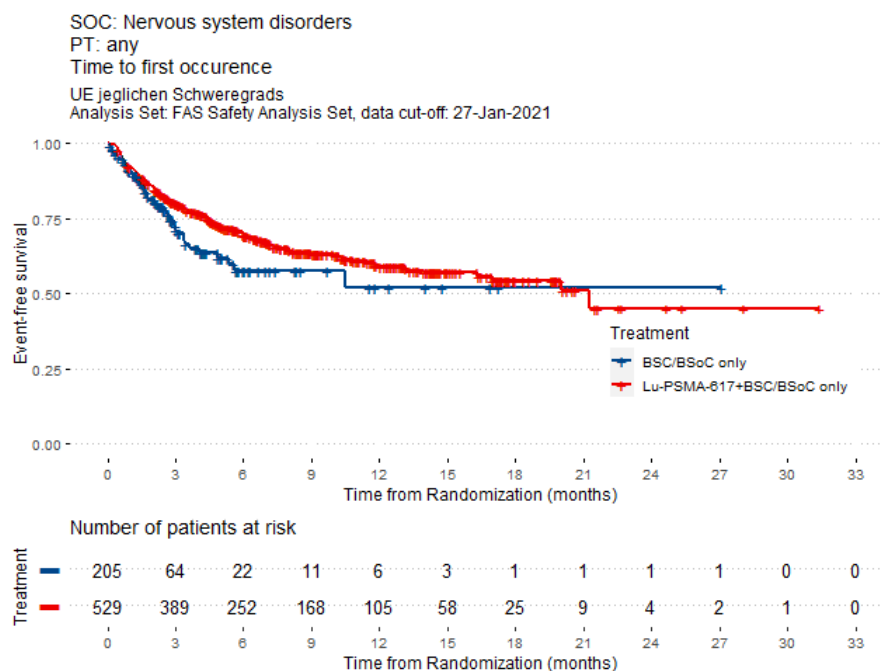


Abbildung 73: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: any

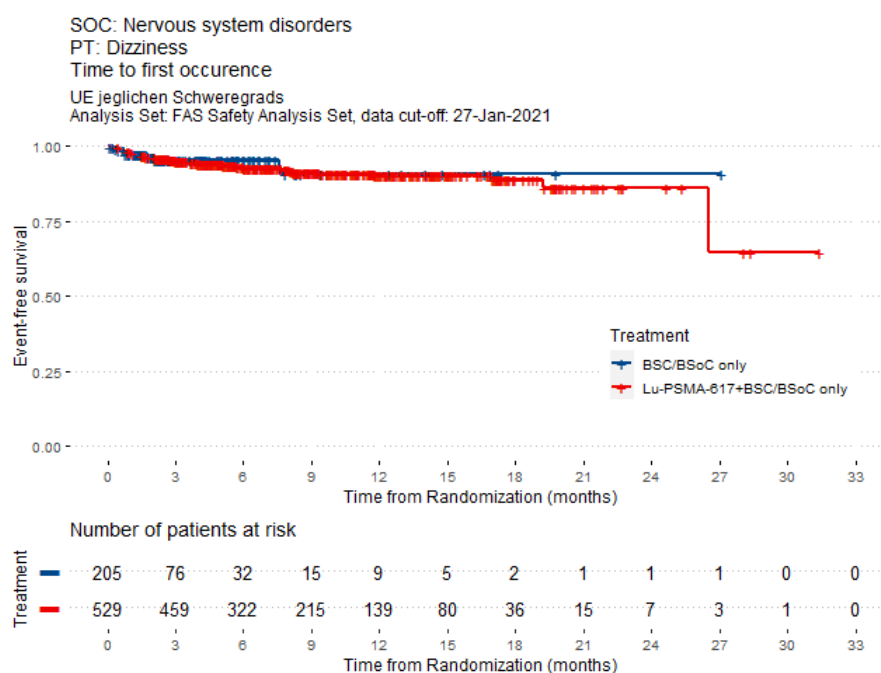


Abbildung 74: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Dizziness

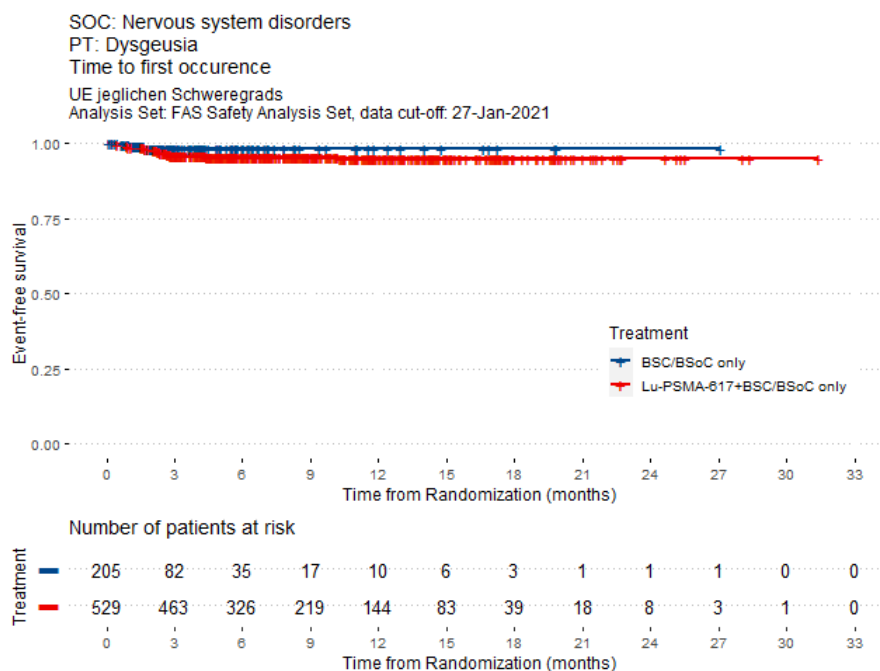


Abbildung 75: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Dysgeusia

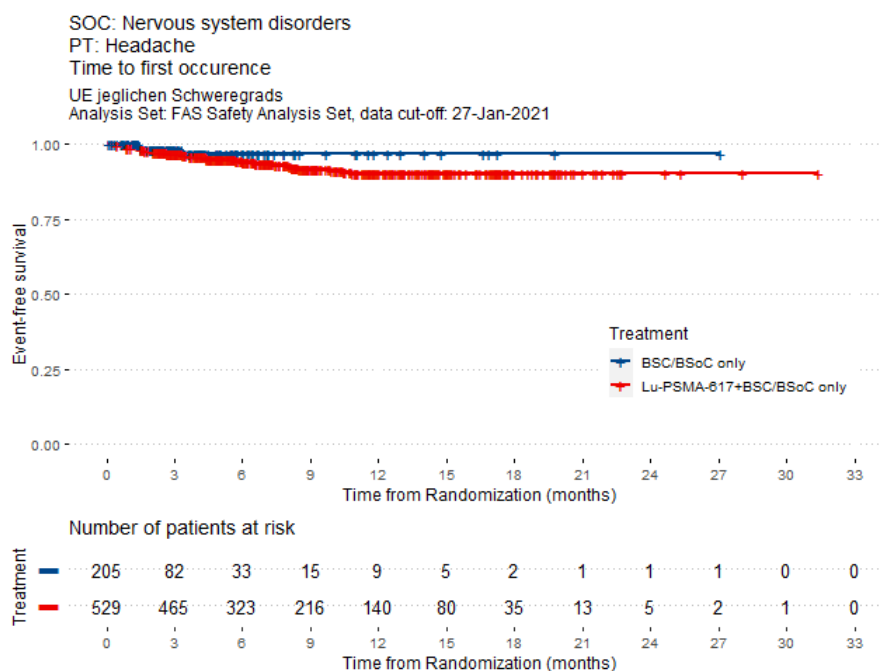


Abbildung 76: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Headache

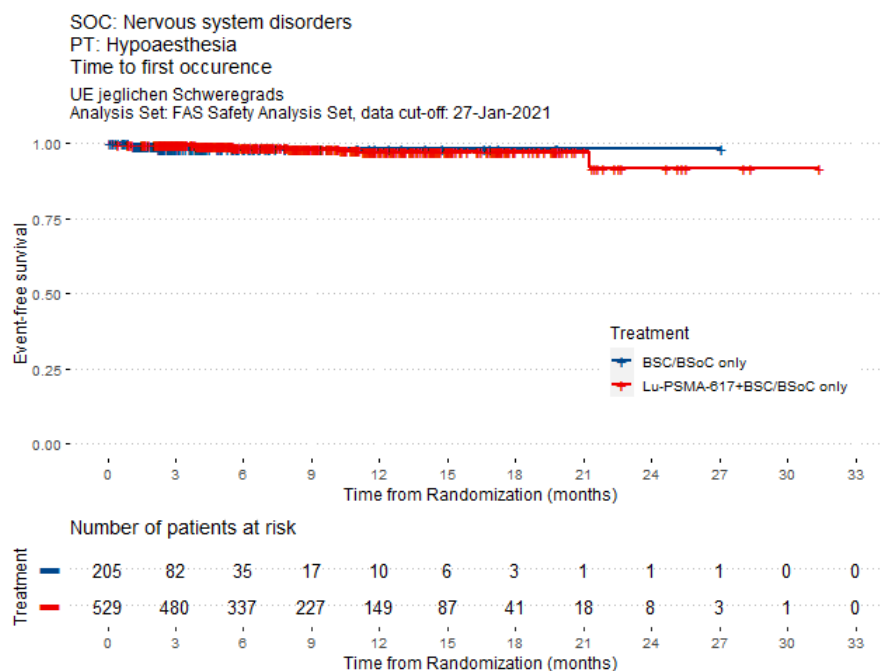


Abbildung 77: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Hypoaesthesia

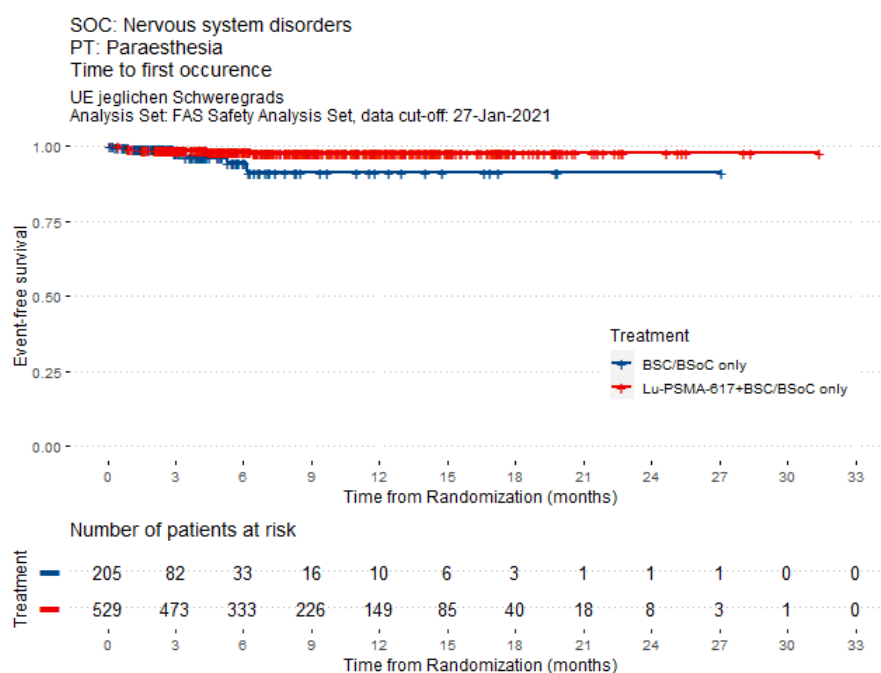


Abbildung 78: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Paraesthesia

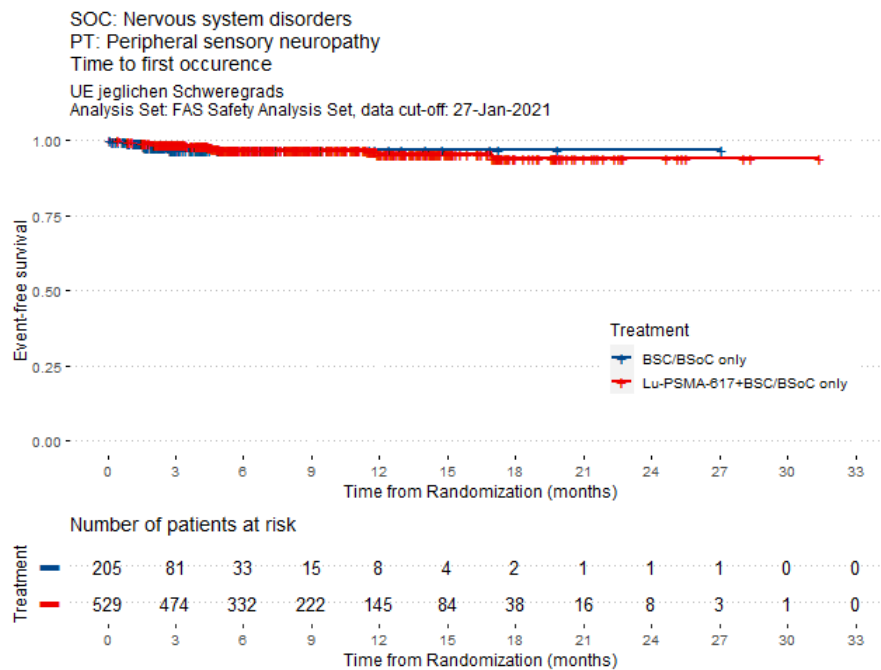


Abbildung 79: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Peripheral sensory neuropathy

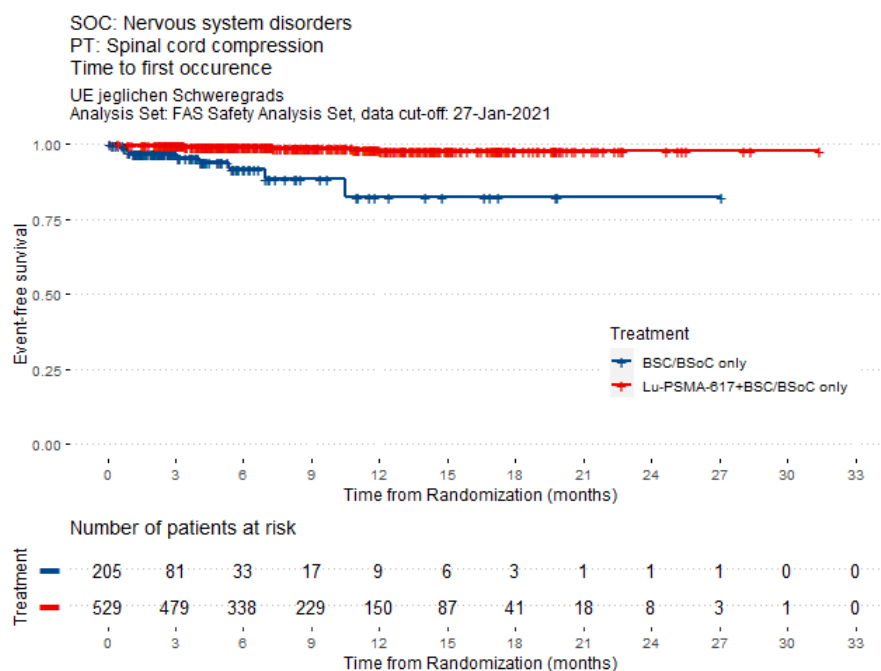


Abbildung 80: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Spinal cord compression

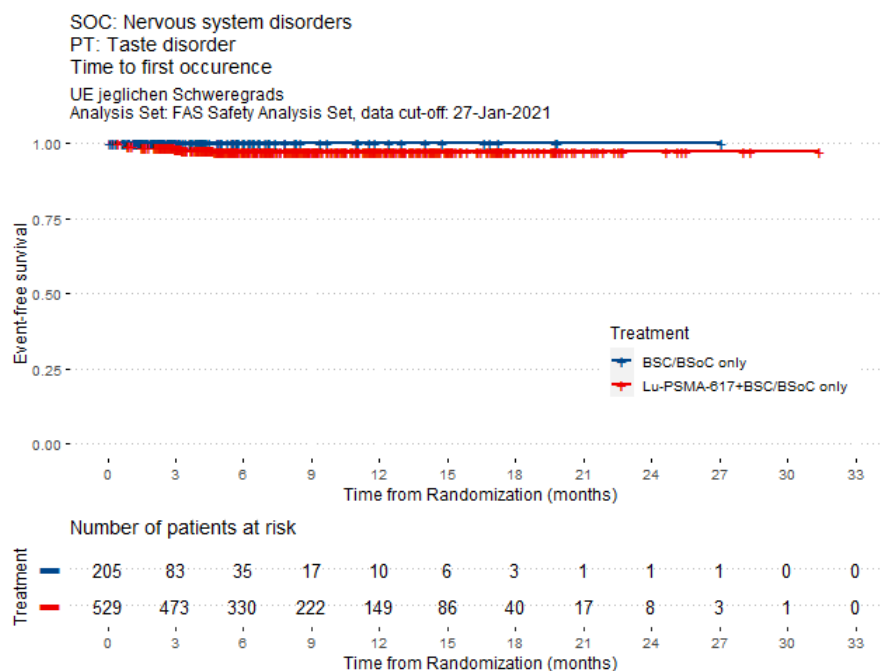


Abbildung 81: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Taste disorder

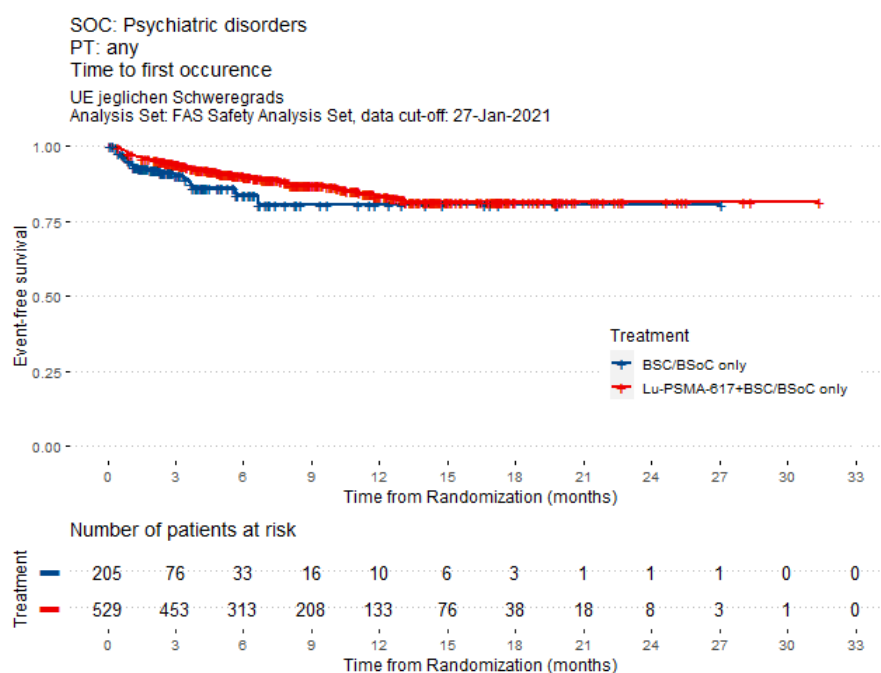


Abbildung 82: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: any

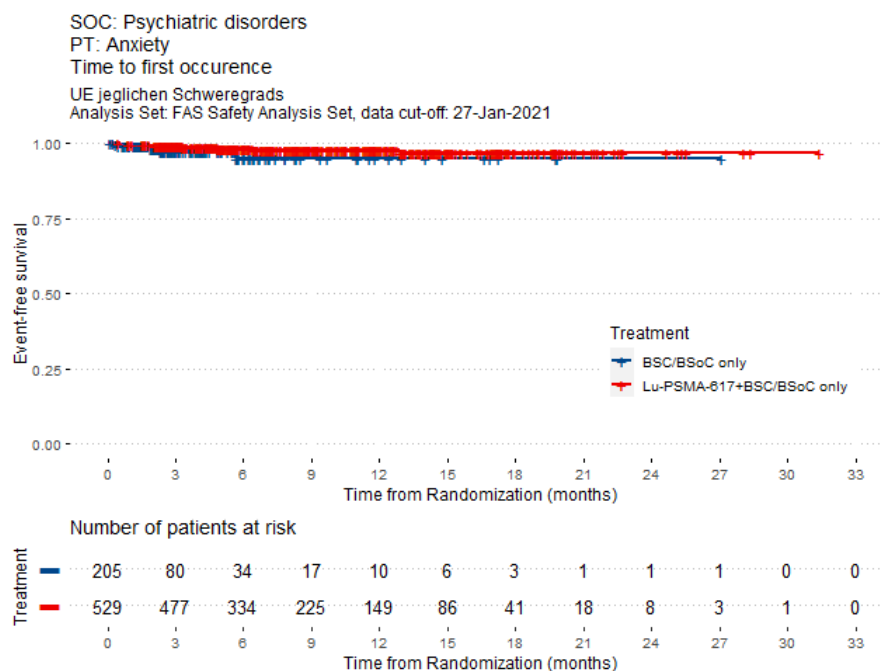


Abbildung 83: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Anxiety

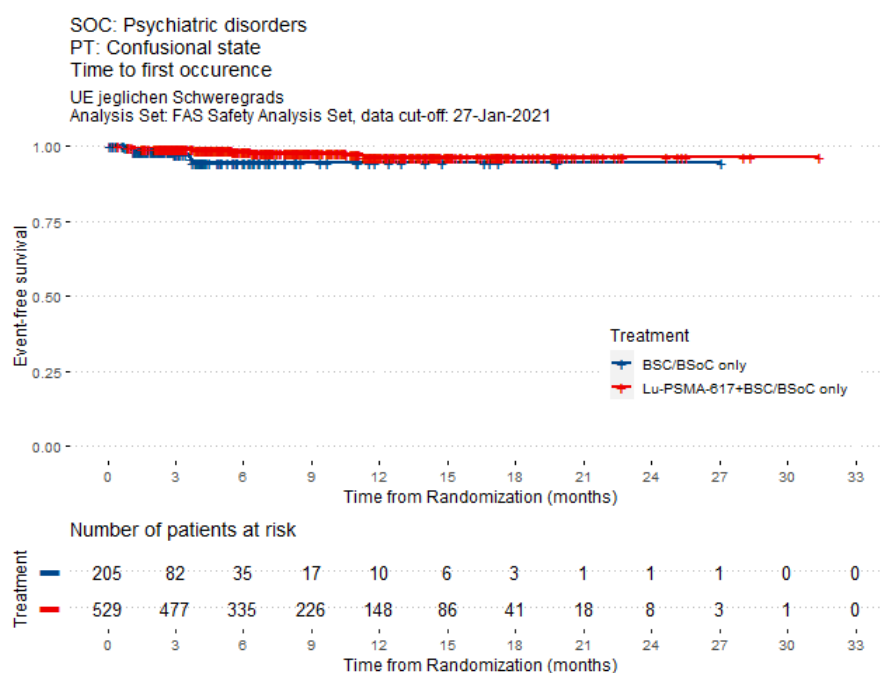


Abbildung 84: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Confusional state

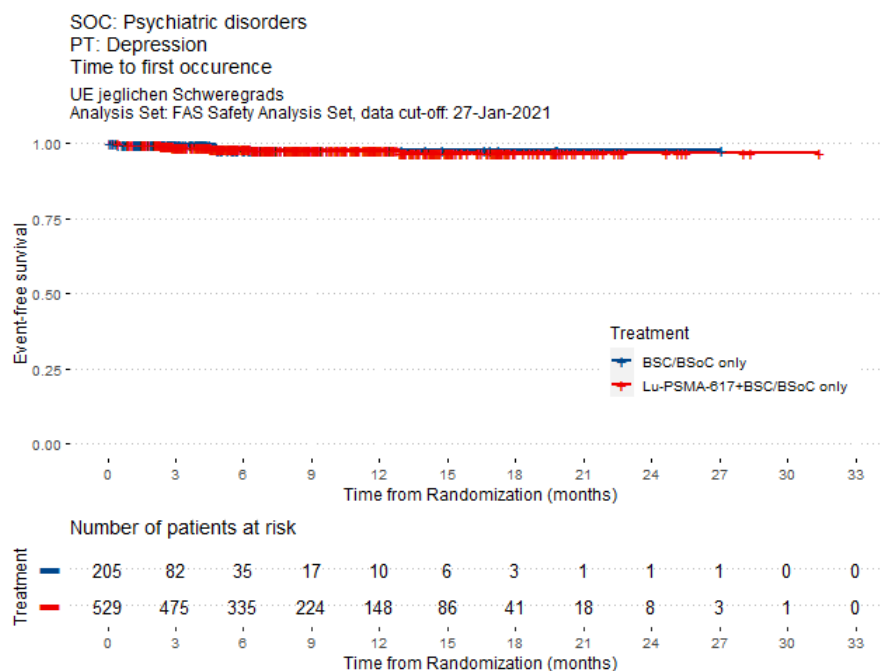


Abbildung 85: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Depression

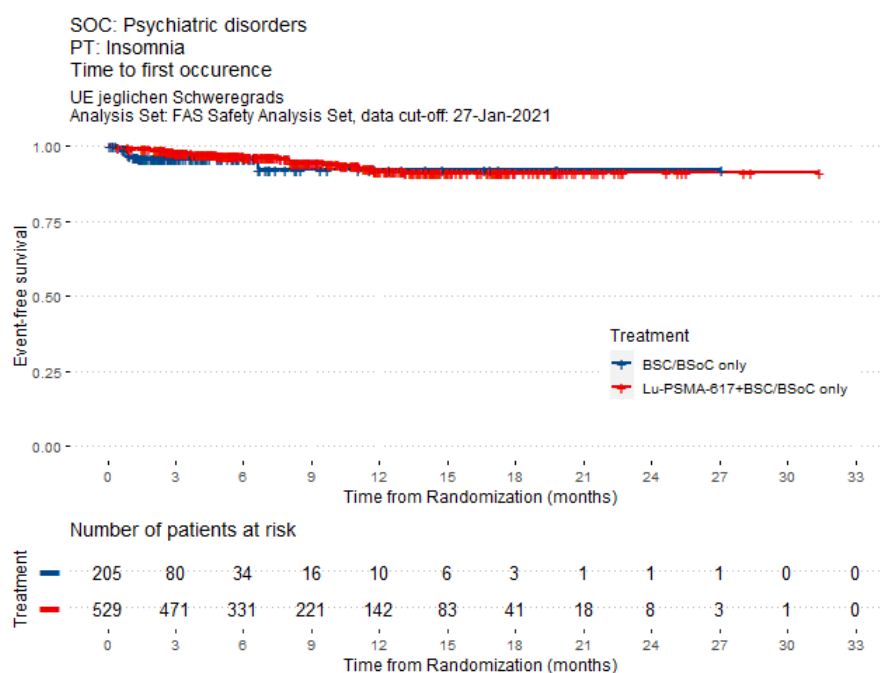


Abbildung 86: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Insomnia

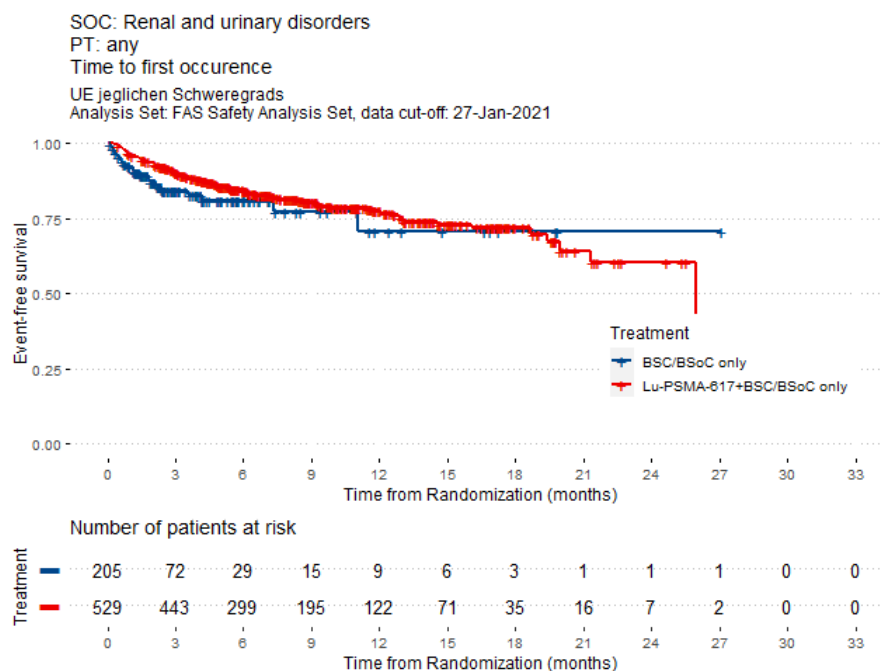


Abbildung 87: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: any

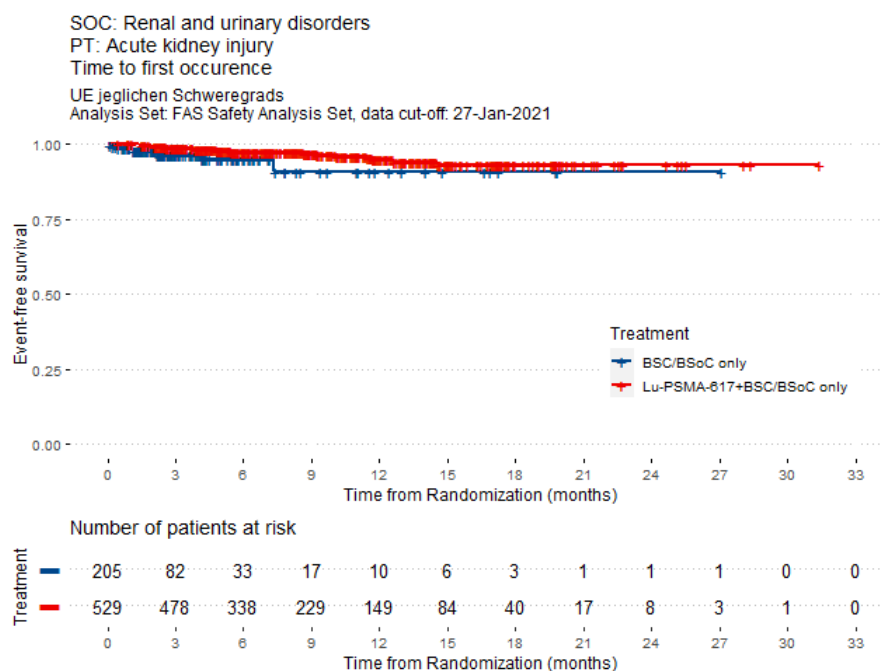


Abbildung 88: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Acute kidney injury

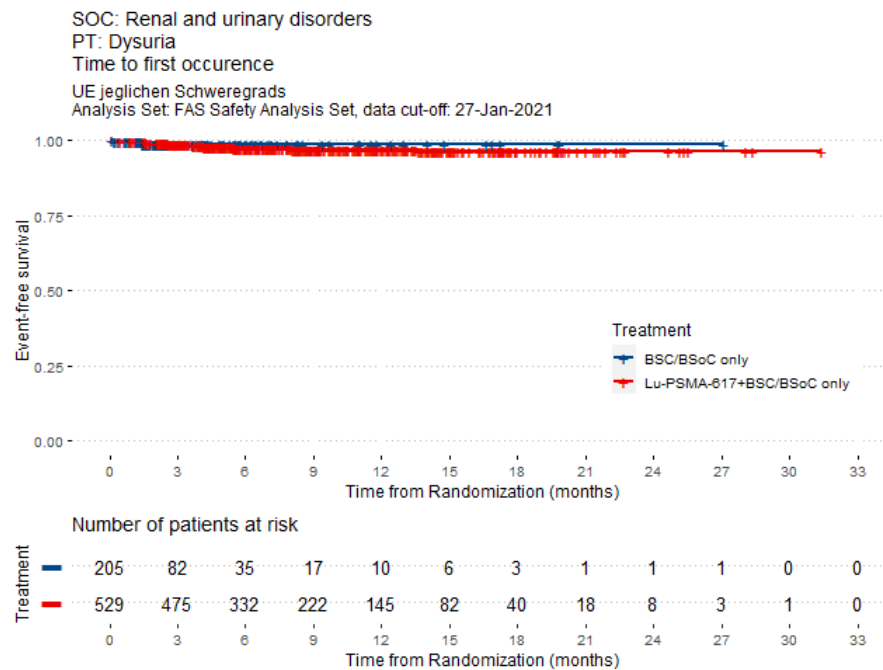


Abbildung 89: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Dysuria

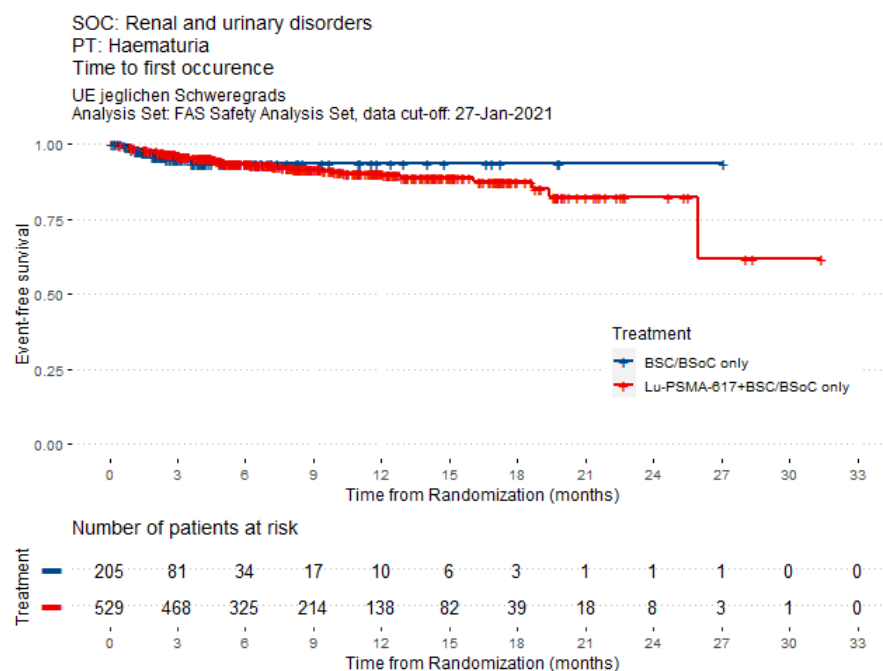


Abbildung 90: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Haematuria

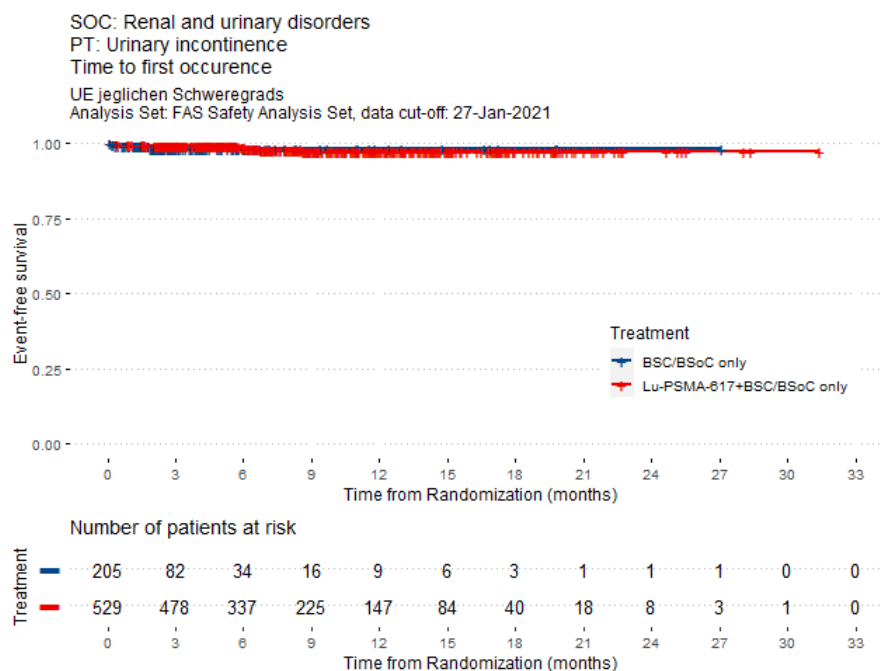


Abbildung 91: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Urinary incontinence

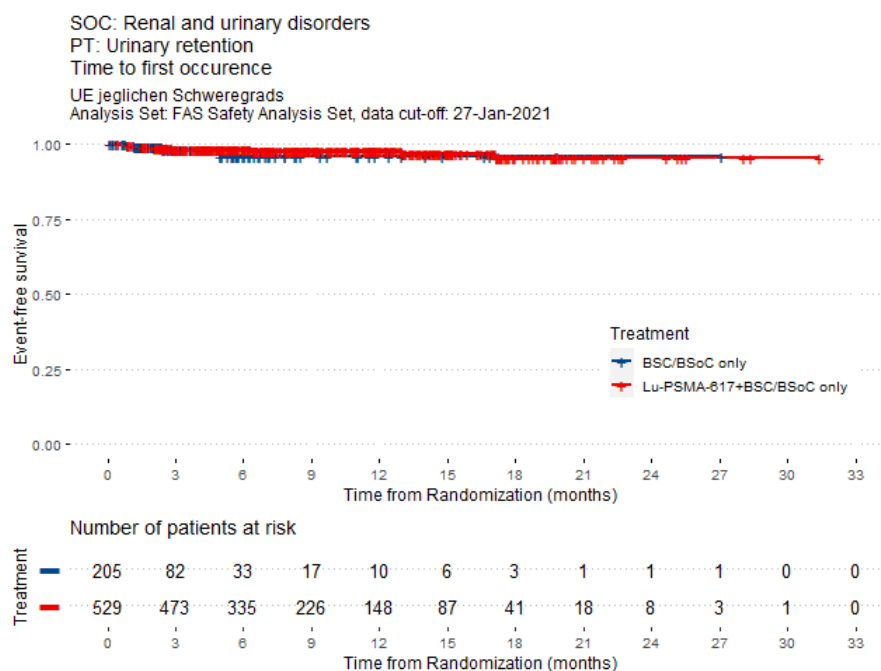


Abbildung 92: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Urinary retention

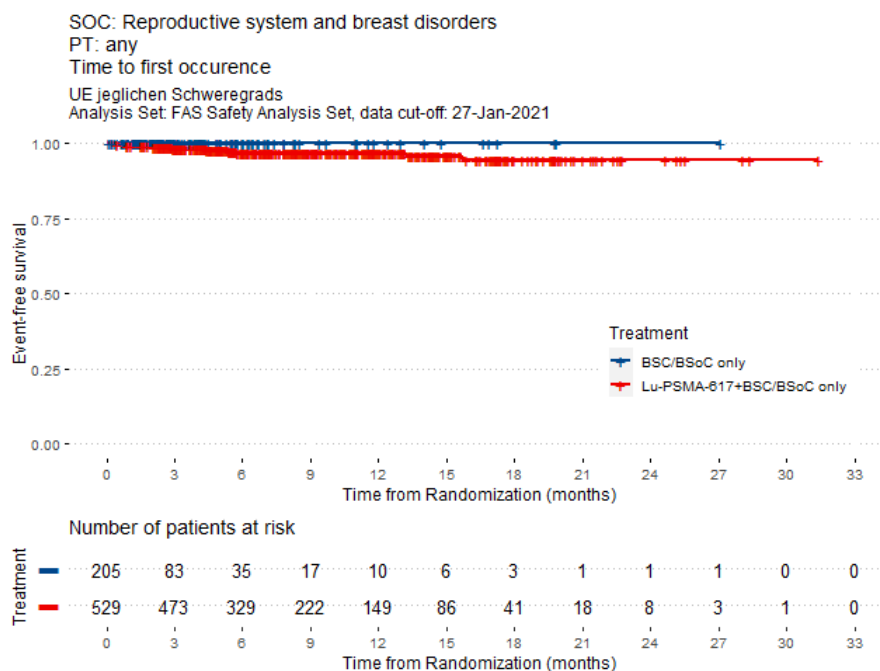


Abbildung 93: UE jeglichen Schweregrads: Time to first occurrence of SOC: Reproductive system and breast disorders; PT: any

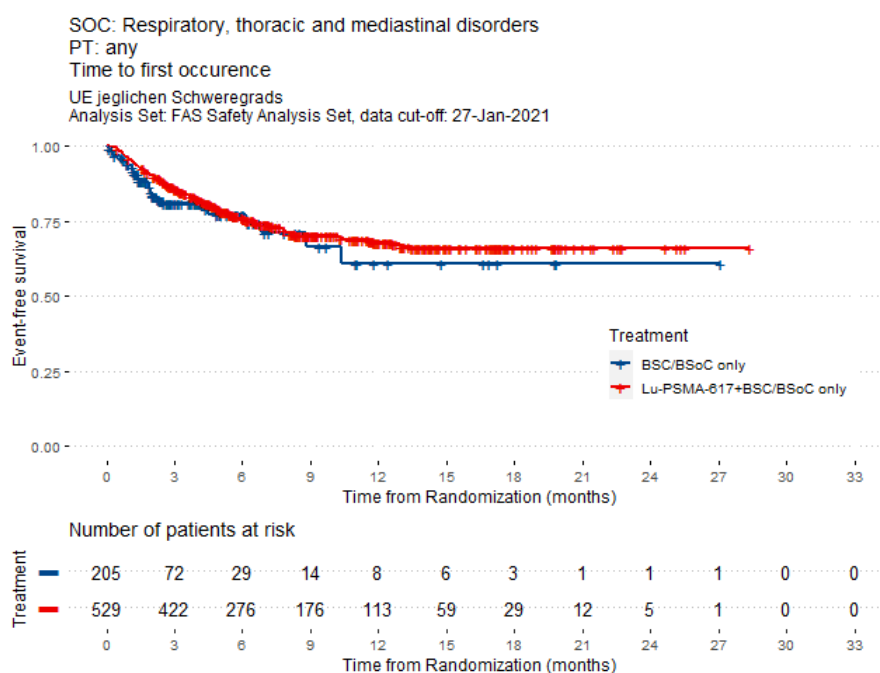


Abbildung 94: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: any

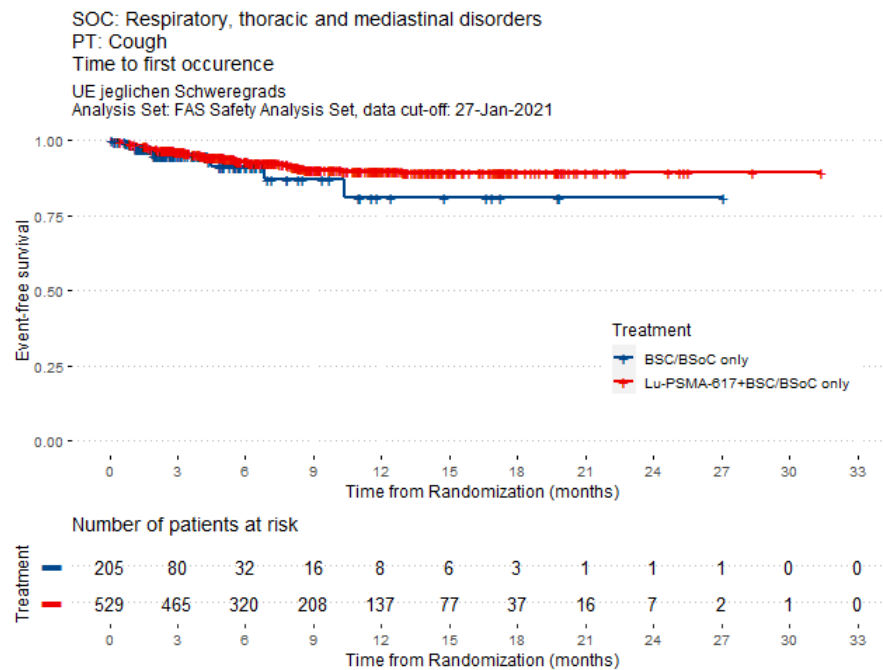


Abbildung 95: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: Cough

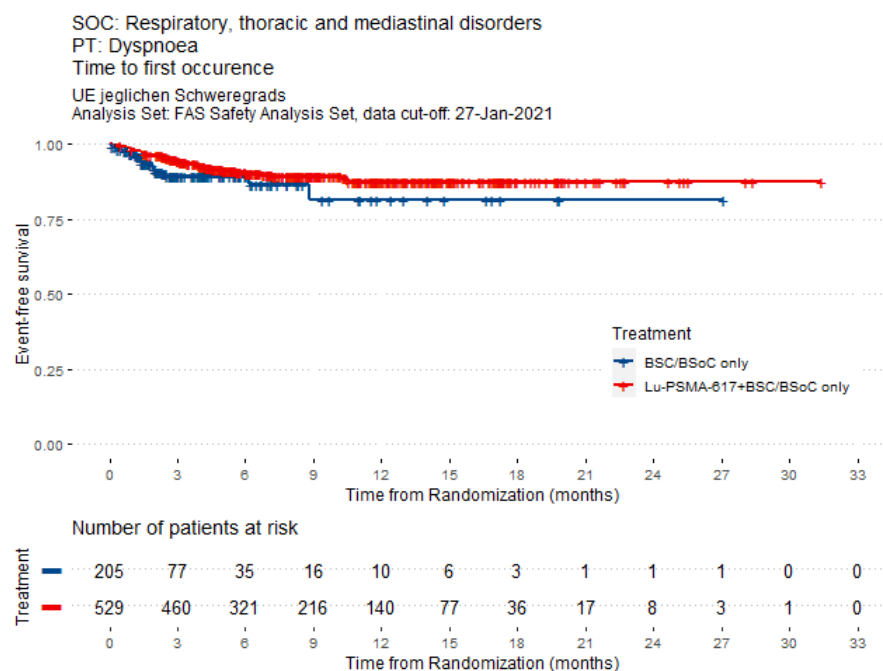


Abbildung 96: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea

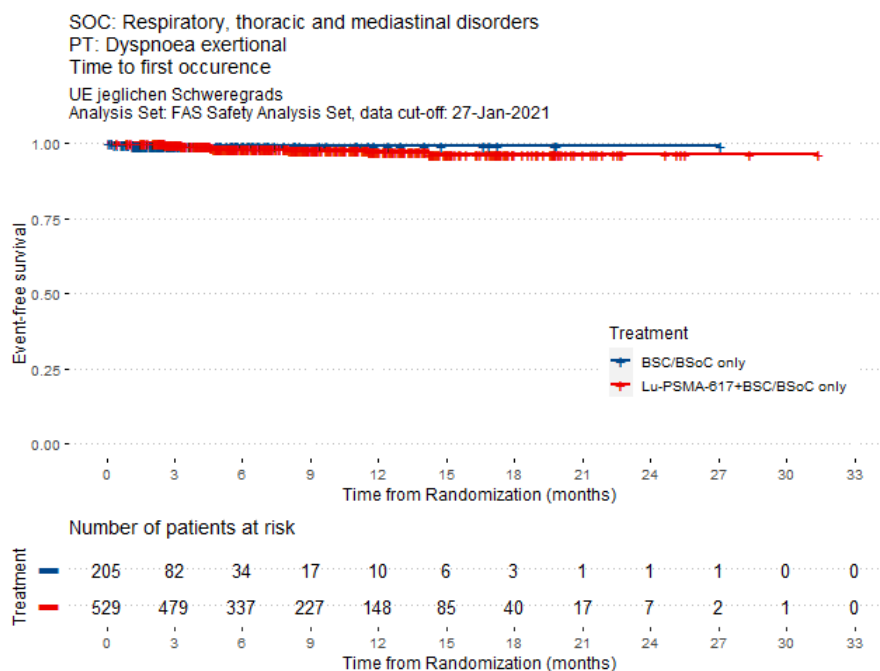


Abbildung 97: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea exertional

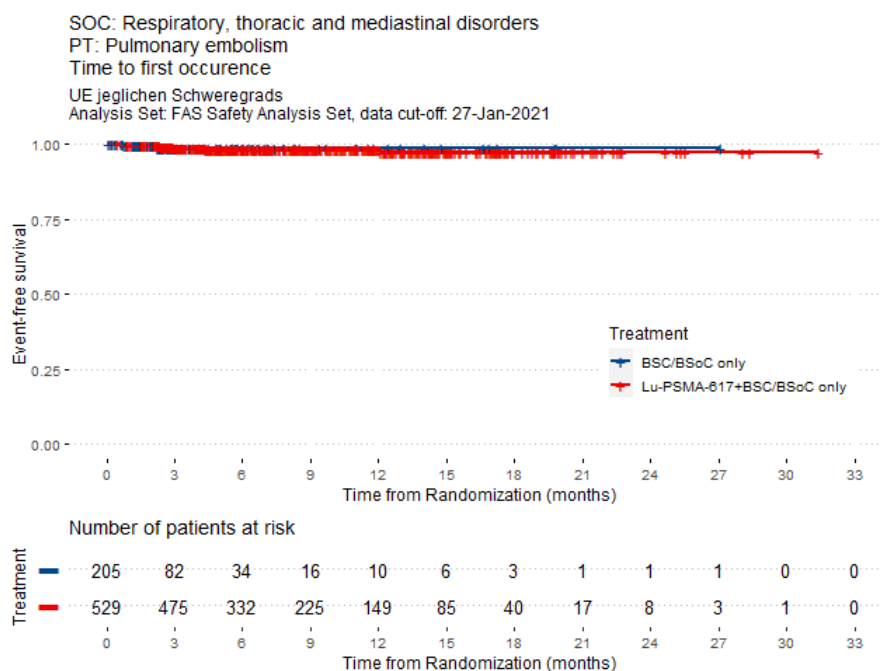


Abbildung 98: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: Pulmonary embolism

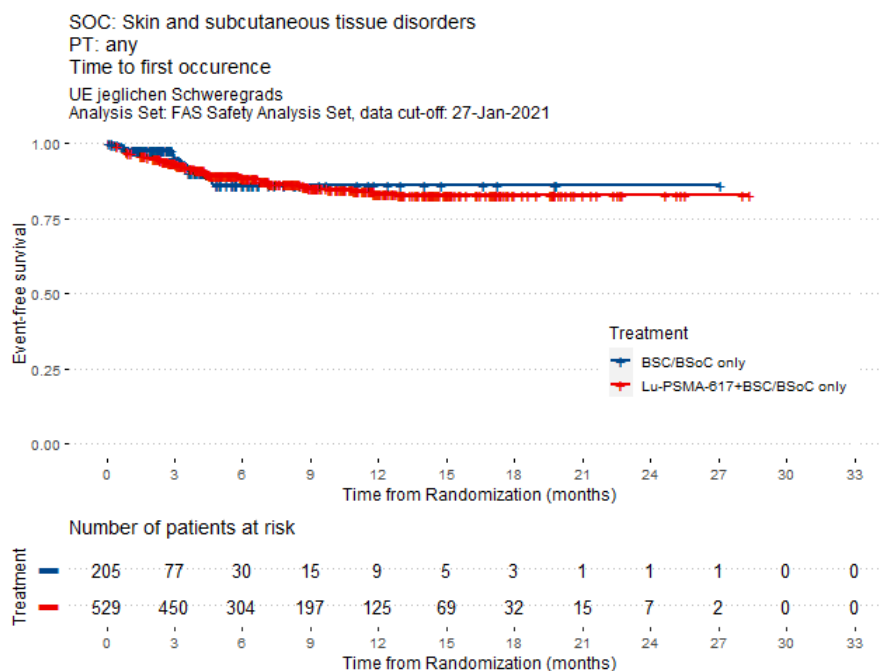


Abbildung 99: UE jeglichen Schweregrads: Time to first occurrence of SOC: Skin and subcutaneous tissue disorders; PT: any

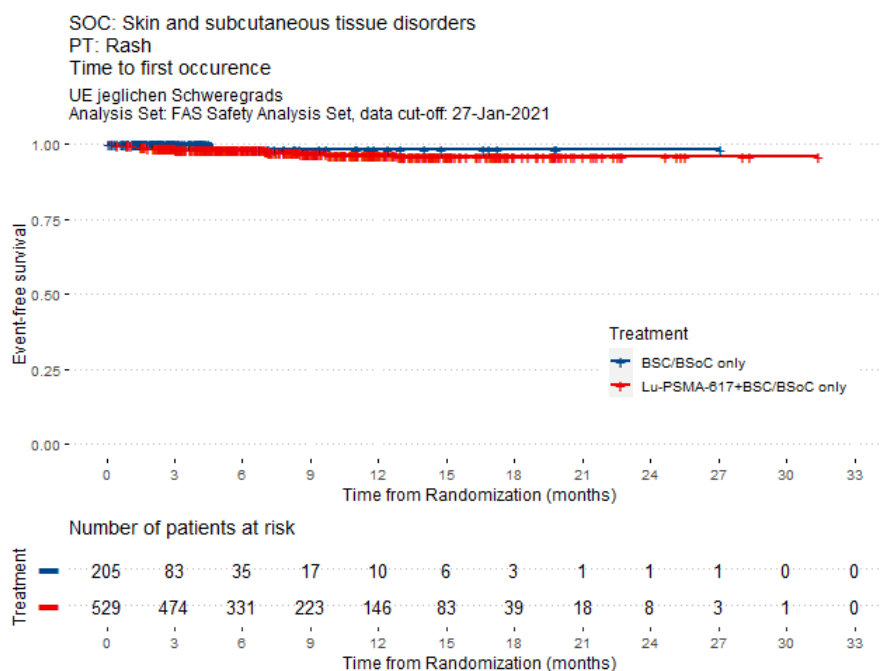


Abbildung 100: UE jeglichen Schweregrads: Time to first occurrence of SOC: Skin and subcutaneous tissue disorders; PT: Rash

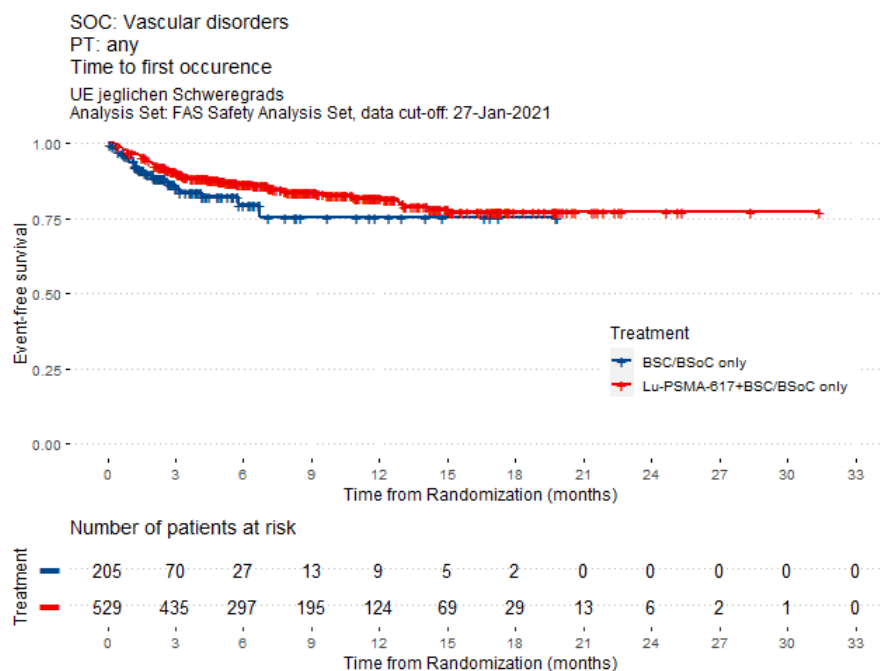


Abbildung 101: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: any

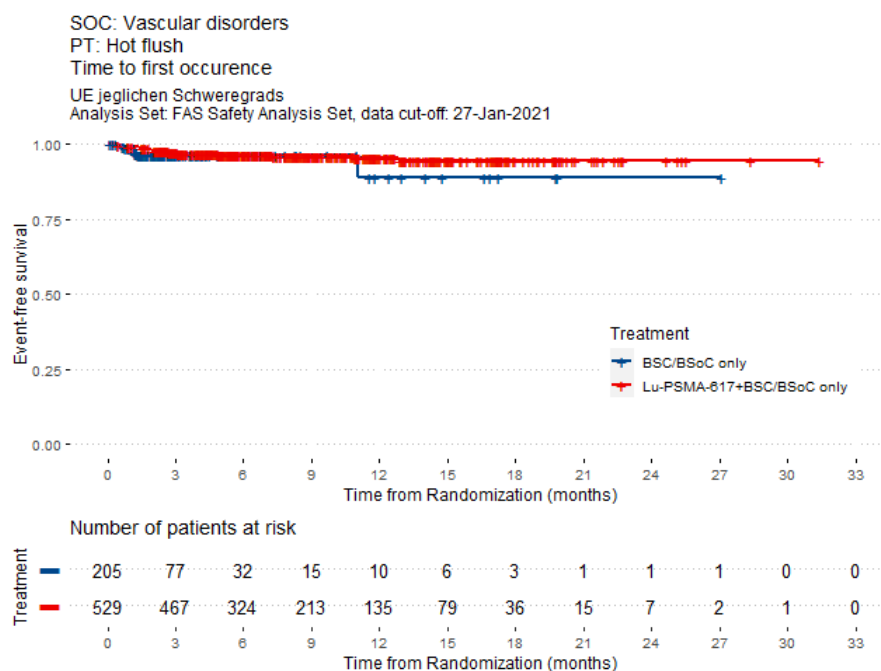


Abbildung 102: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: Hot flush

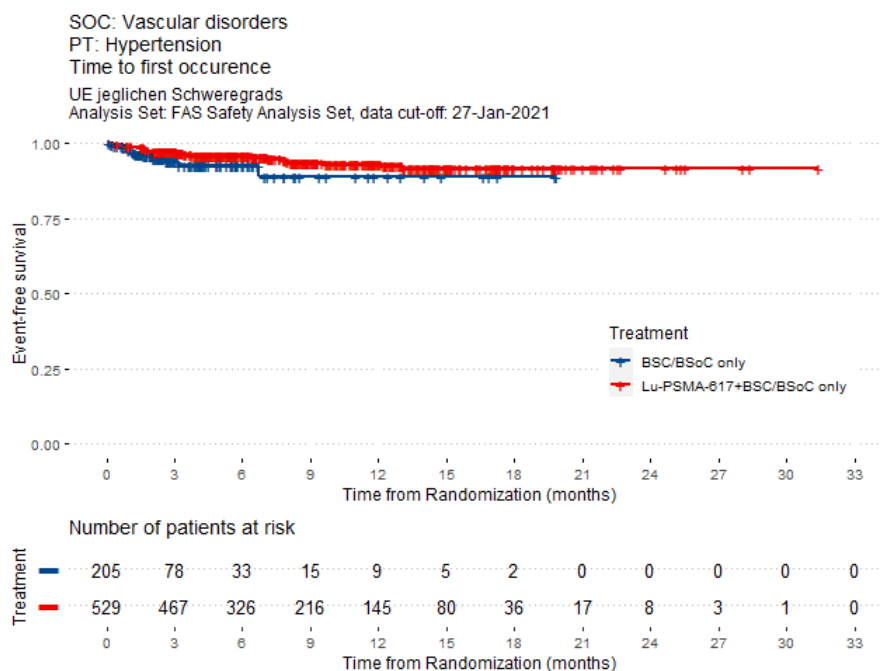


Abbildung 103: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: Hypertension

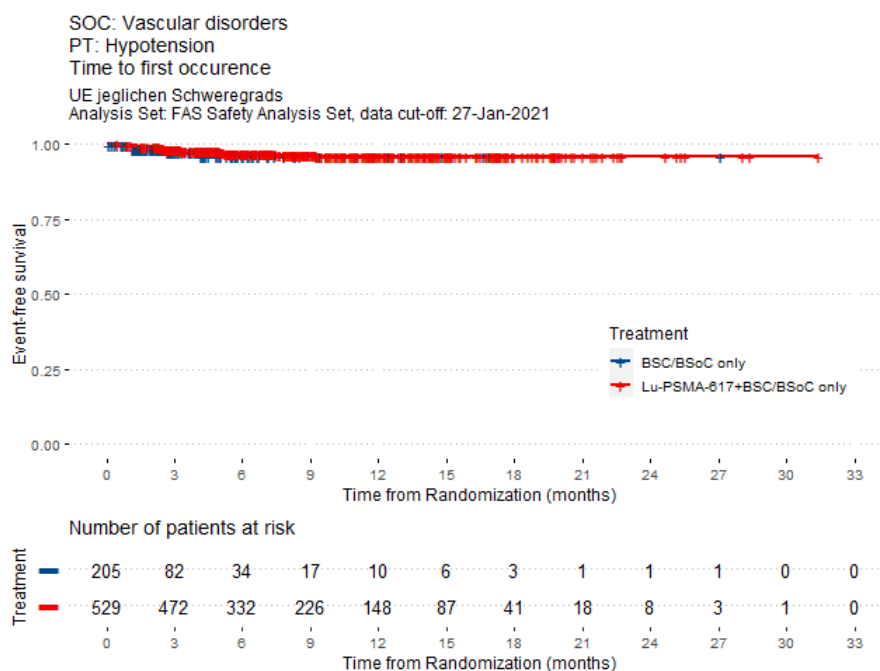
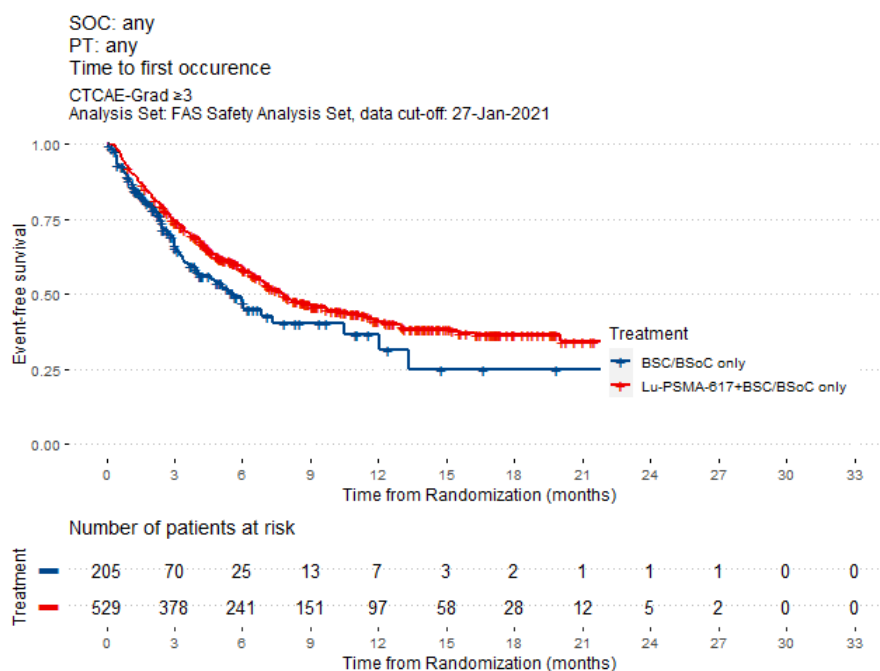
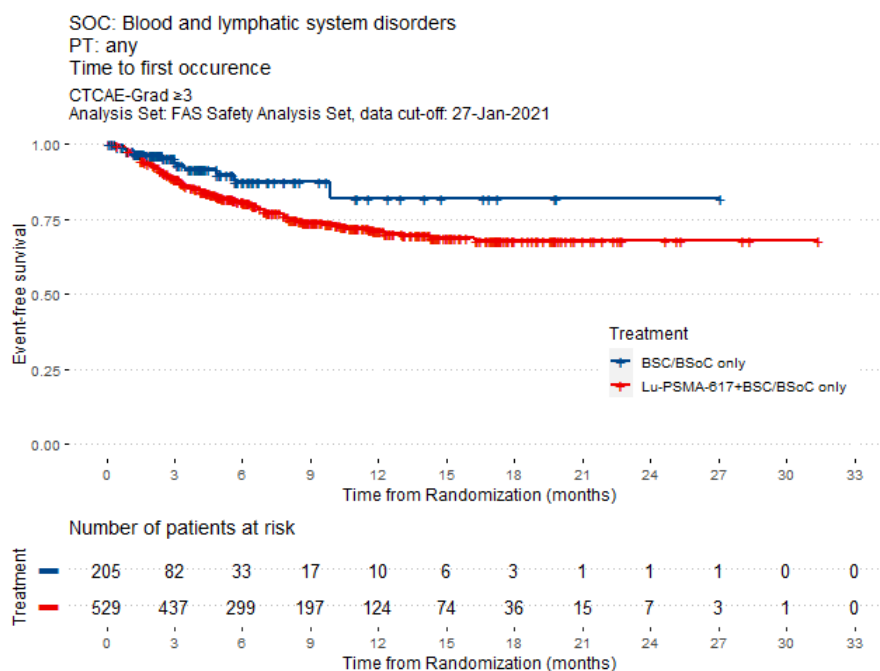


Abbildung 104: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: Hypotension

Anhang 4-H.1.2: Schwere UE (CTCAE-Grad ≥ 3)Abbildung 105: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: any; PT: anyAbbildung 106: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: any

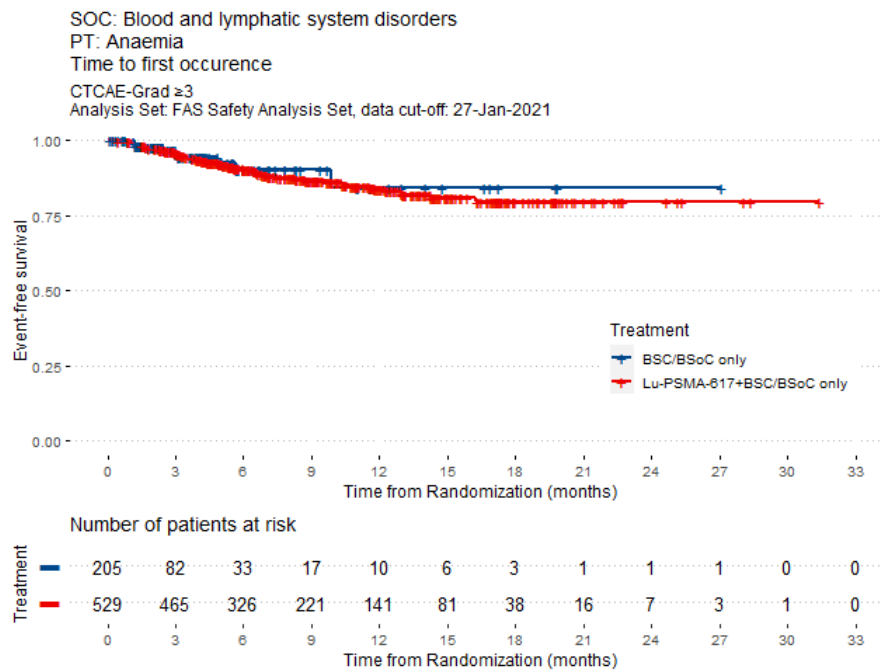


Abbildung 107: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Anaemia

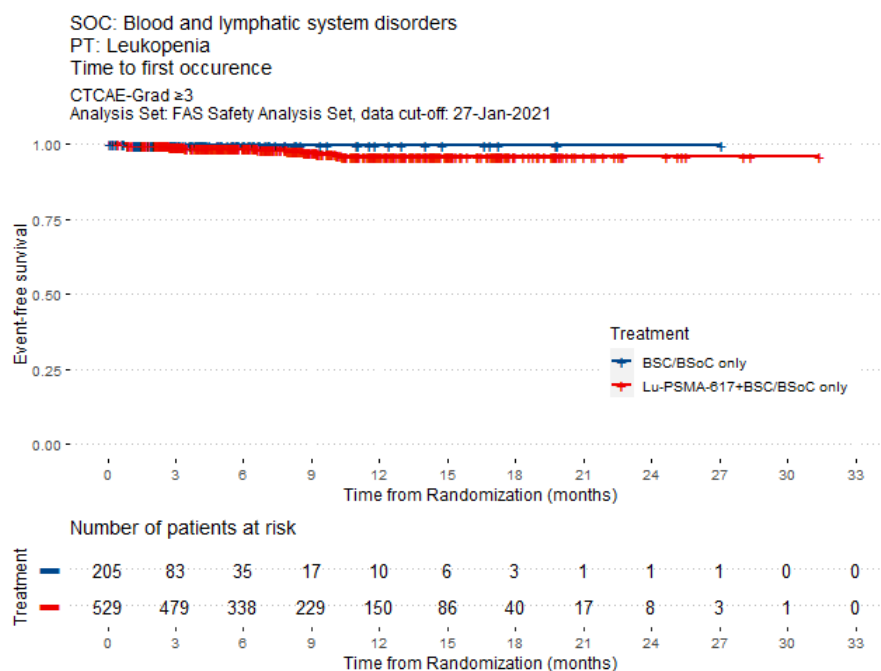


Abbildung 108: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Leukopenia

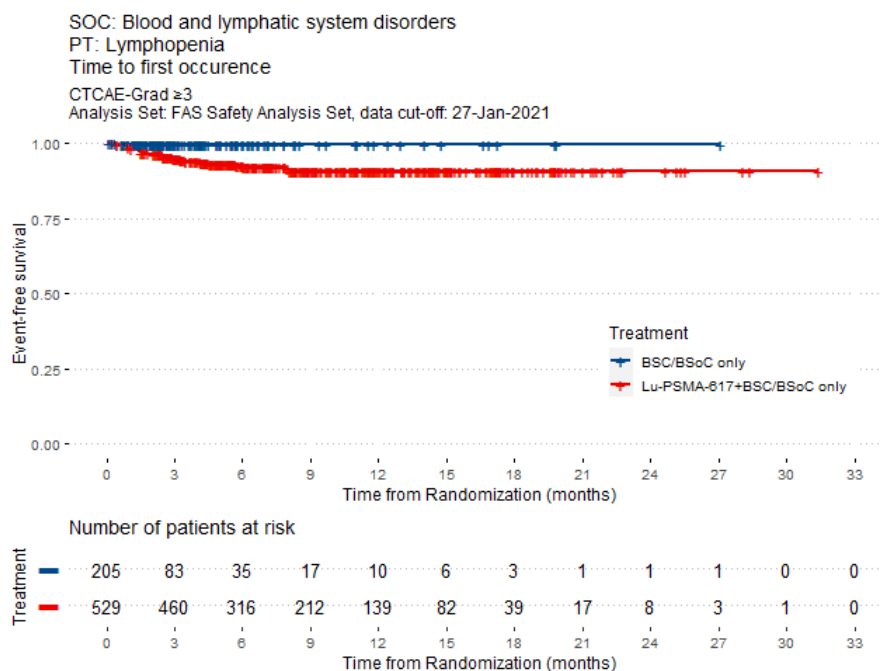


Abbildung 109: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Lymphopenia

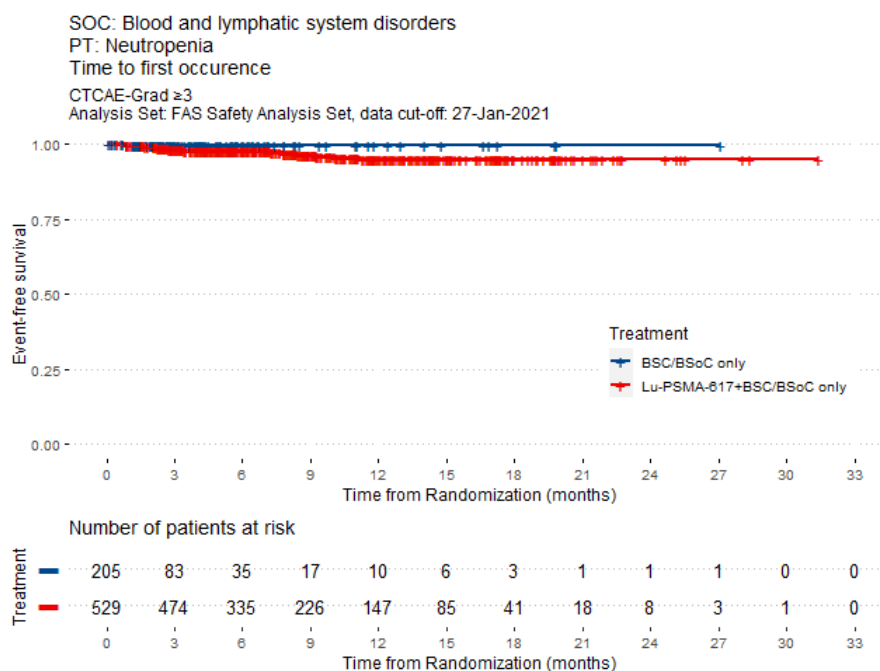


Abbildung 110: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Neutropenia

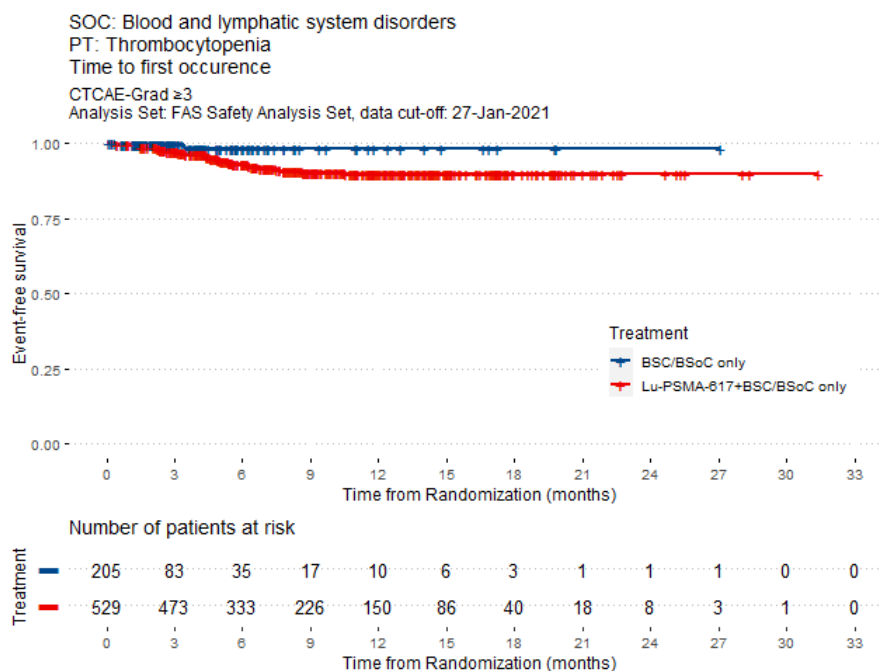


Abbildung 111: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Thrombocytopenia

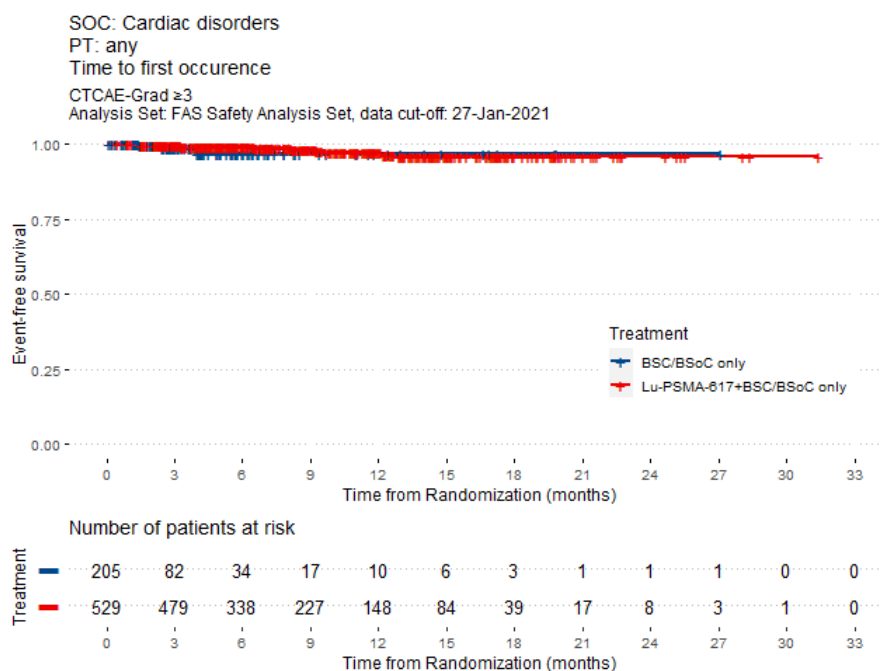


Abbildung 112: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Cardiac disorders; PT: any

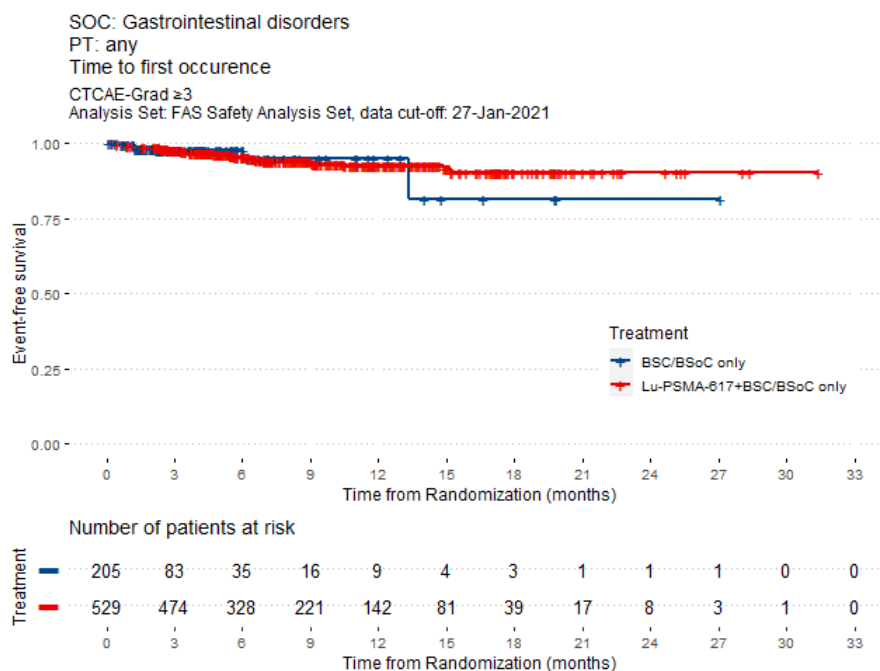


Abbildung 113: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Gastrointestinal disorders; PT: any

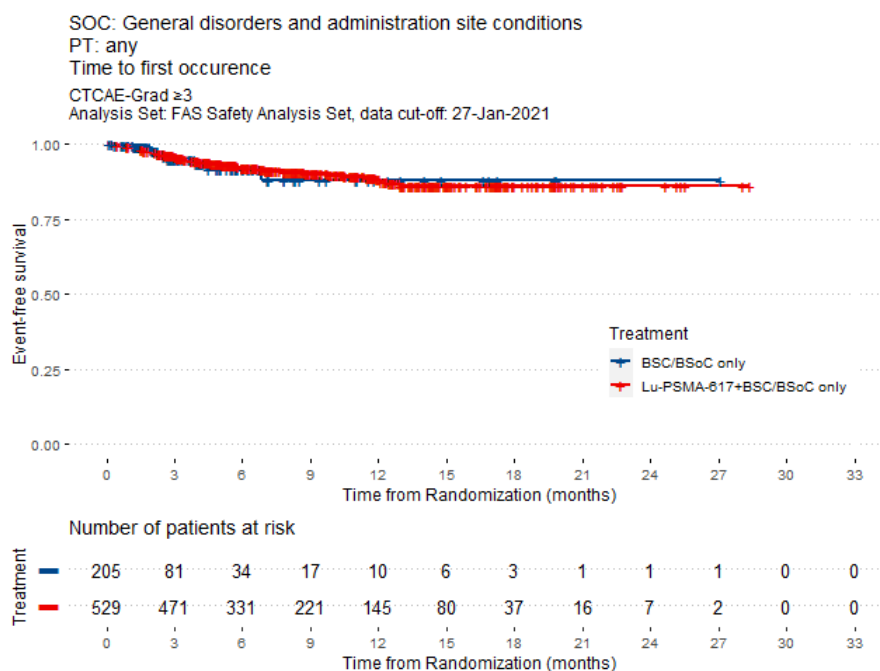


Abbildung 114: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: General disorders and administration site conditions; PT: any

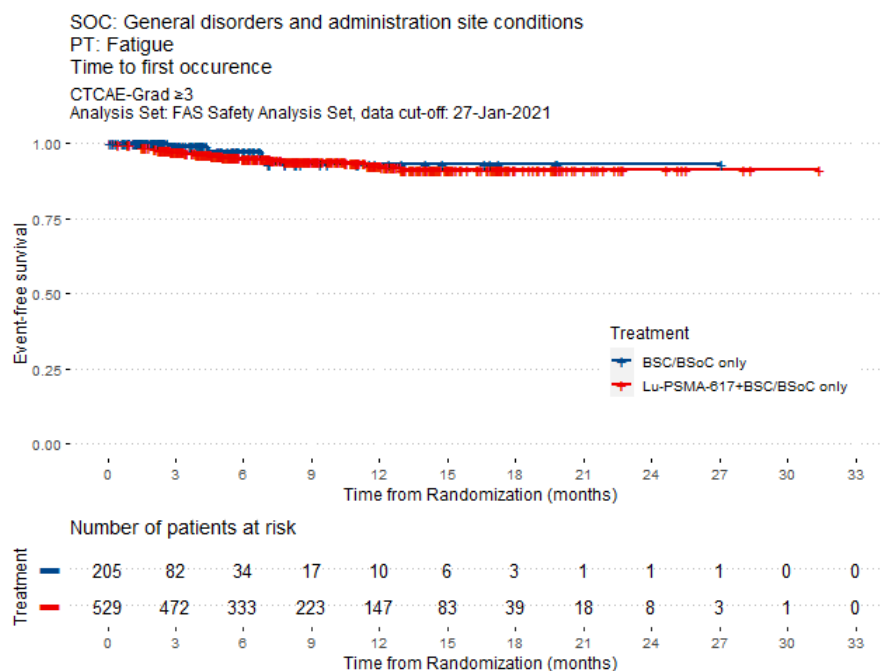


Abbildung 115: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: General disorders and administration site conditions; PT: Fatigue

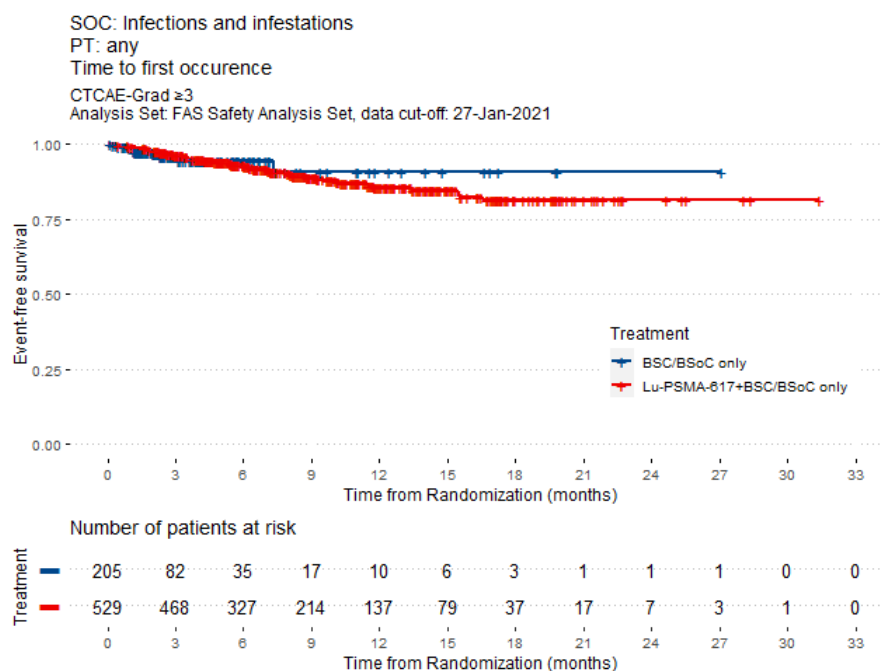


Abbildung 116: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Infections and infestations; PT: any

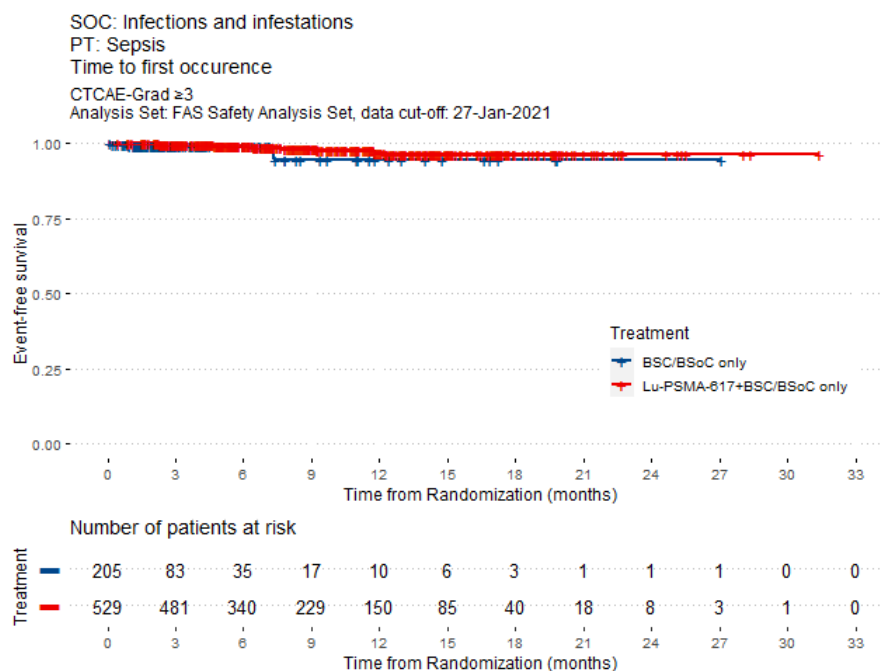


Abbildung 117: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Infections and infestations; PT: Sepsis

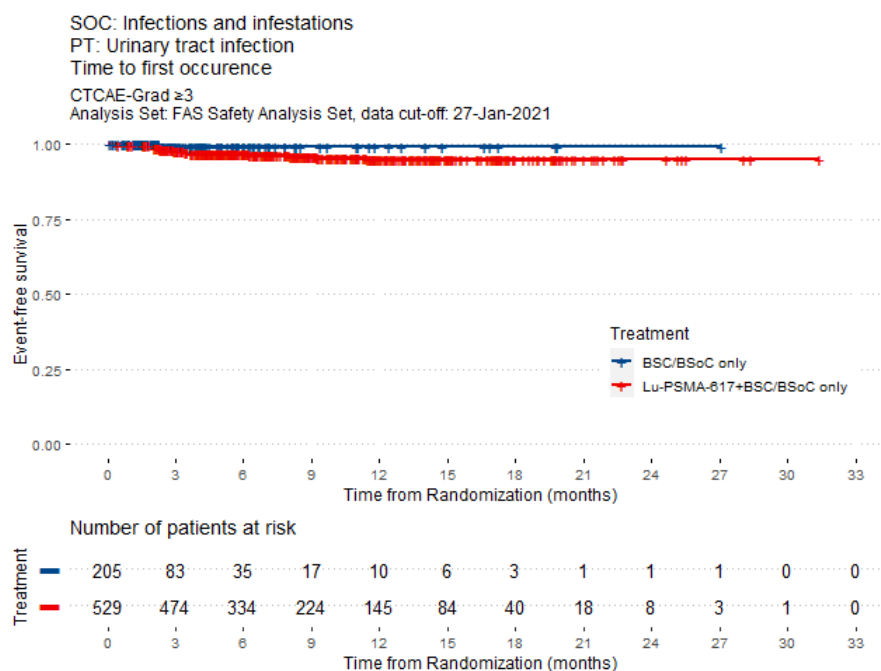


Abbildung 118: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Infections and infestations; PT: Urinary tract infection

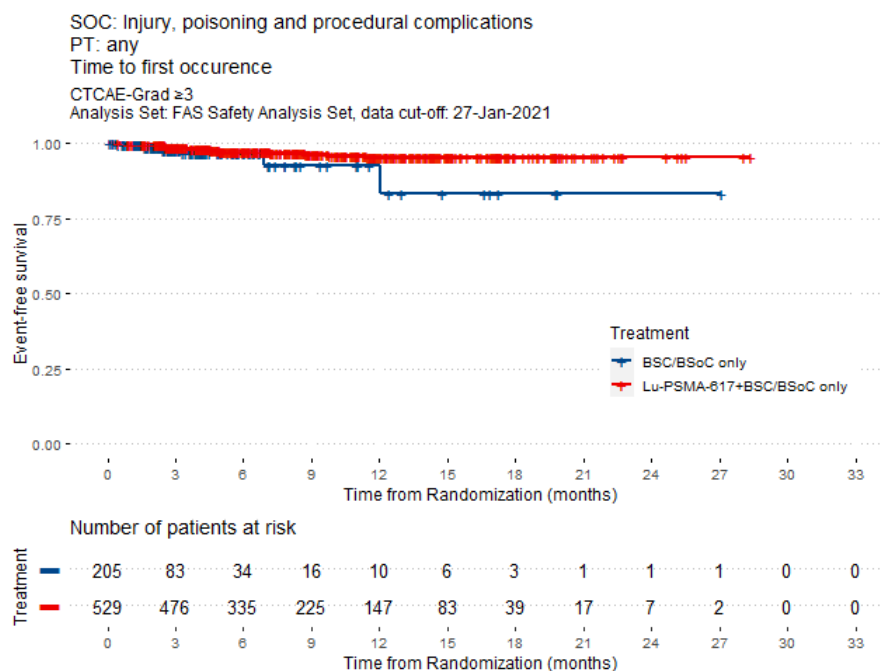


Abbildung 119: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: any

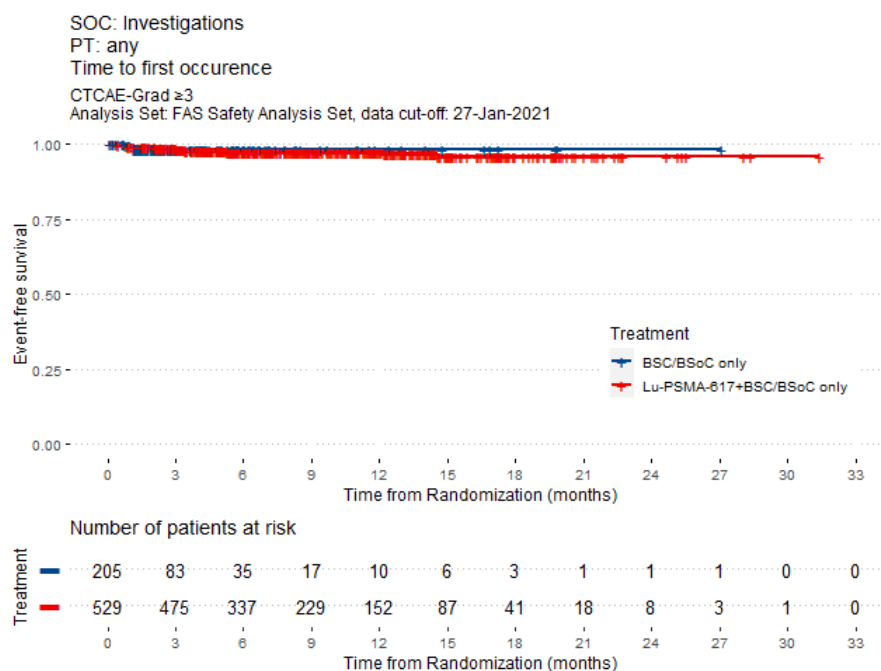


Abbildung 120: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Investigations; PT: any

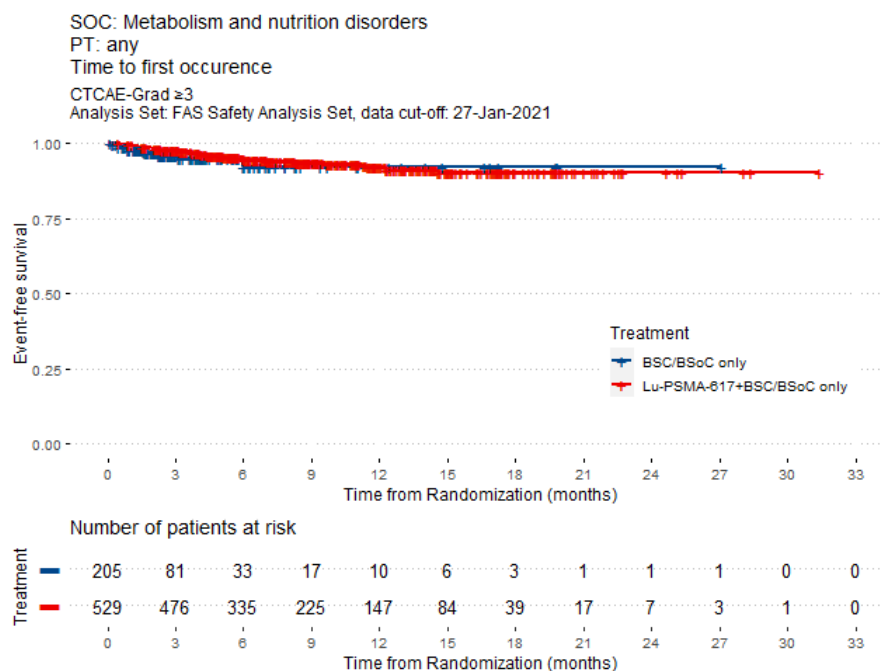


Abbildung 121: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: any

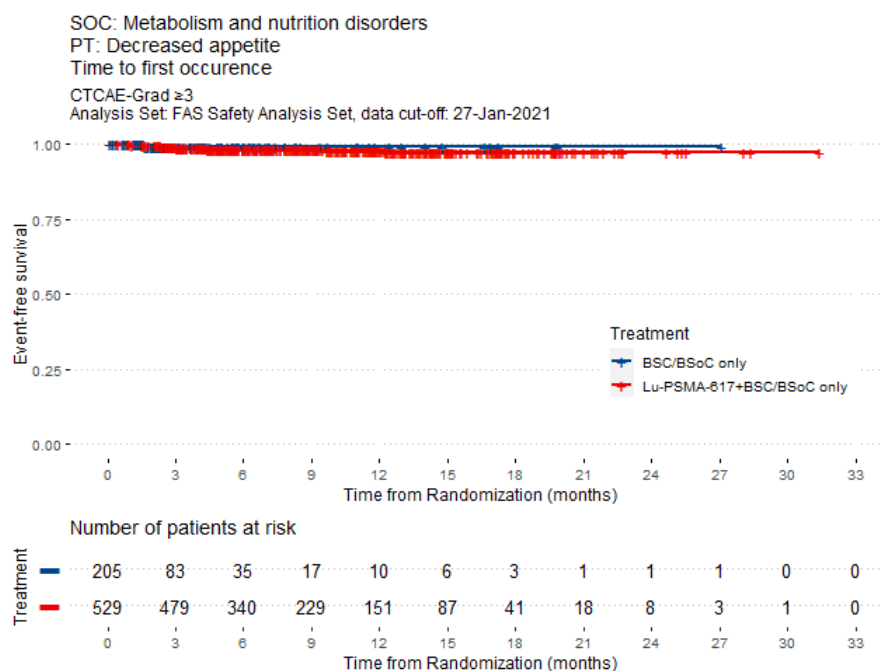


Abbildung 122: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Decreased appetite

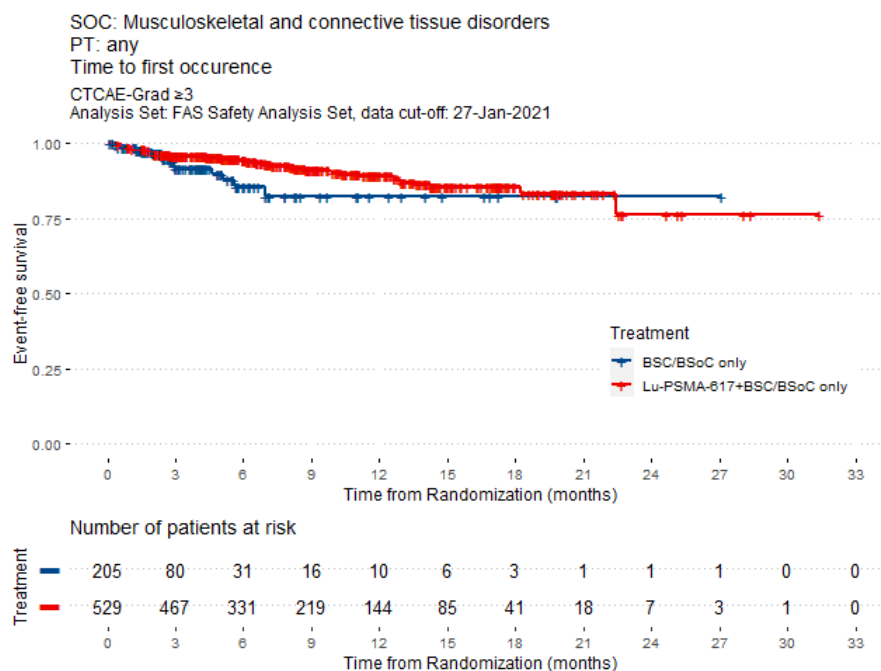


Abbildung 123: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: any

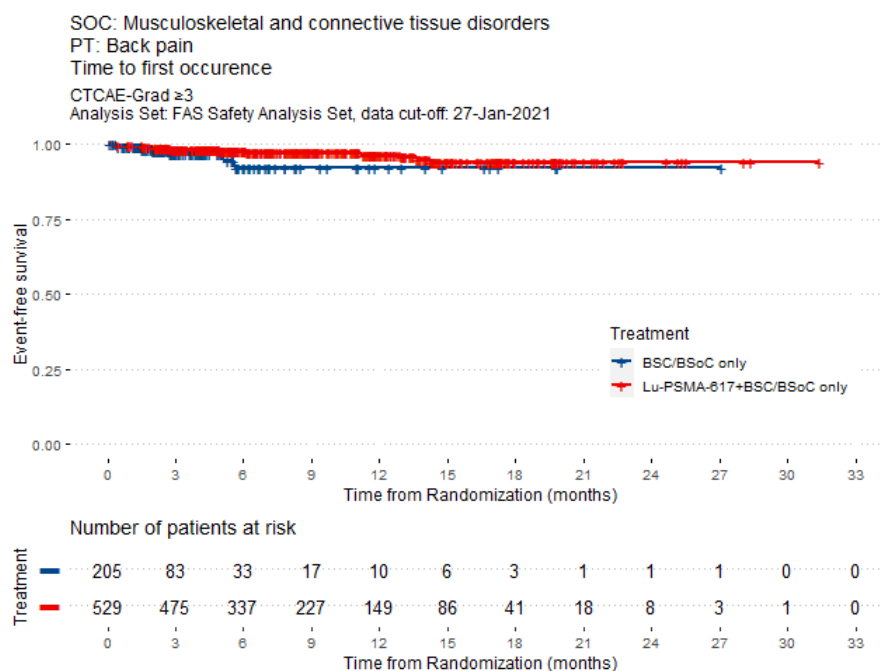


Abbildung 124: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Back pain

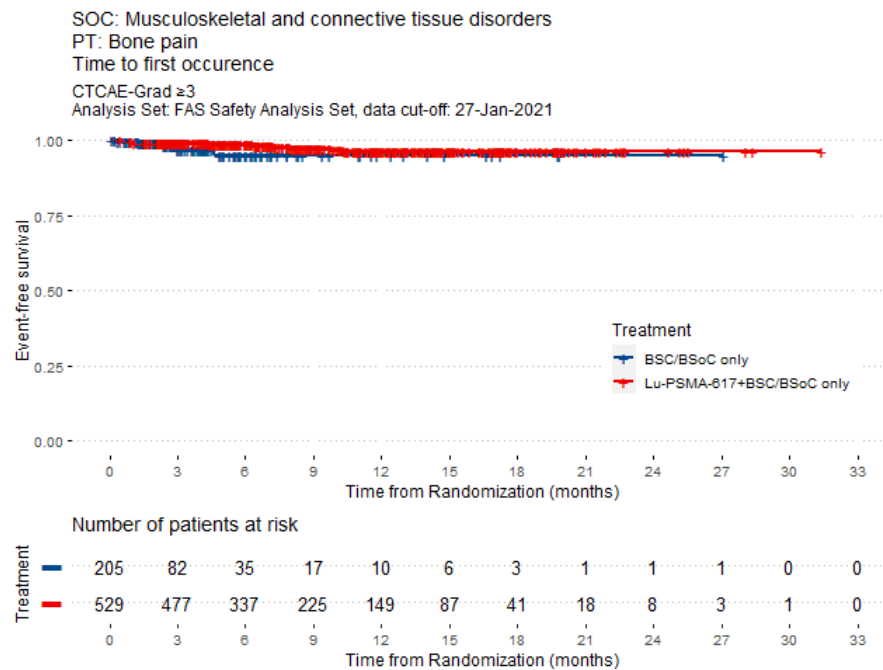


Abbildung 125: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Bone pain

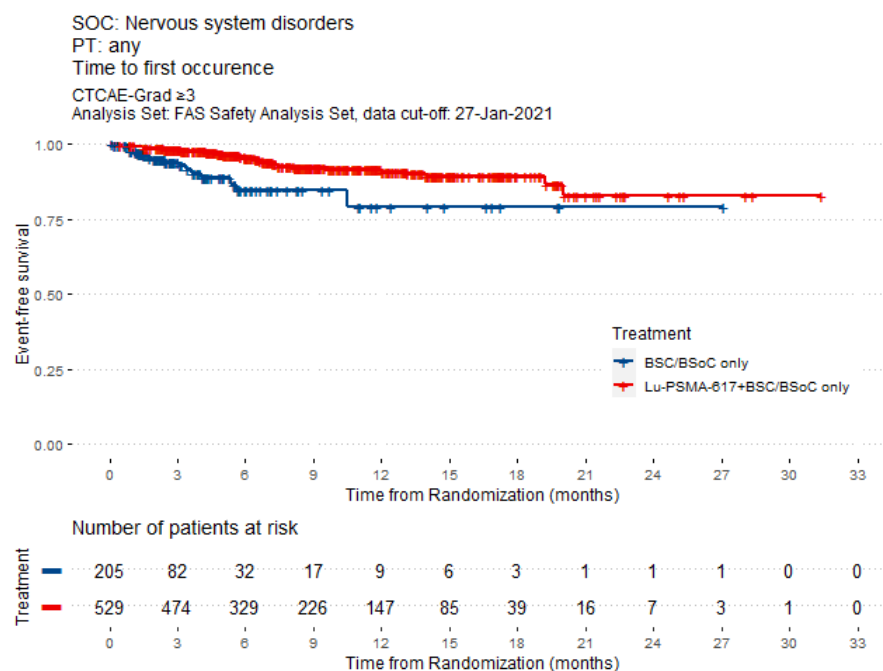


Abbildung 126: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Nervous system disorders; PT: any

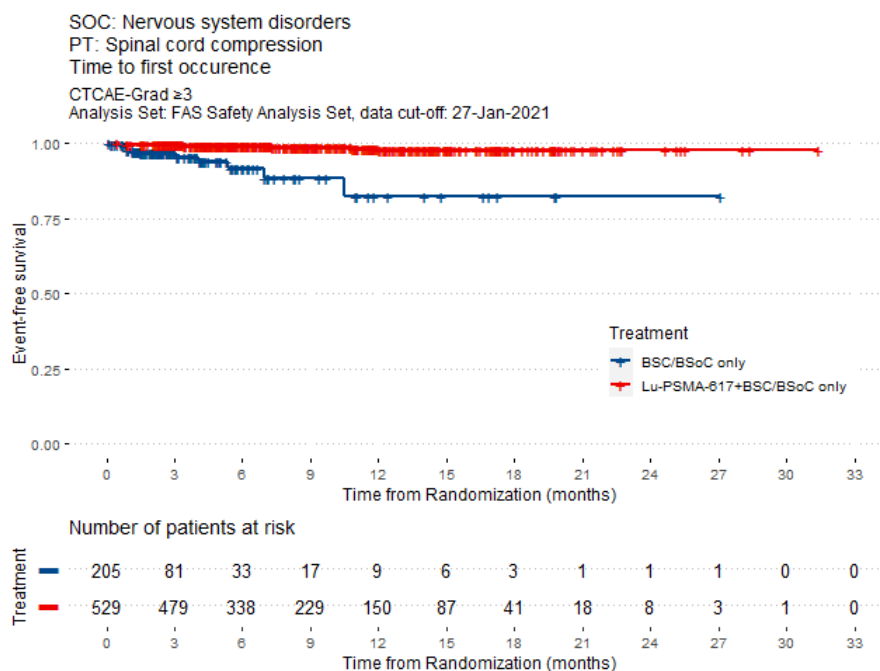


Abbildung 127: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Nervous system disorders; PT: Spinal cord compression

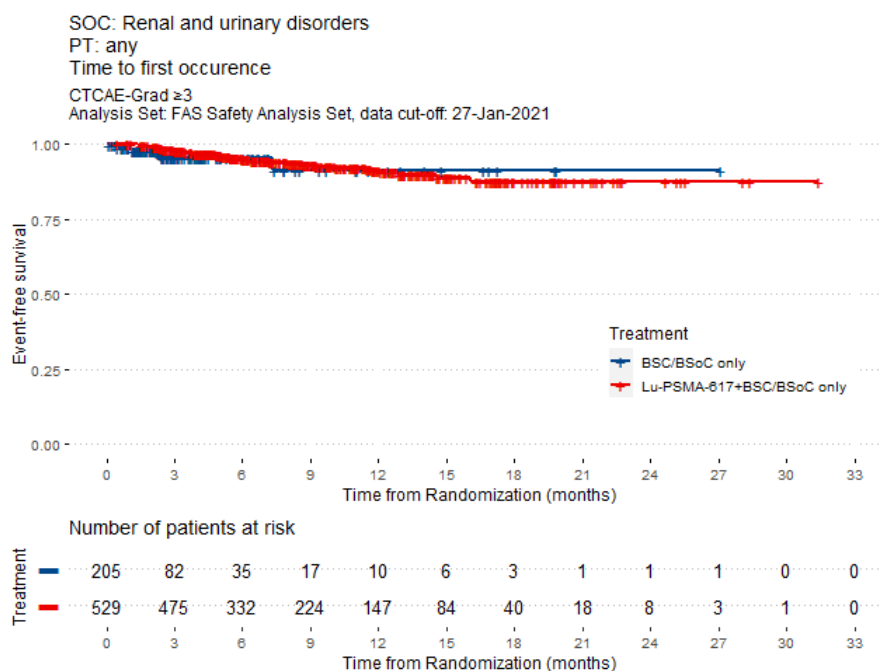


Abbildung 128: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Renal and urinary disorders; PT: any

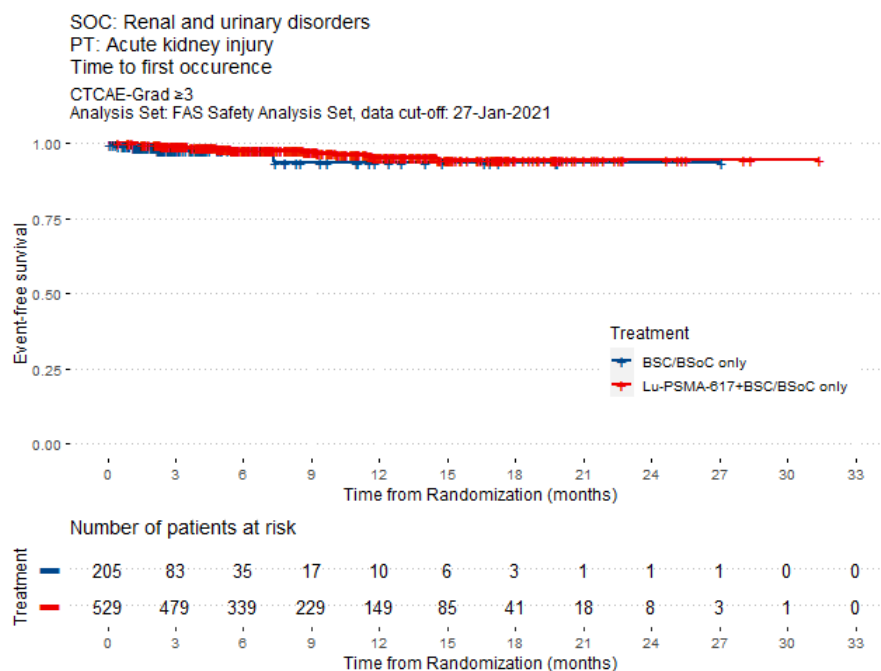


Abbildung 129: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Renal and urinary disorders; PT: Acute kidney injury

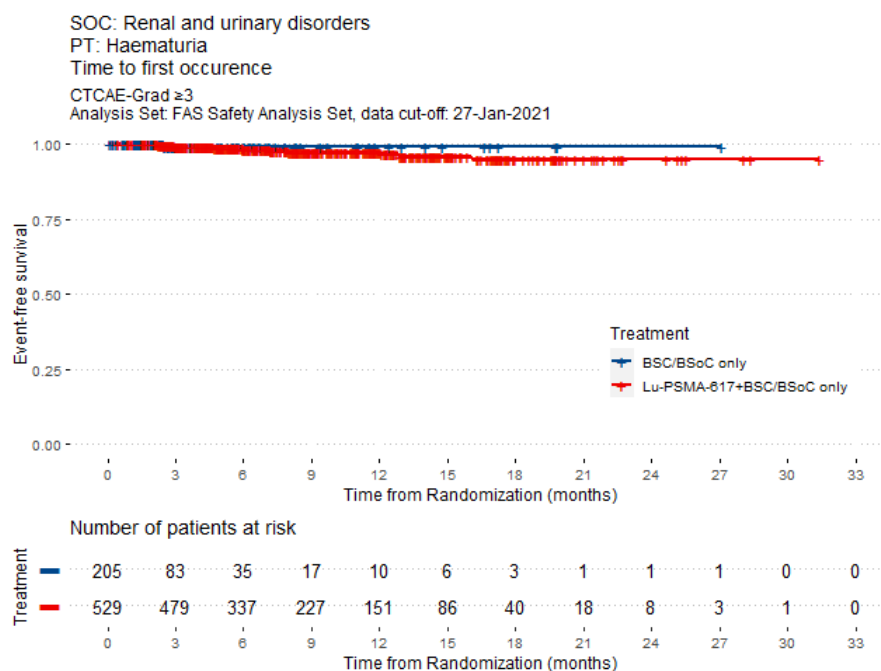


Abbildung 130: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Renal and urinary disorders; PT: Haematuria

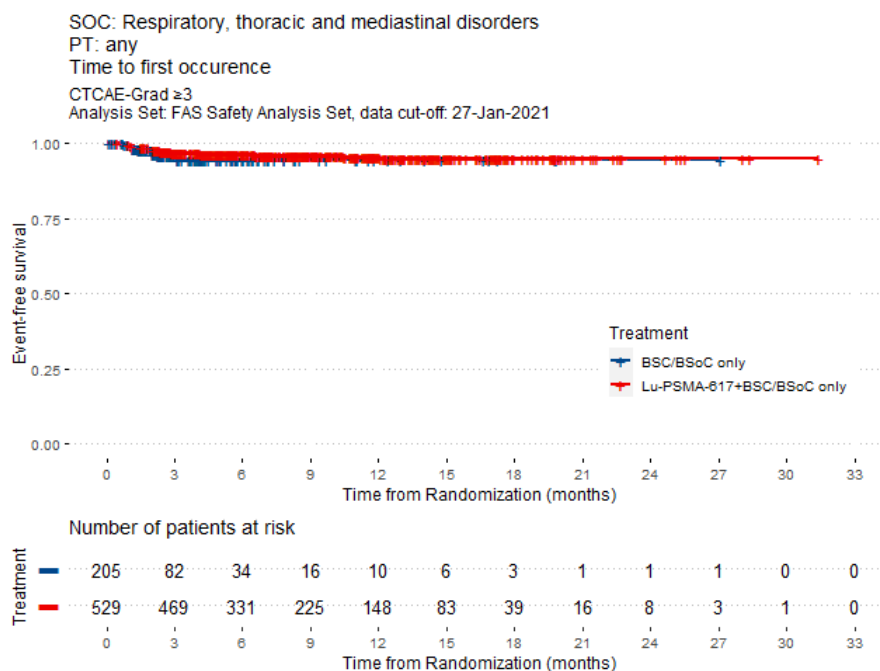


Abbildung 131: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: any

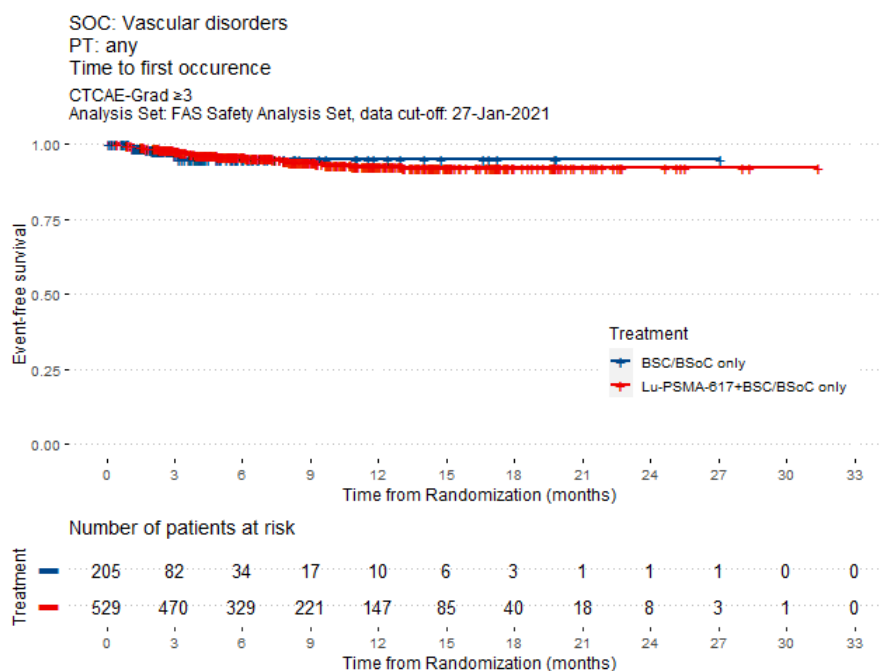


Abbildung 132: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Vascular disorders; PT: any

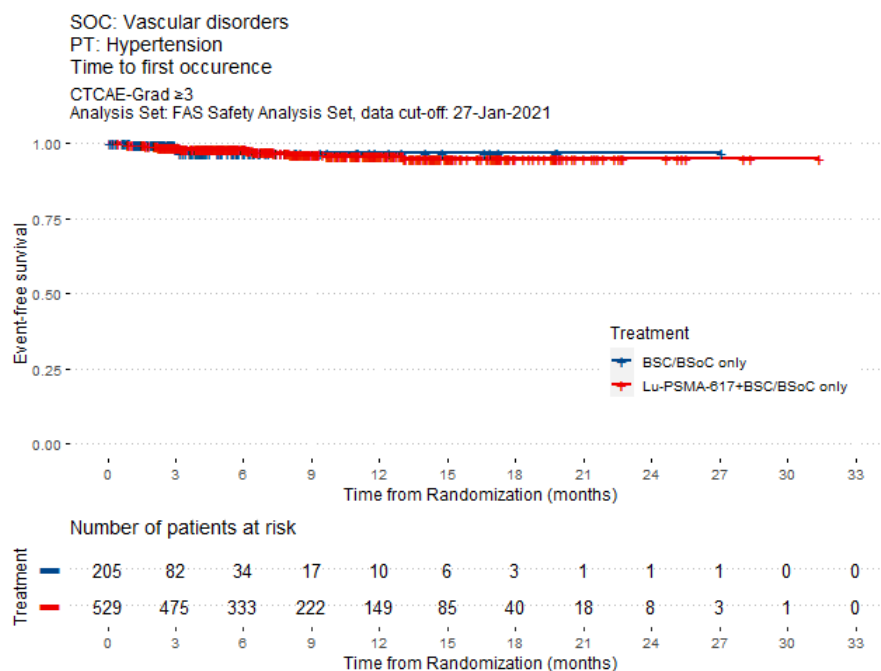


Abbildung 133: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Vascular disorders; PT: Hypertension

Anhang 4-H.1.3: Schwerwiegende UE

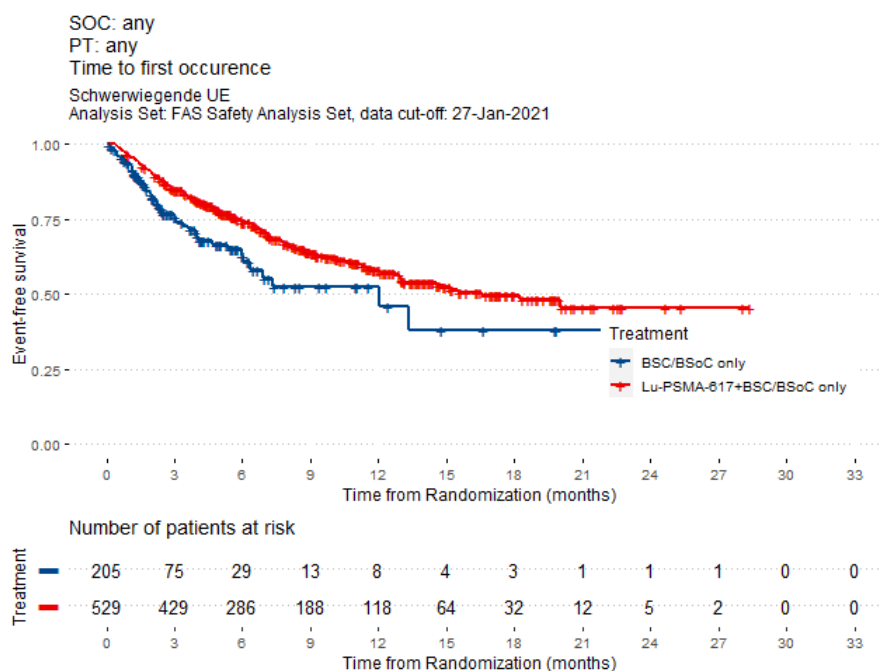


Abbildung 134: Schwerwiegende UE: Time to first occurrence of SOC: any; PT: any

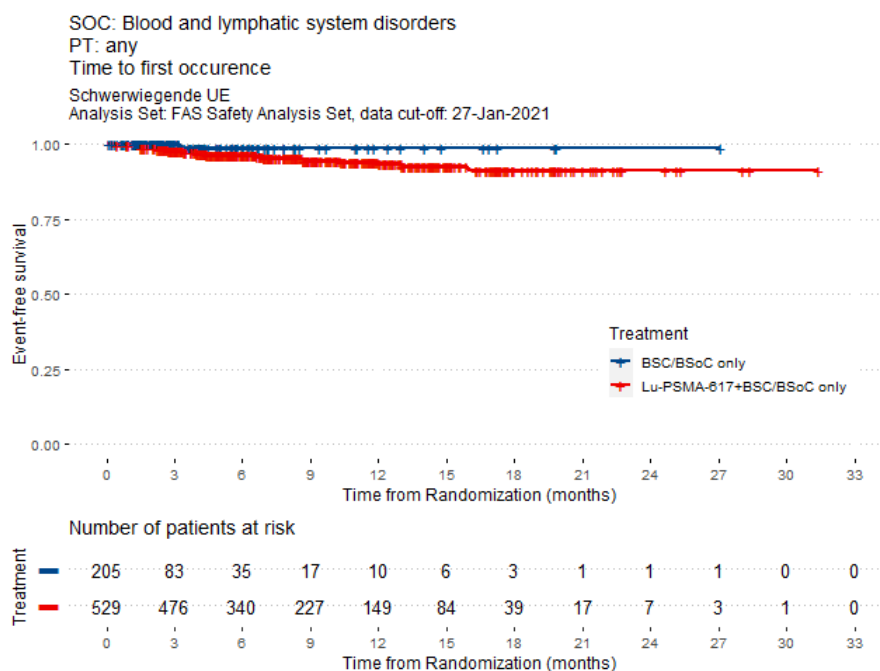


Abbildung 135: Schwerwiegende UE: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: any

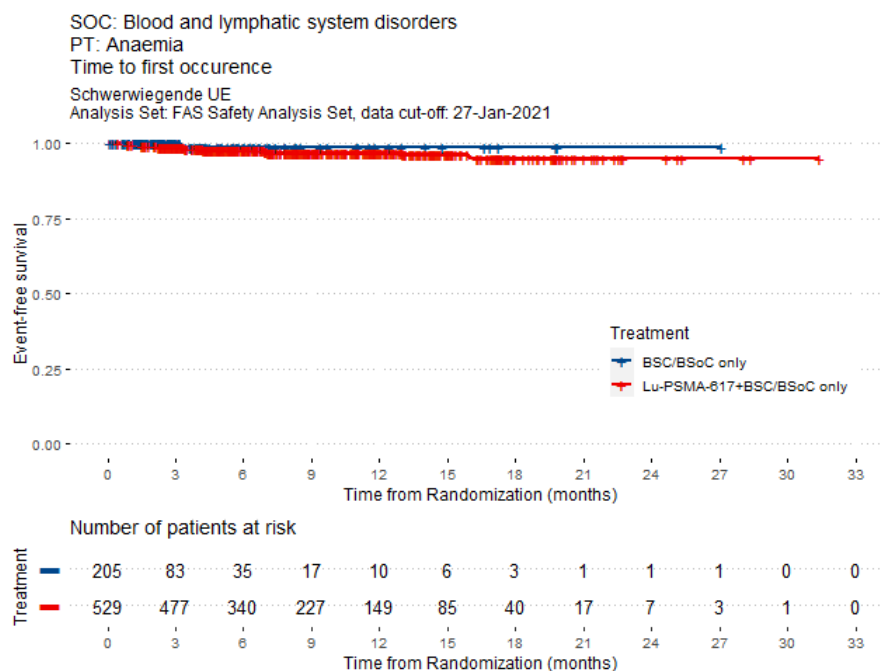


Abbildung 136: Schwerwiegende UE: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Anaemia

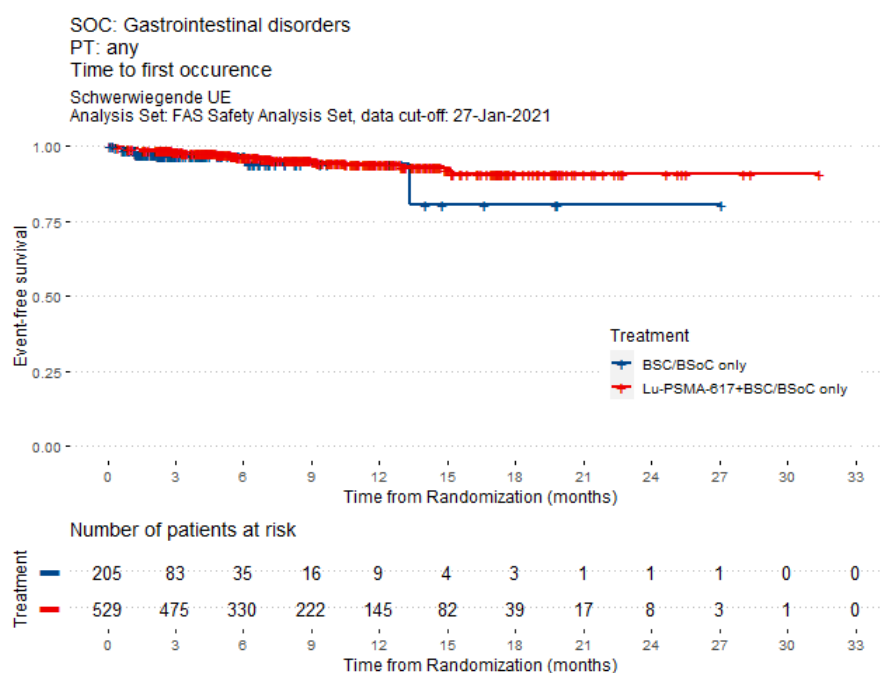


Abbildung 137: Schwerwiegende UE: Time to first occurrence of SOC: Gastrointestinal disorders; PT: any

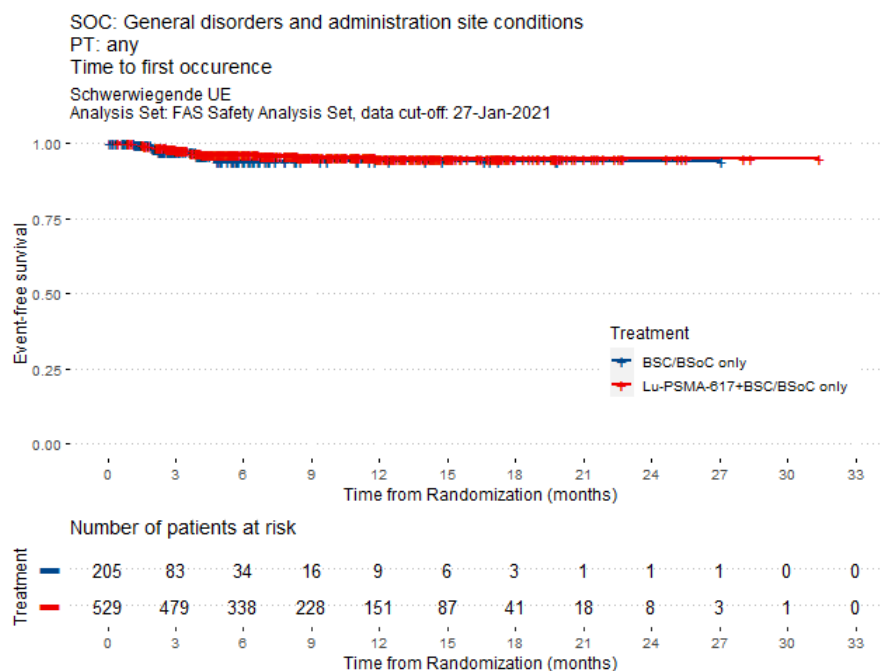


Abbildung 138: Schwerwiegende UE: Time to first occurrence of SOC: General disorders and administration site conditions; PT: any

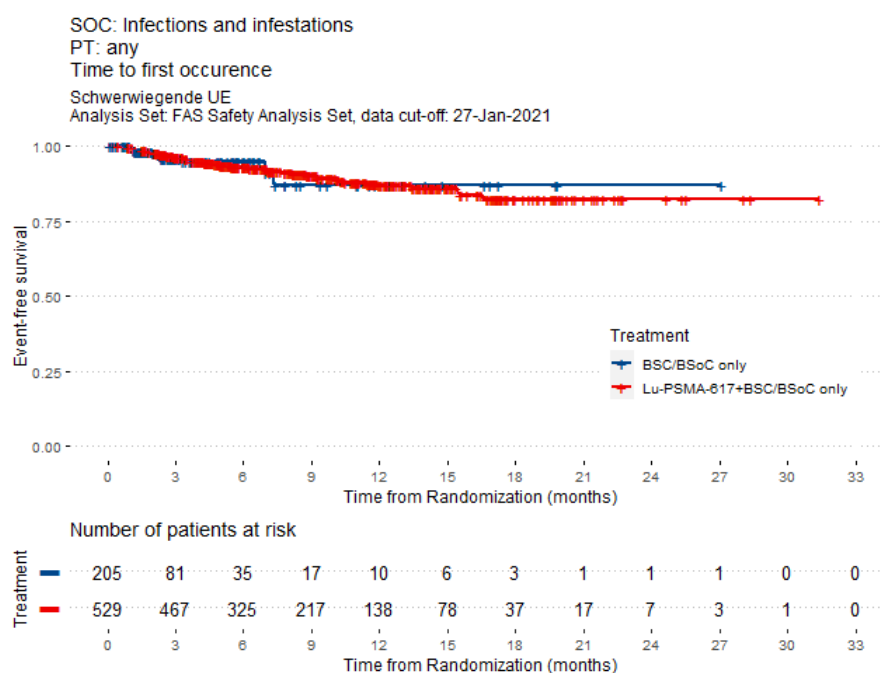


Abbildung 139: Schwerwiegende UE: Time to first occurrence of SOC: Infections and infestations; PT: any

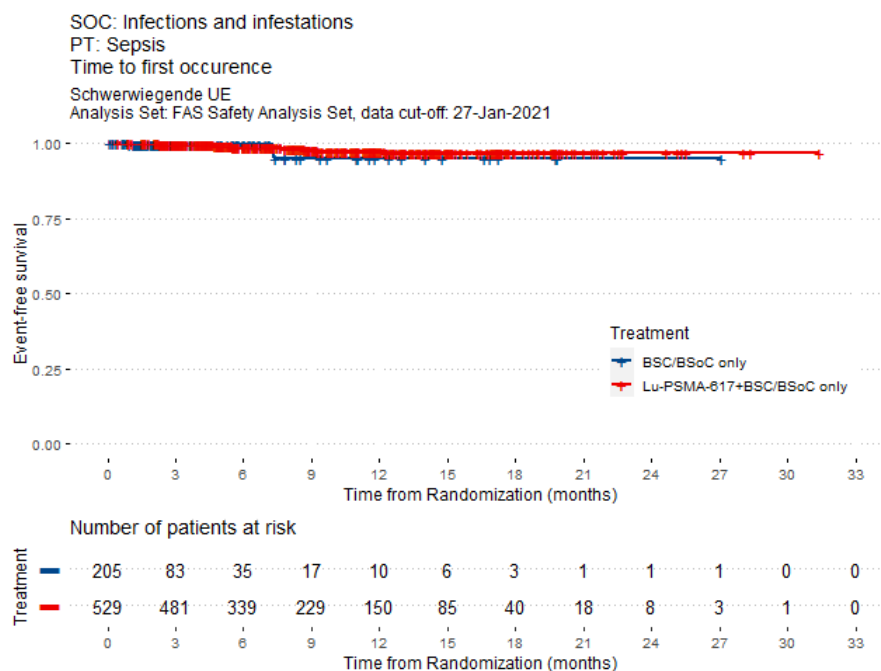


Abbildung 140: Schwerwiegende UE: Time to first occurrence of SOC: Infections and infestations; PT: Sepsis

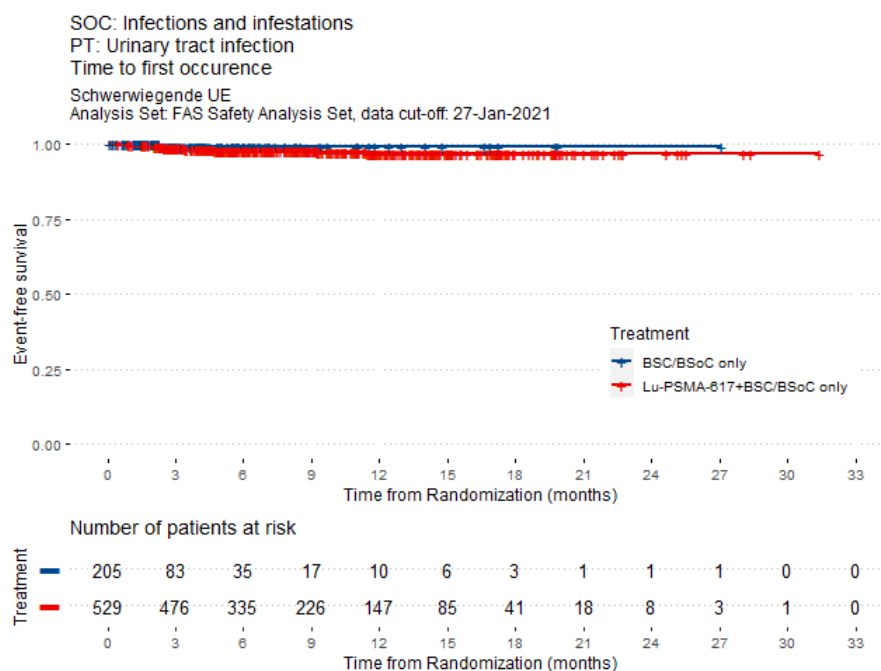


Abbildung 141: Schwerwiegende UE: Time to first occurrence of SOC: Infections and infestations; PT: Urinary tract infection

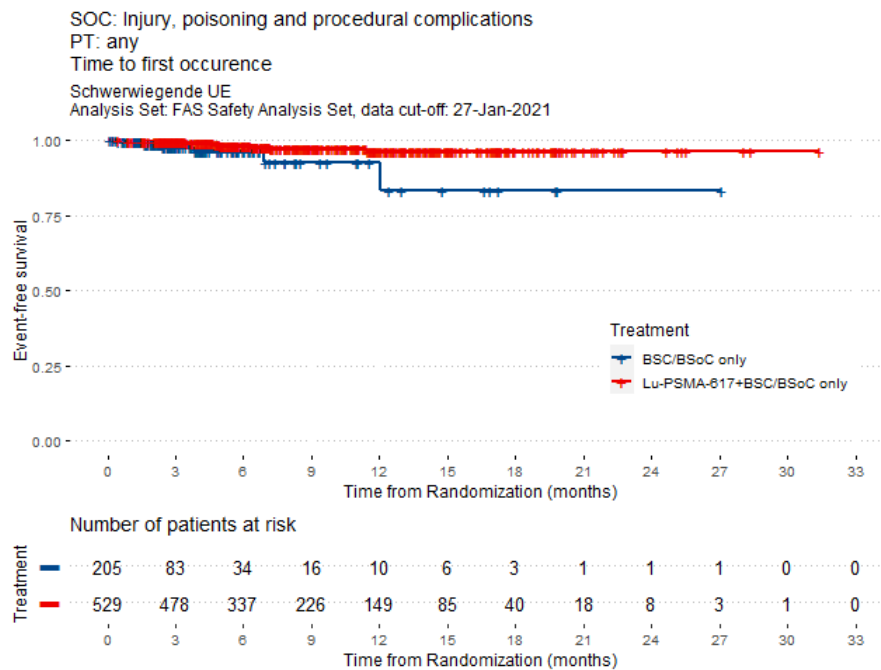


Abbildung 142: Schwerwiegende UE: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: any

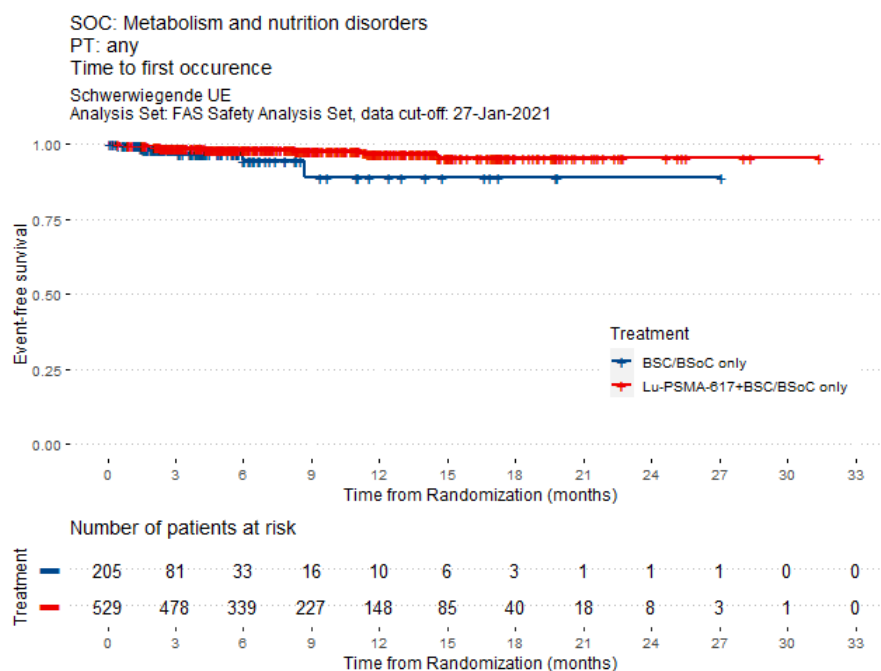


Abbildung 143: Schwerwiegende UE: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: any

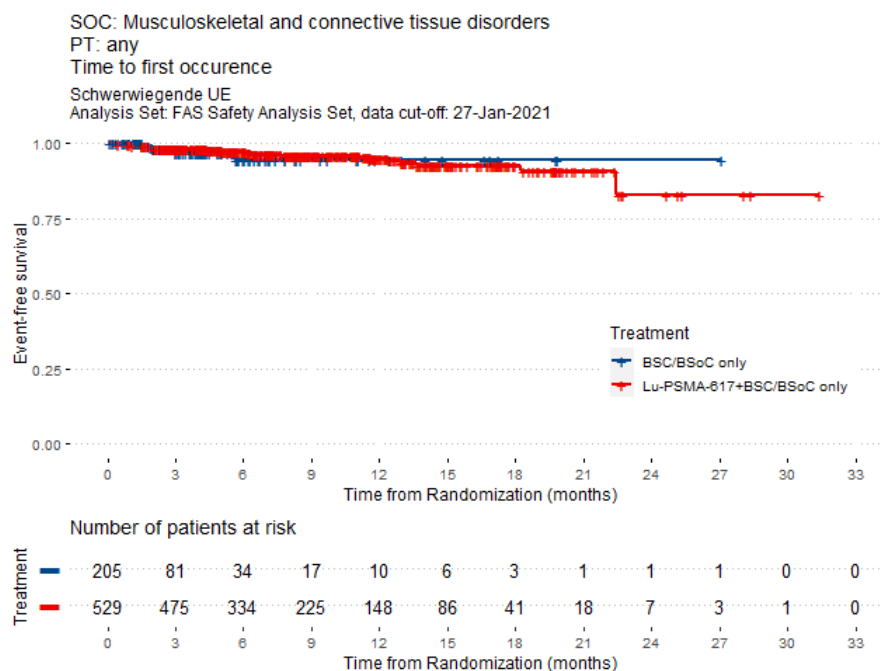


Abbildung 144: Schwerwiegende UE: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: any

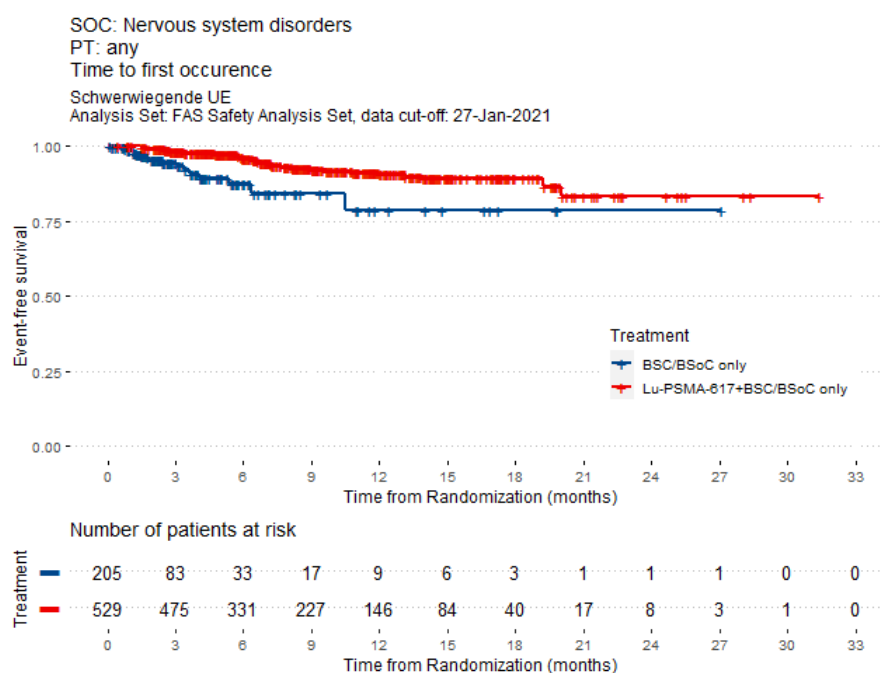


Abbildung 145: Schwerwiegende UE: Time to first occurrence of SOC: Nervous system disorders; PT: any

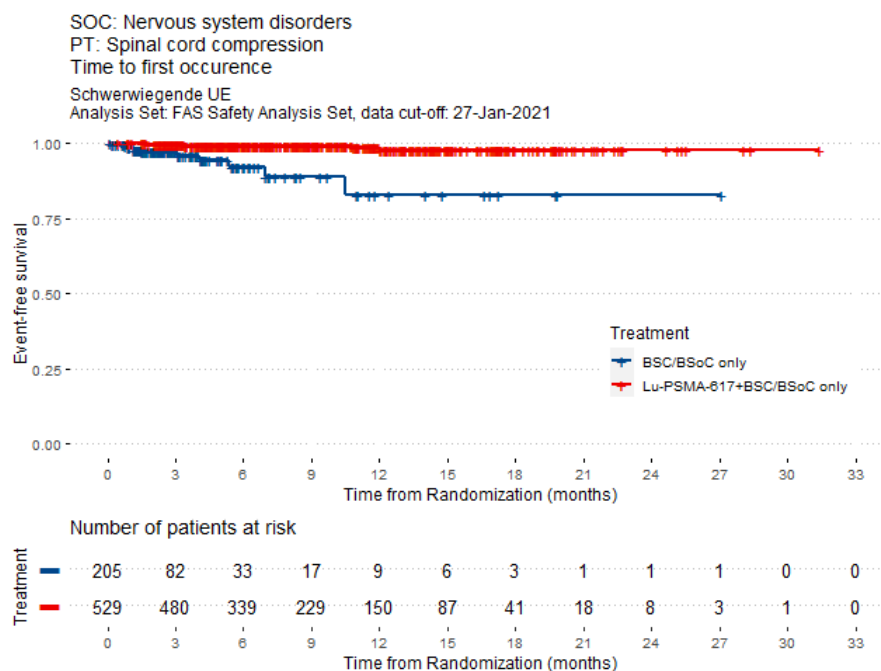


Abbildung 146: Schwerwiegende UE: Time to first occurrence of SOC: Nervous system disorders; PT: Spinal cord compression

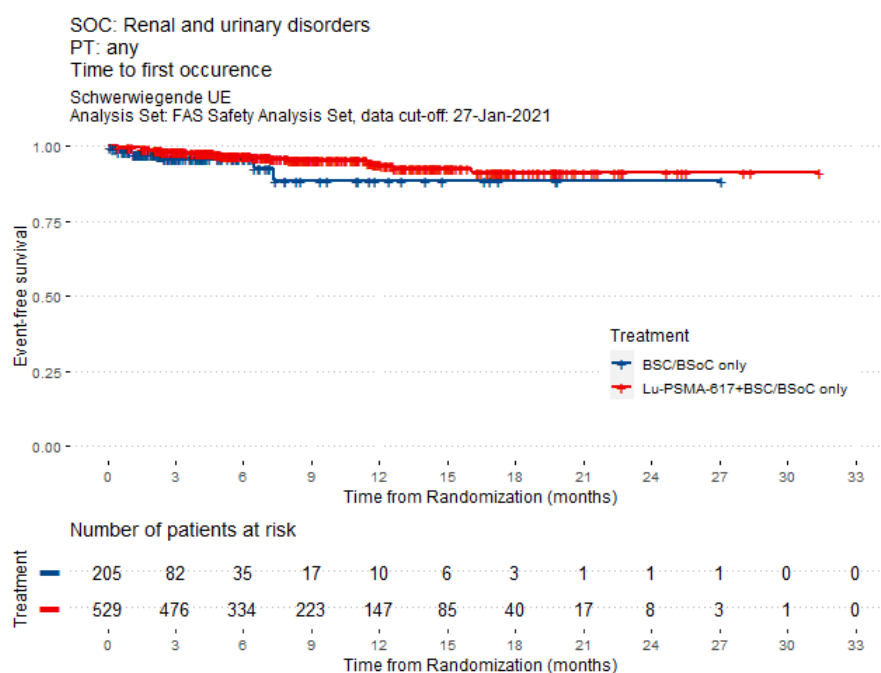


Abbildung 147: Schwerwiegende UE: Time to first occurrence of SOC: Renal and urinary disorders; PT: any

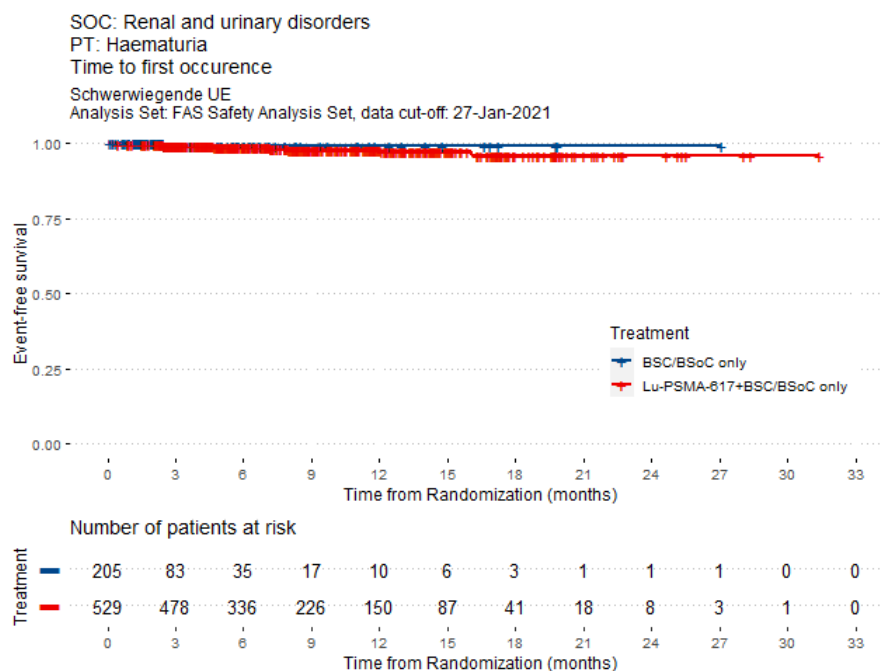


Abbildung 148: Schwerwiegende UE: Time to first occurrence of SOC: Renal and urinary disorders; PT: Haematuria

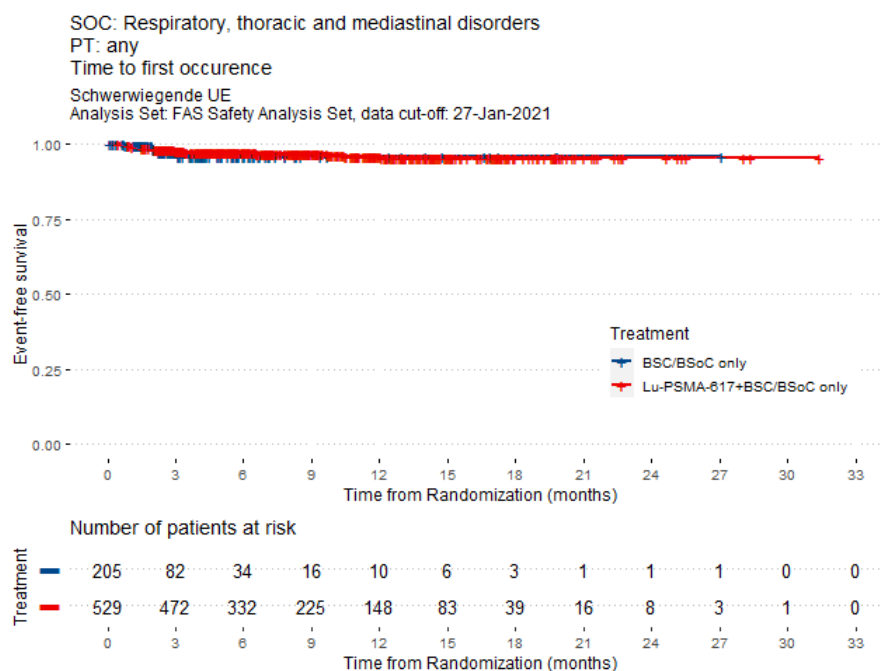


Abbildung 149: Schwerwiegende UE: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: any

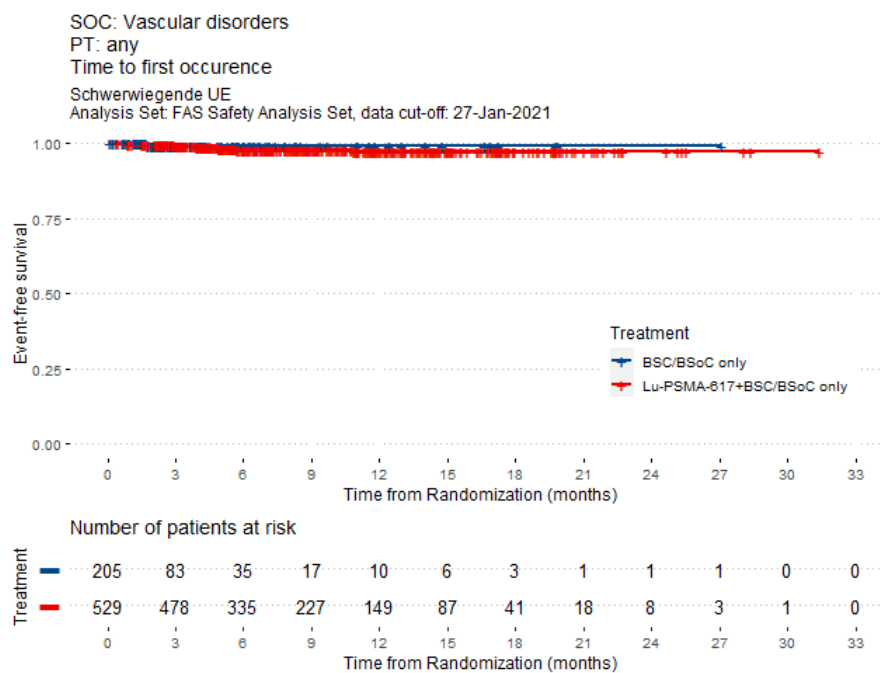


Abbildung 150: Schwerwiegende UE: Time to first occurrence of SOC: Vascular disorders;
PT: any

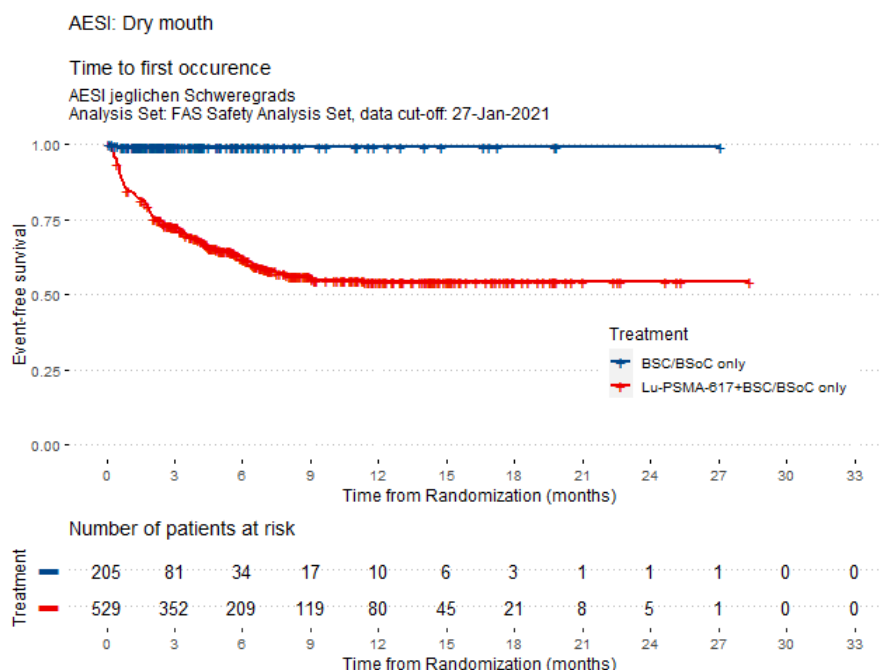
Anhang 4-H.2: Unerwünschte Ereignisse von besonderem Interesse**Anhang 4-H.2.1: UE jeglichen Schweregrads**

Abbildung 151: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Dry mouth

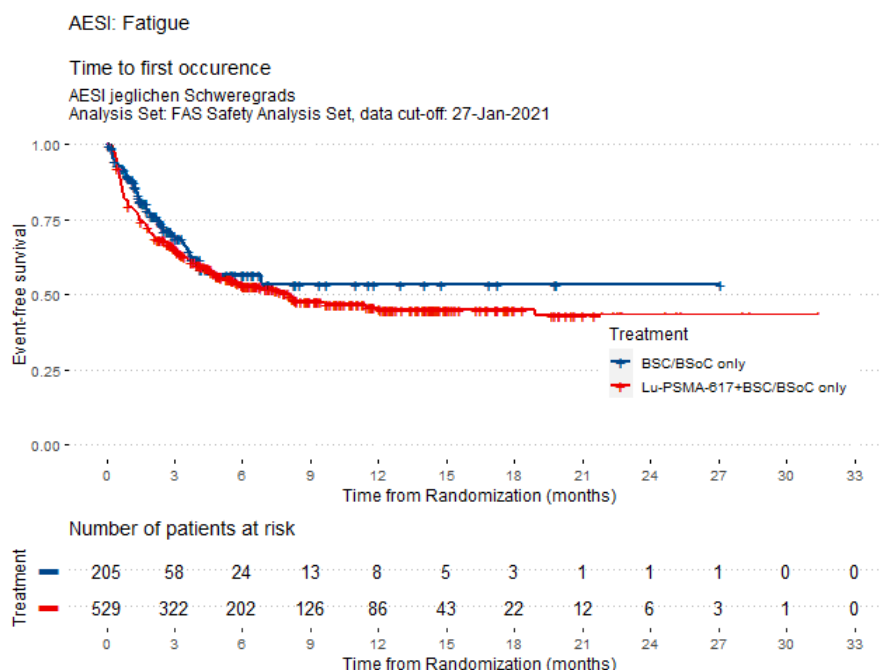


Abbildung 152: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Fatigue

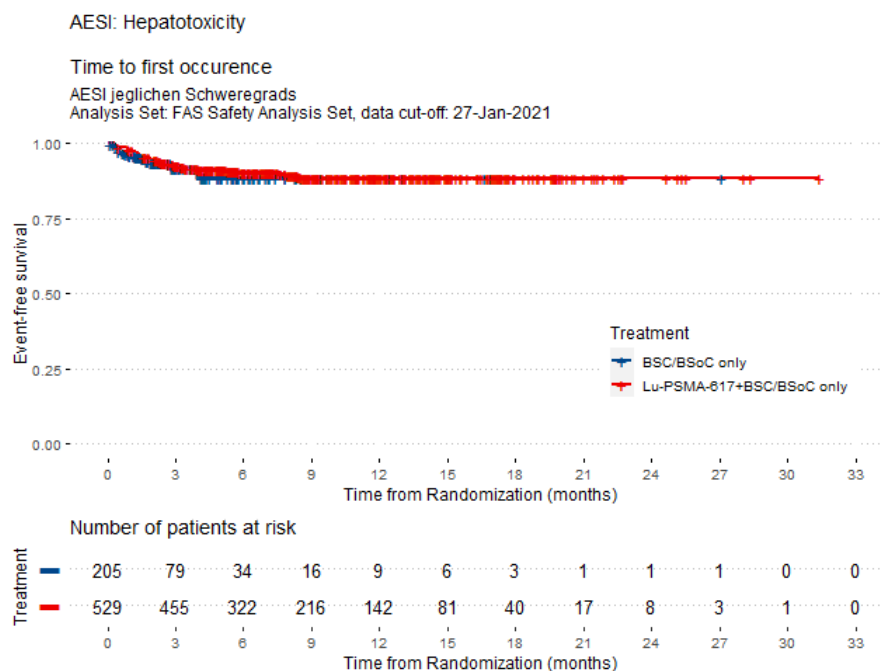


Abbildung 153: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Hepatotoxicity

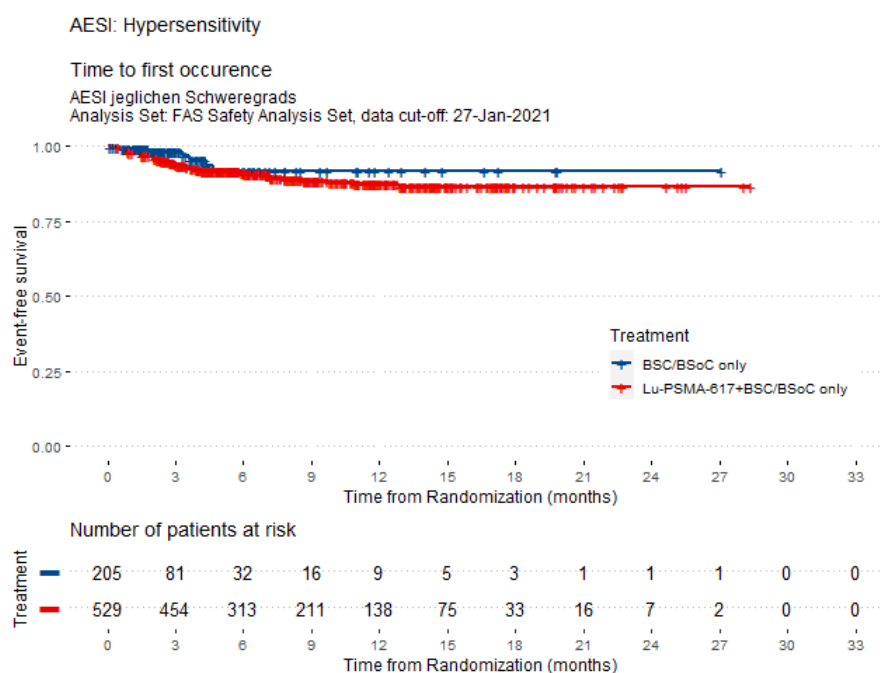


Abbildung 154: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Hypersensitivity

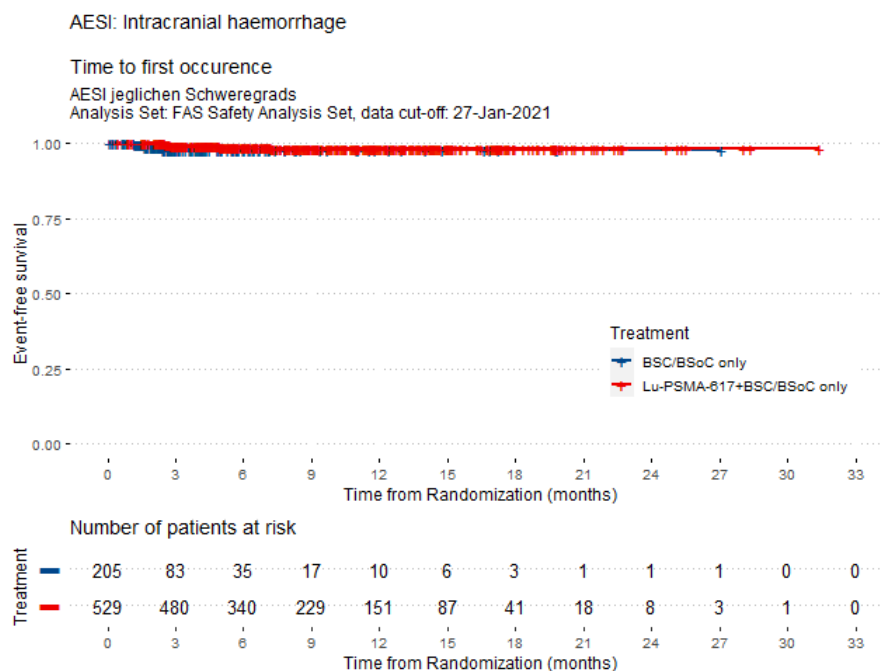


Abbildung 155: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Intracranial haemorrhage

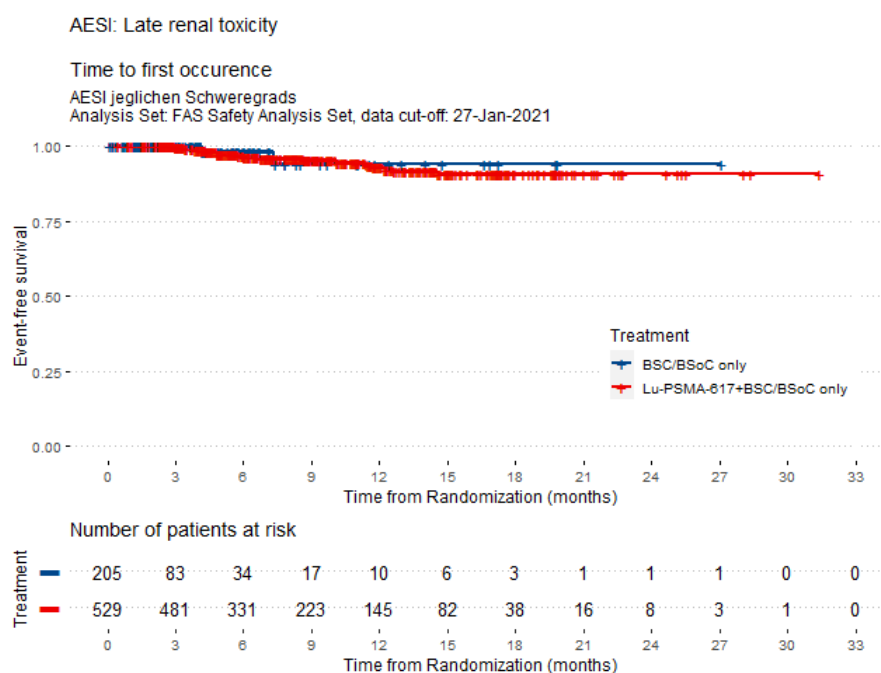


Abbildung 156: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Late renal toxicity

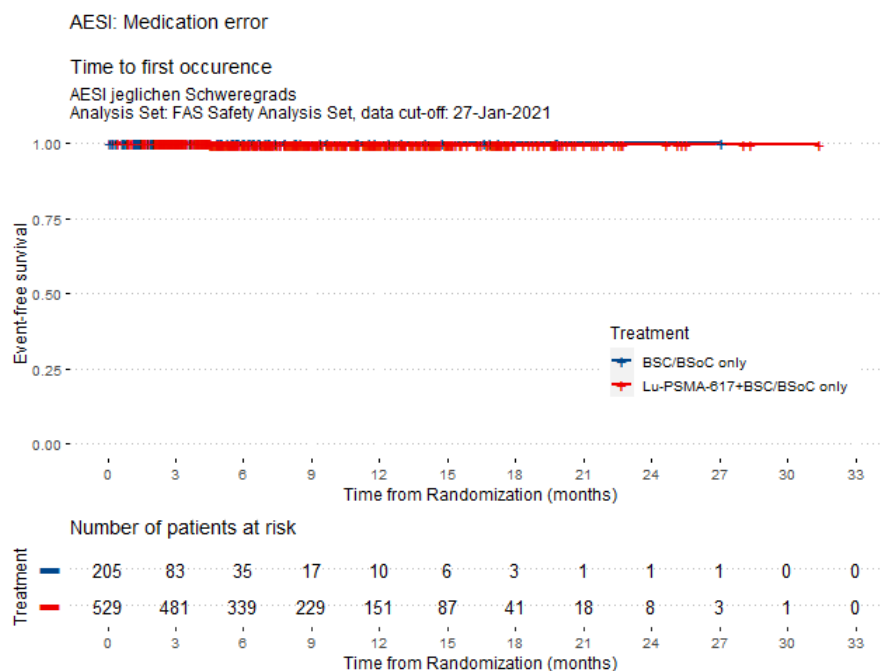


Abbildung 157: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Medication error

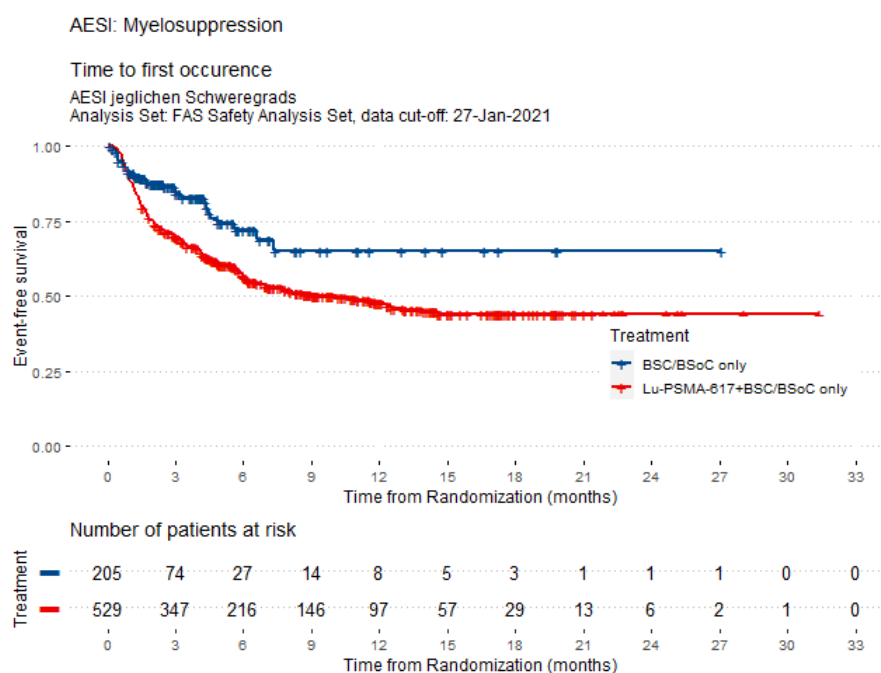


Abbildung 158: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Myelosuppression

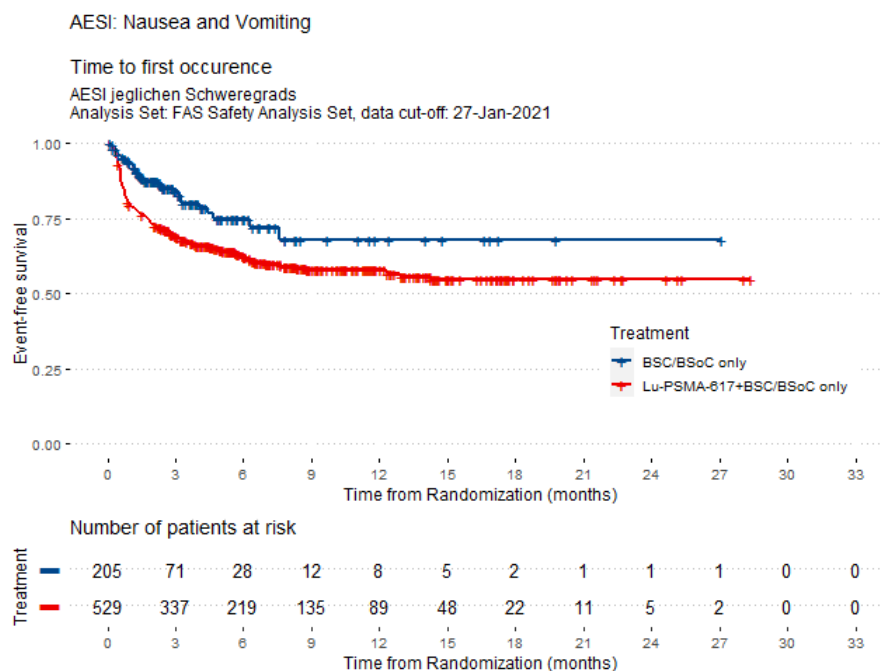


Abbildung 159: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Nausea and Vomiting

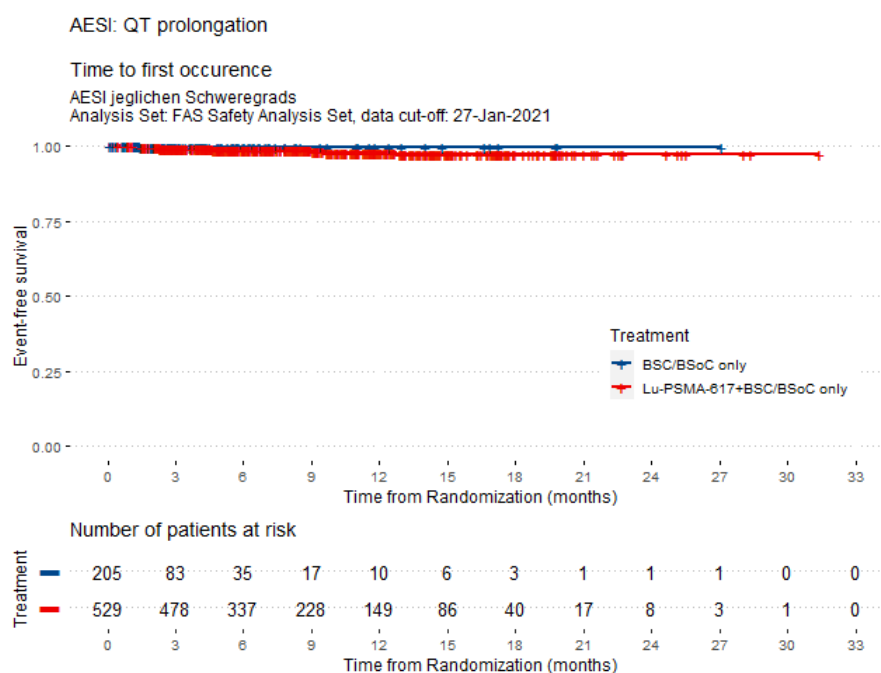


Abbildung 160: AESI jeglichen Schweregrads: Time to first occurrence of AESI: QT prolongation

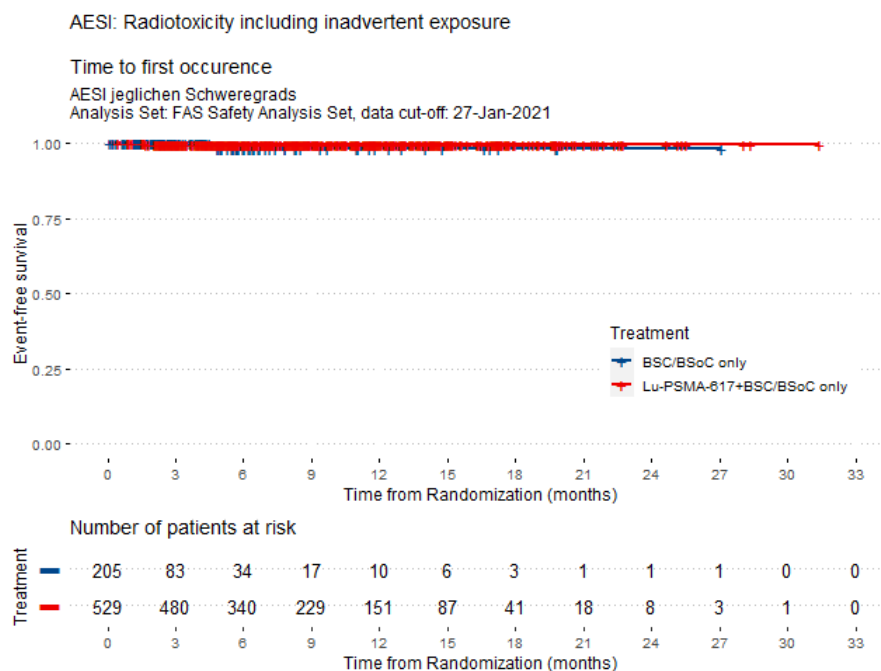


Abbildung 161: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Radiotoxicity including inadvertent exposure

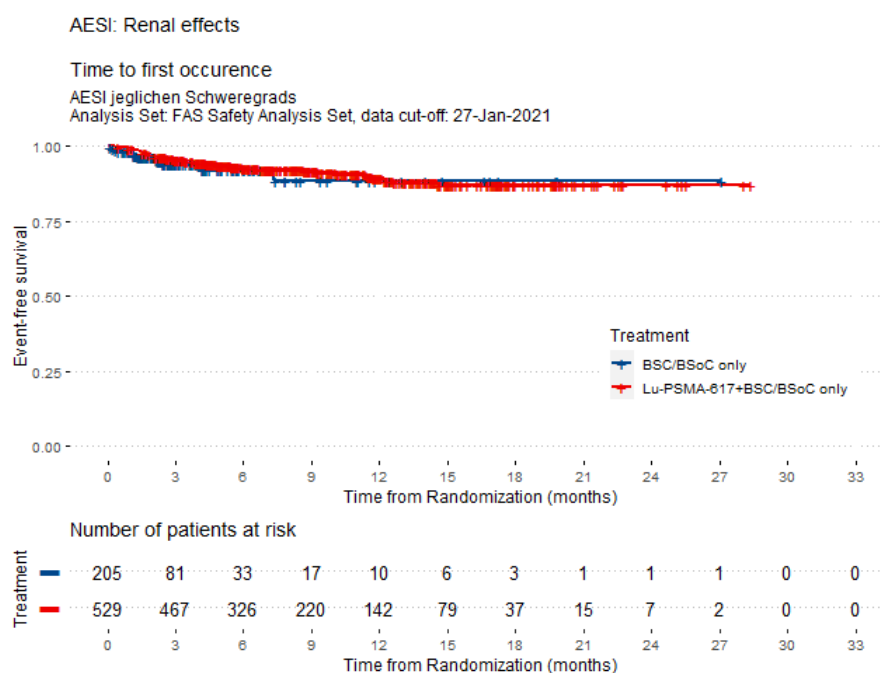


Abbildung 162: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Renal effects

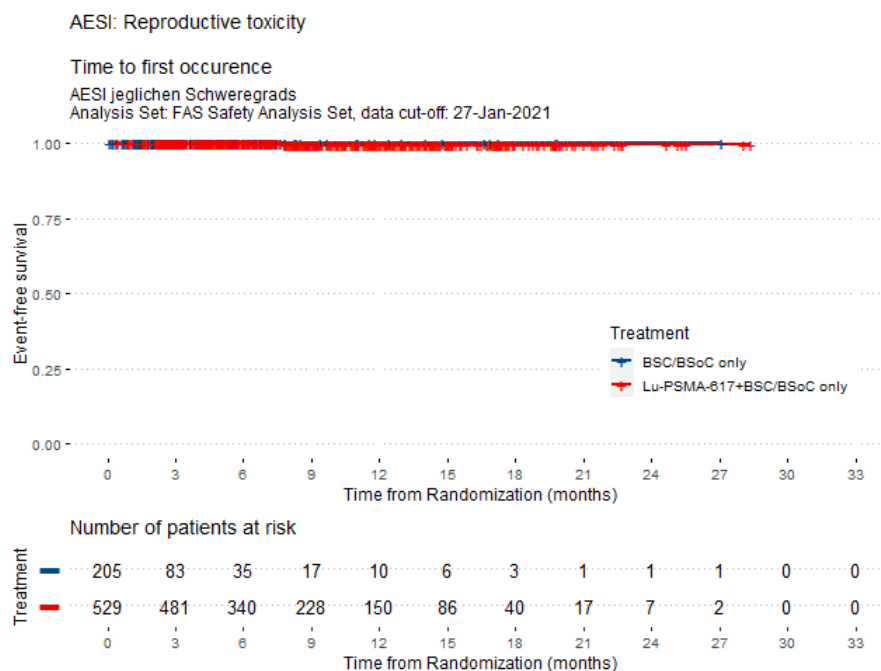


Abbildung 163: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Reproductive toxicity

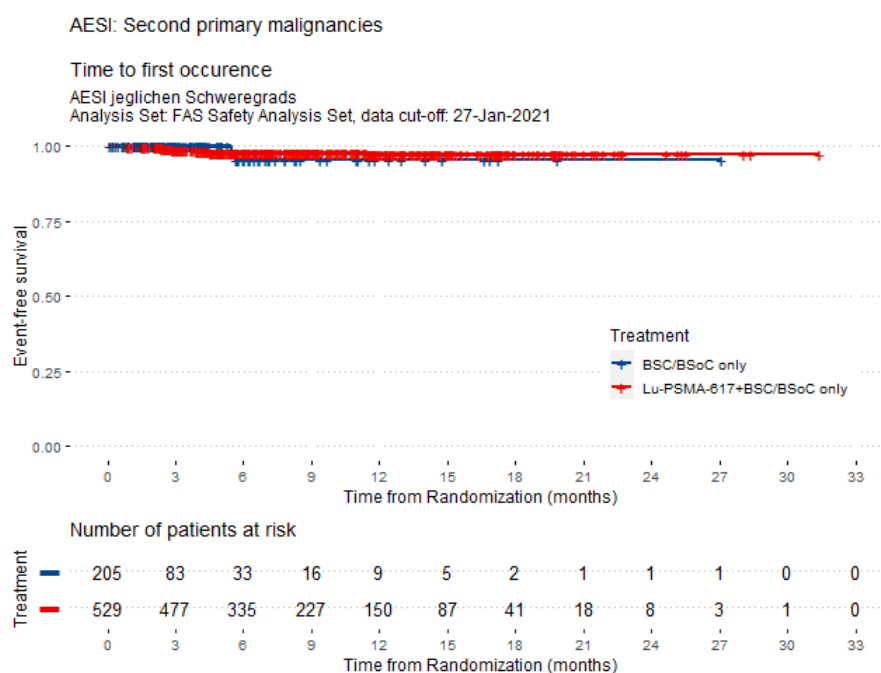


Abbildung 164: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Second primary malignancies

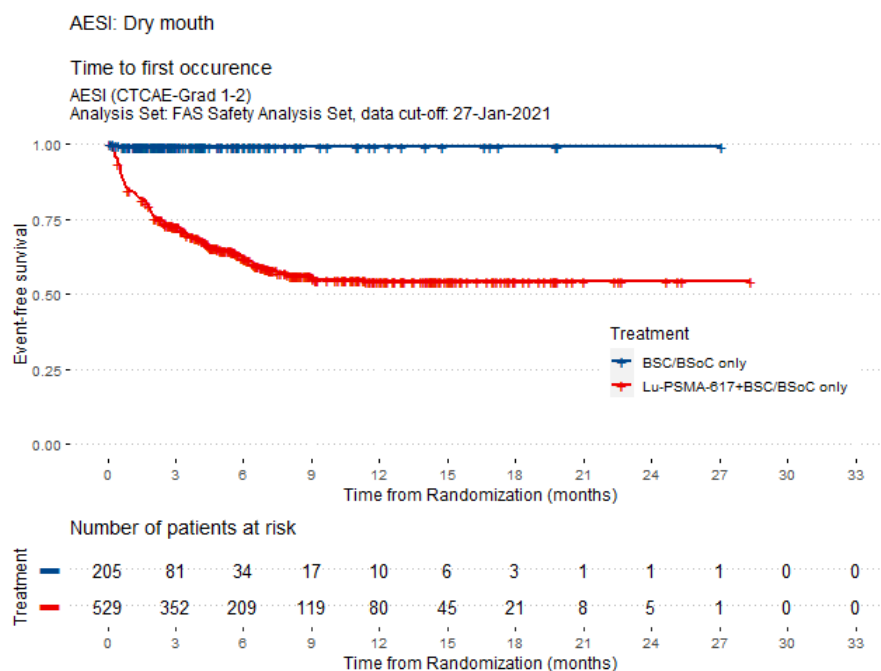
Anhang 4-H.2.2: Nicht-schwere UE (CTCAE-Grad 1-2)

Abbildung 165: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Dry mouth

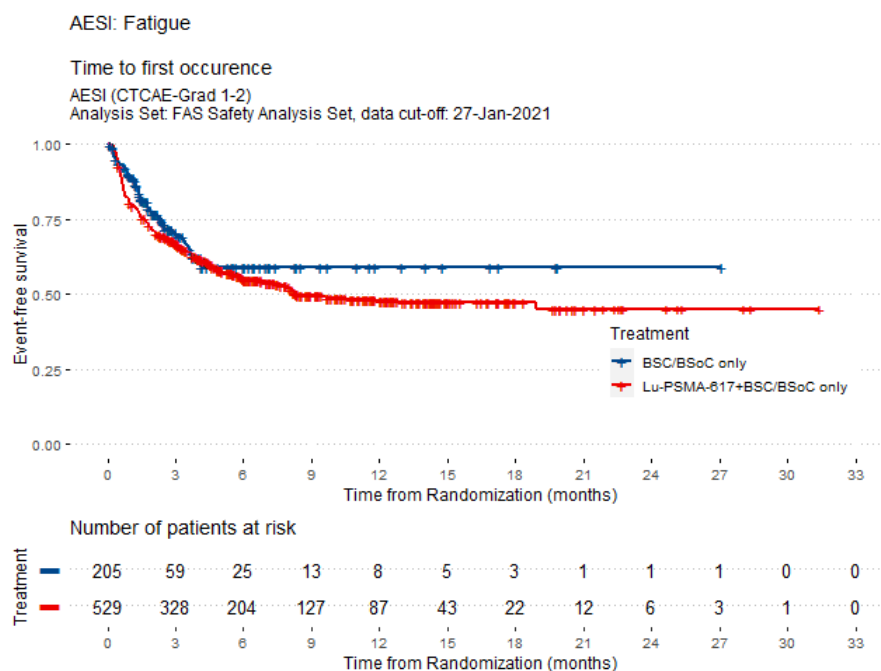


Abbildung 166: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Fatigue

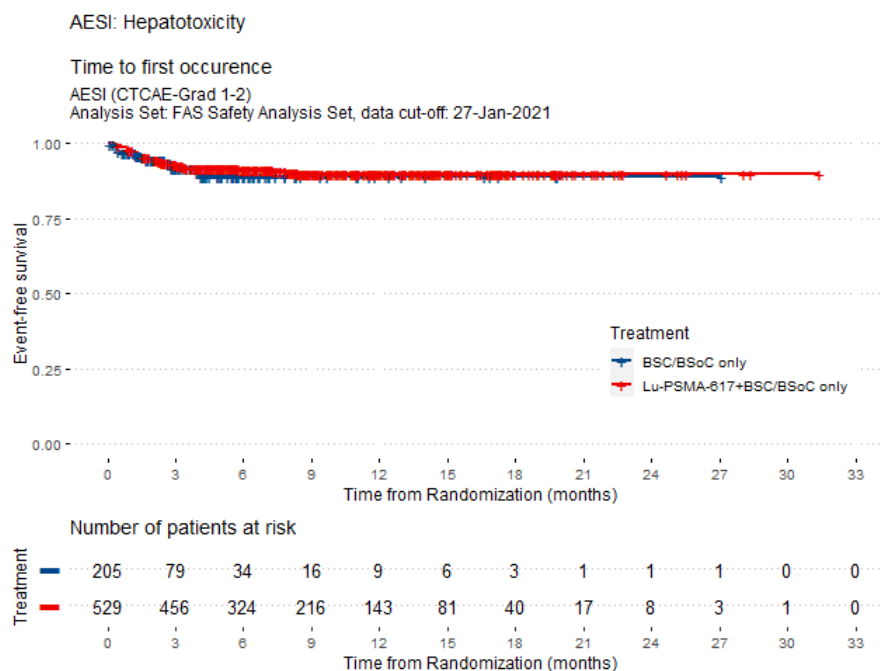


Abbildung 167: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Hepatotoxicity

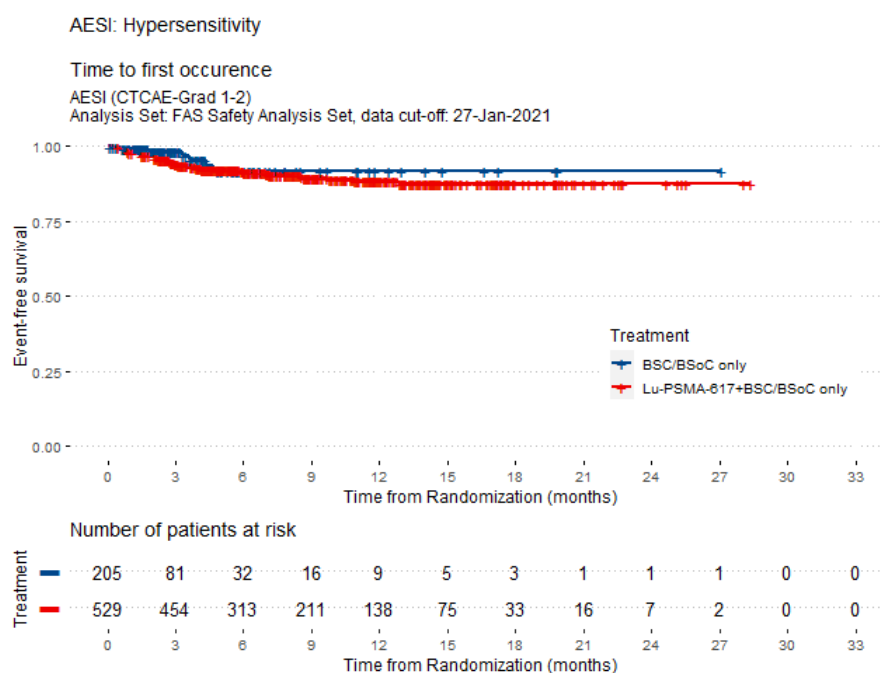


Abbildung 168: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Hypersensitivity

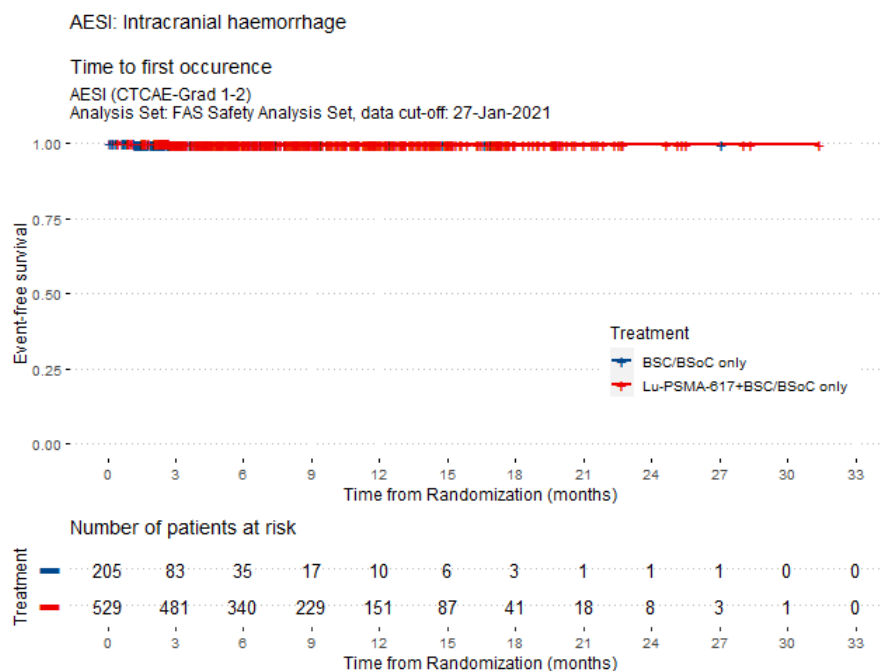


Abbildung 169: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Intracranial haemorrhage

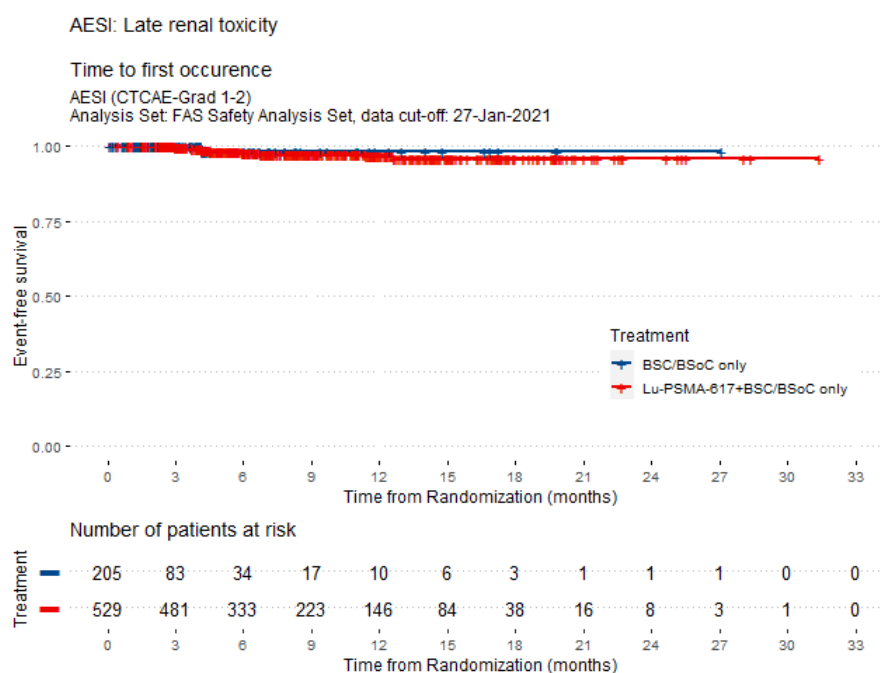


Abbildung 170: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Late renal toxicity

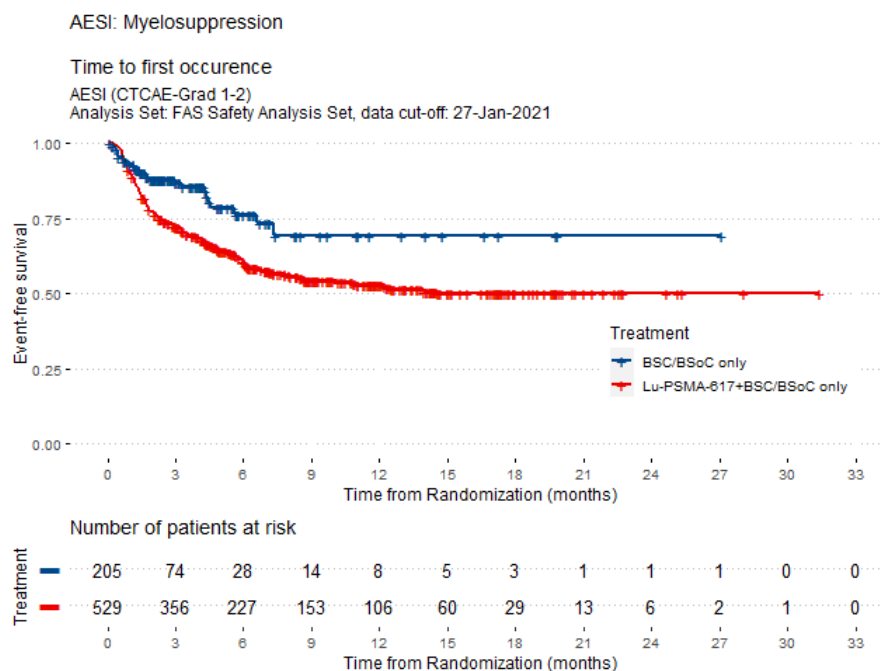


Abbildung 171: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Myelosuppression

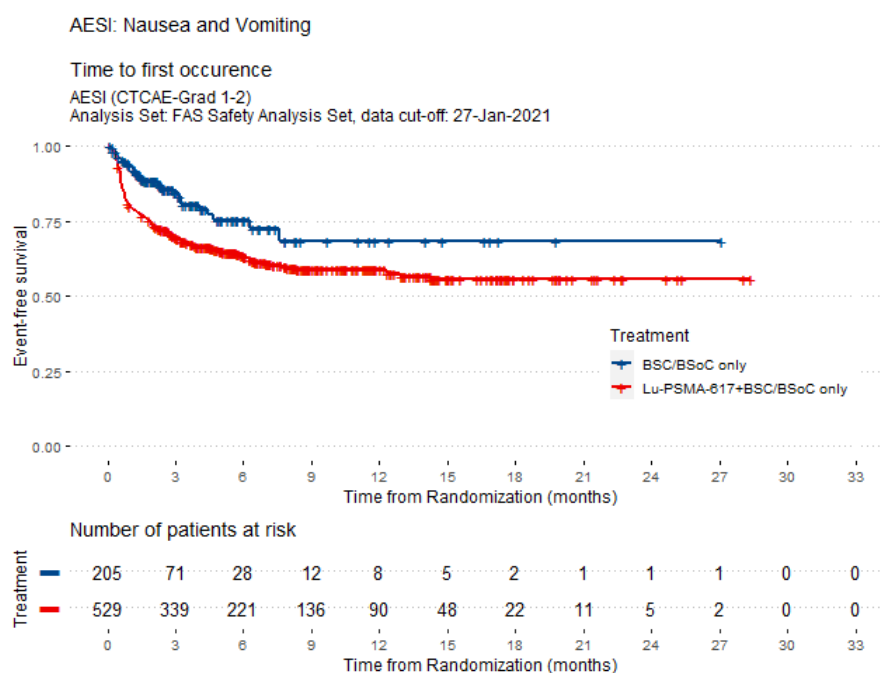


Abbildung 172: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Nausea and Vomiting

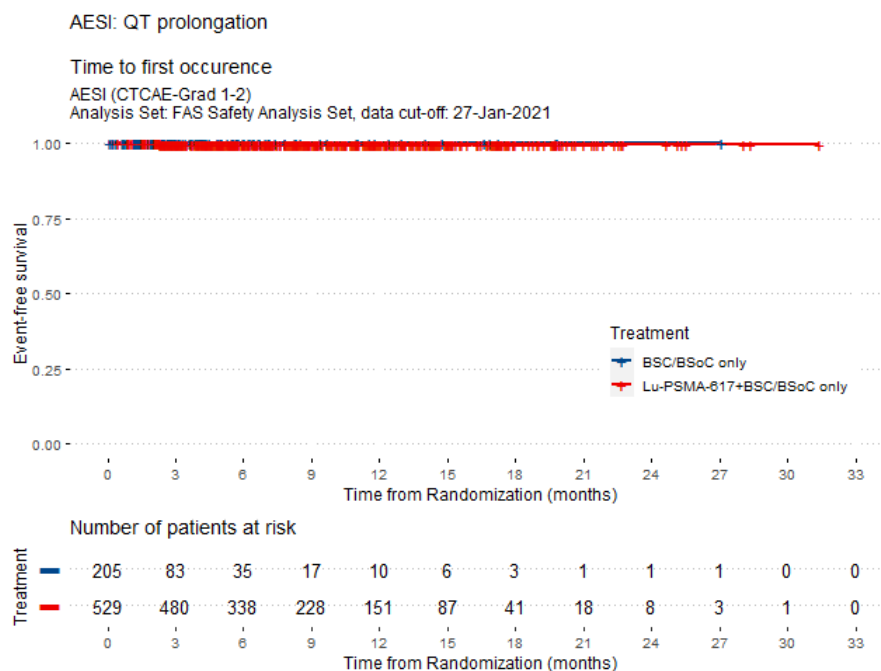


Abbildung 173: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: QT prolongation

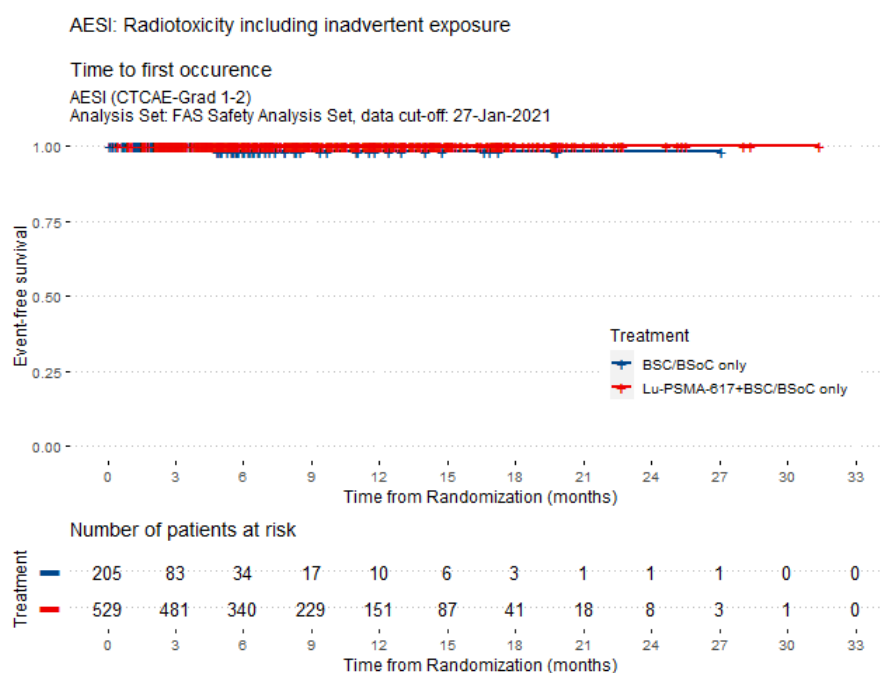


Abbildung 174: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Radiotoxicity including inadvertent exposure

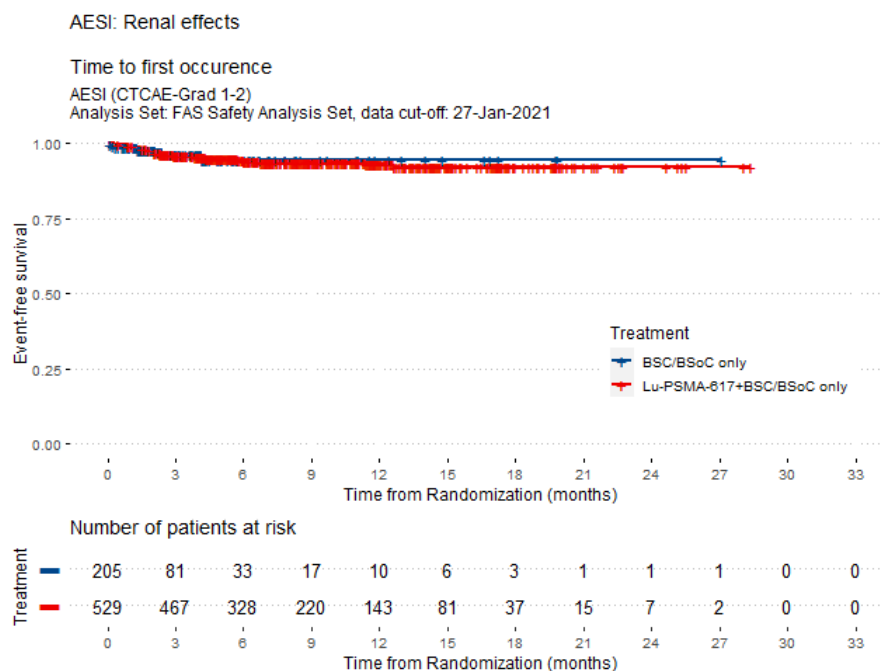


Abbildung 175: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Renal effects

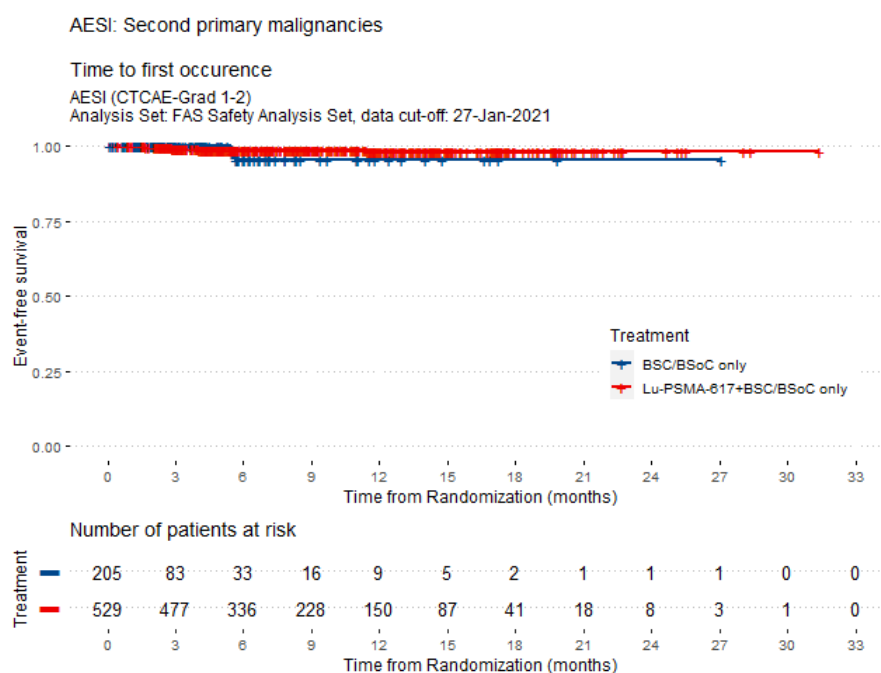
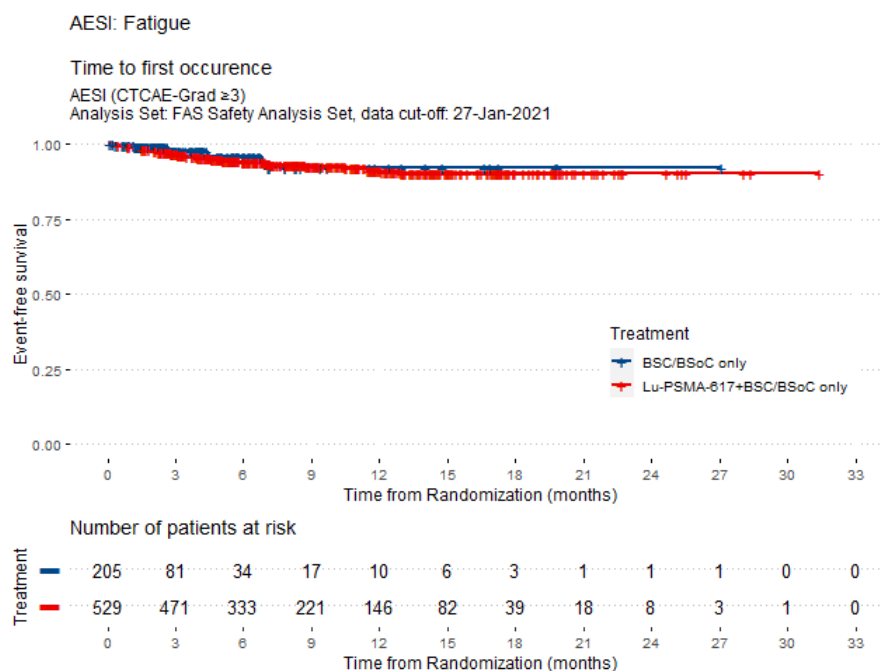
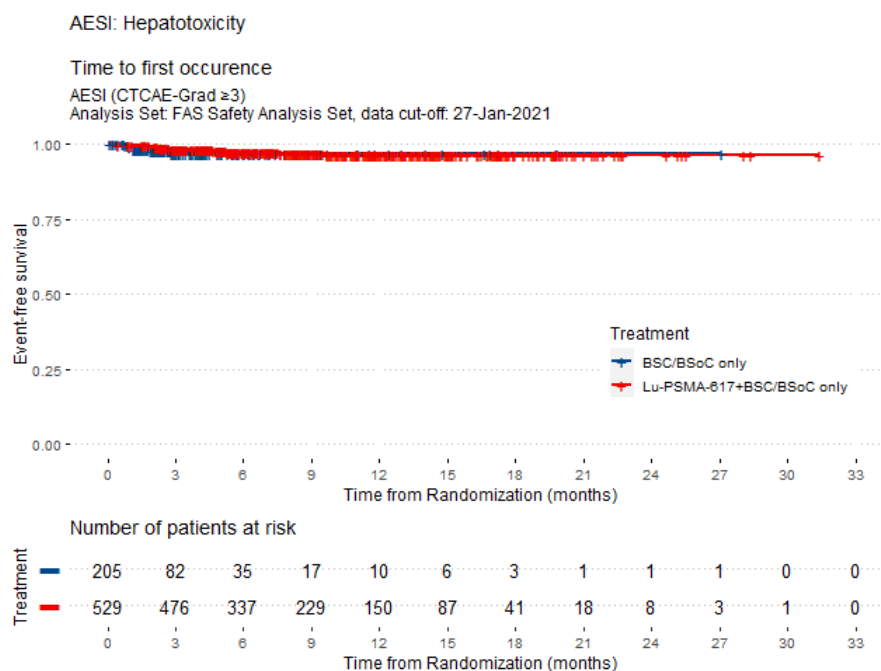
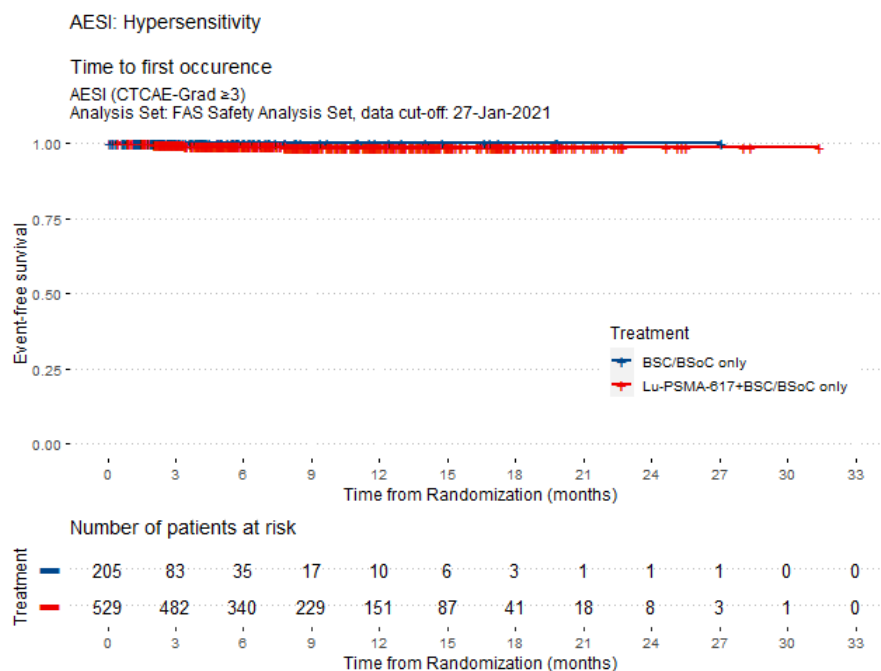
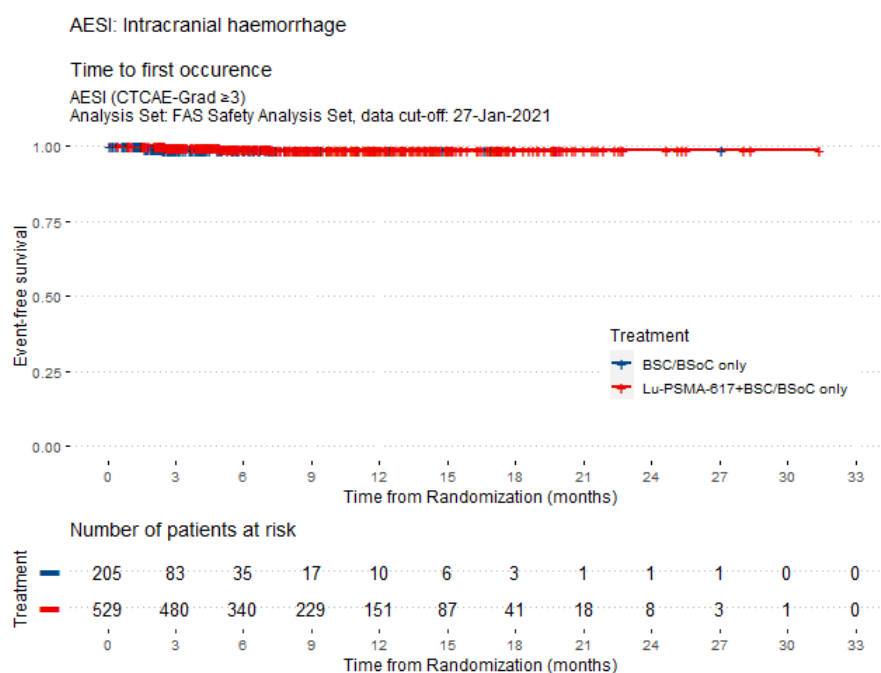


Abbildung 176: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Second primary malignancies

Anhang 4-H.2.3: Schwere UE (CTCAE-Grad ≥ 3)Abbildung 177: AESi (CTCAE-Grad ≥ 3): Time to first occurrence of AESi: FatigueAbbildung 178: AESi (CTCAE-Grad ≥ 3): Time to first occurrence of AESi: Hepatotoxicity

Abbildung 179: AESi (CTCAE-Grad ≥ 3): Time to first occurrence of AESi: HypersensitivityAbbildung 180: AESi (CTCAE-Grad ≥ 3): Time to first occurrence of AESi: Intracranial haemorrhage

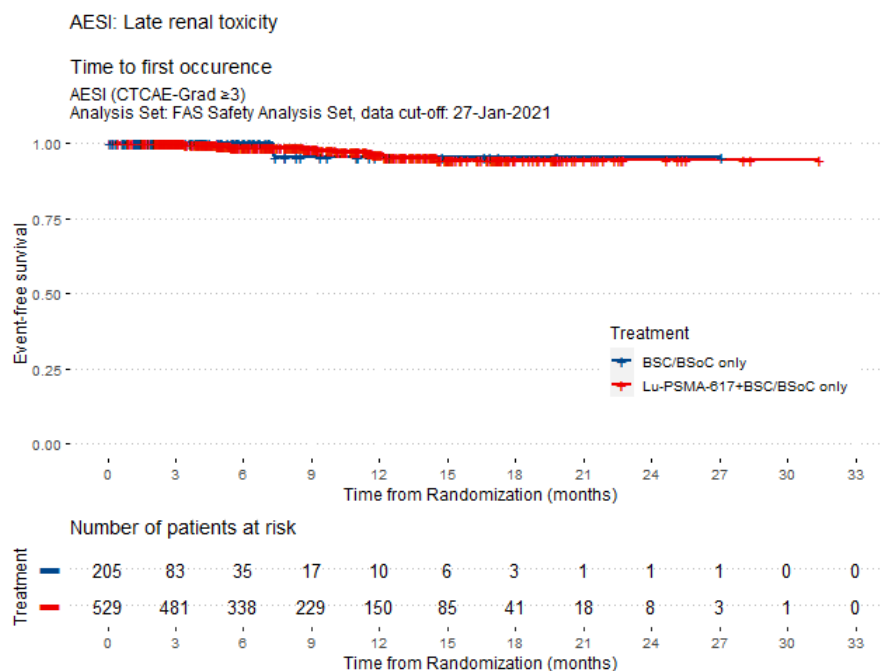


Abbildung 181: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Late renal toxicity

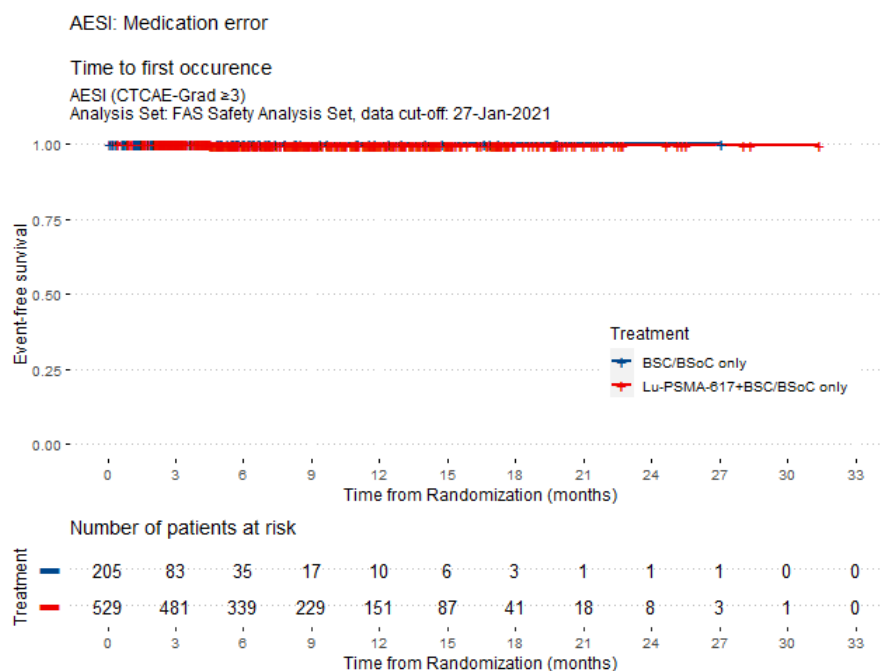


Abbildung 182: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Medication error

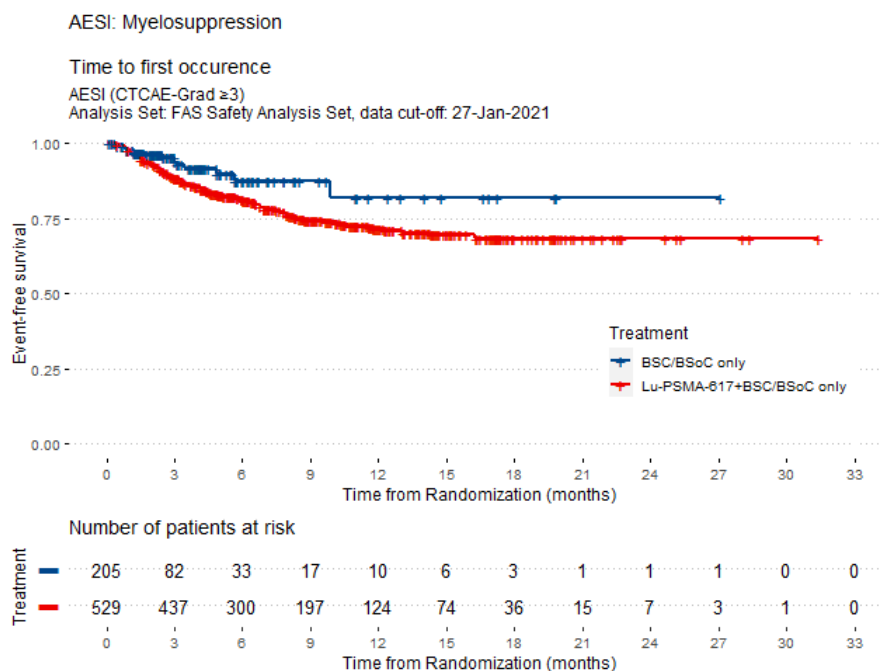


Abbildung 183: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Myelosuppression

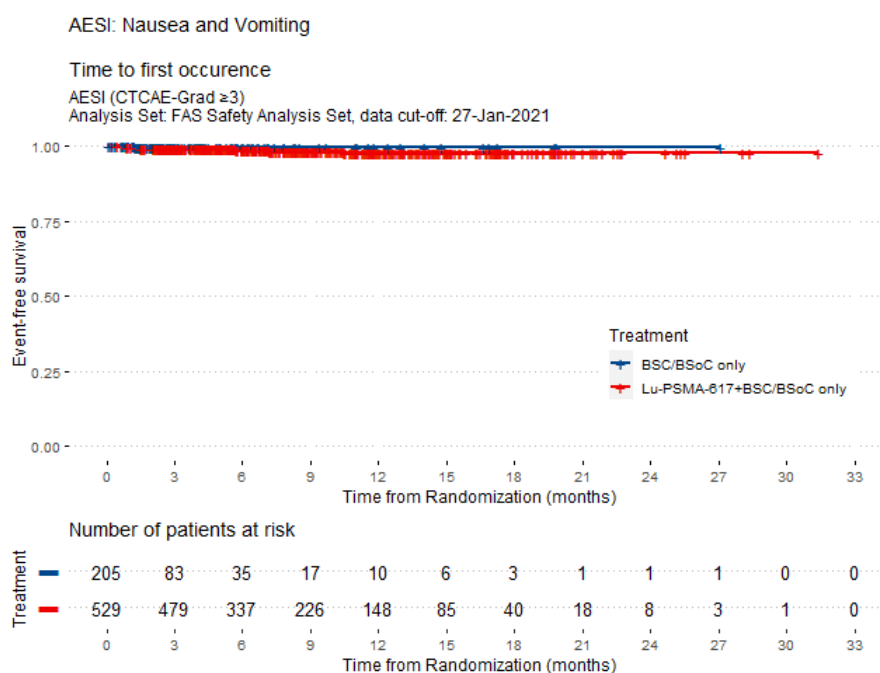
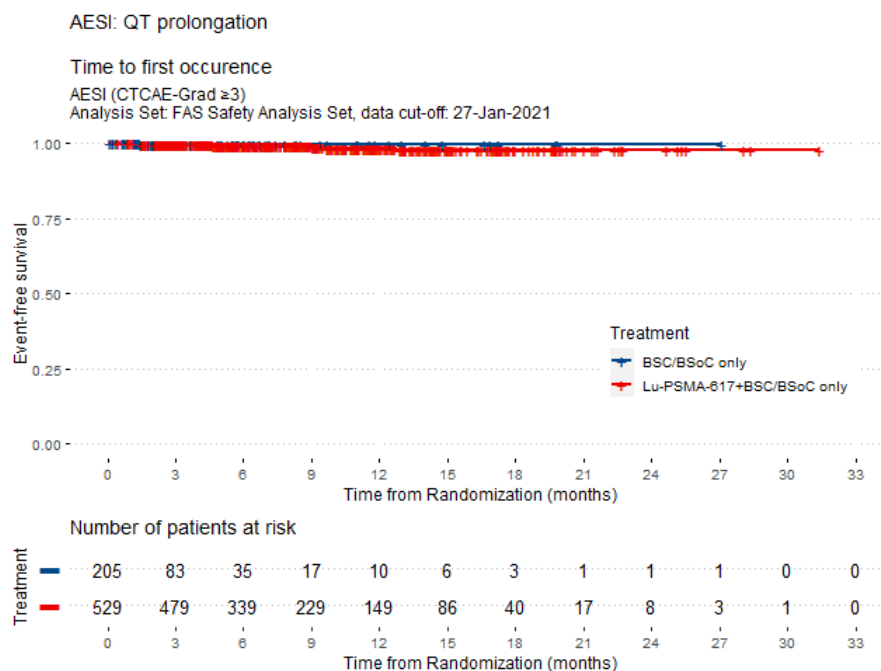
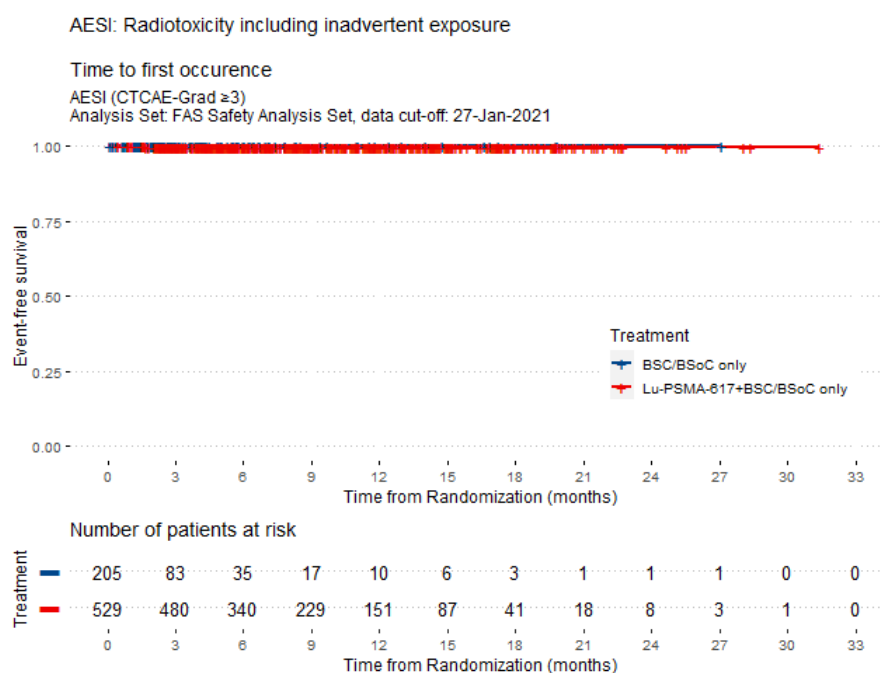
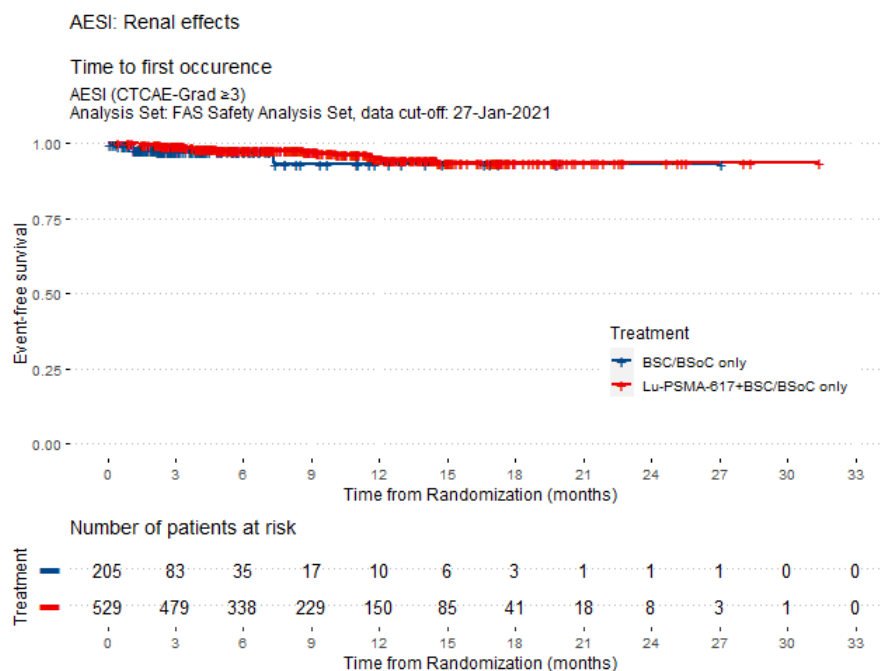
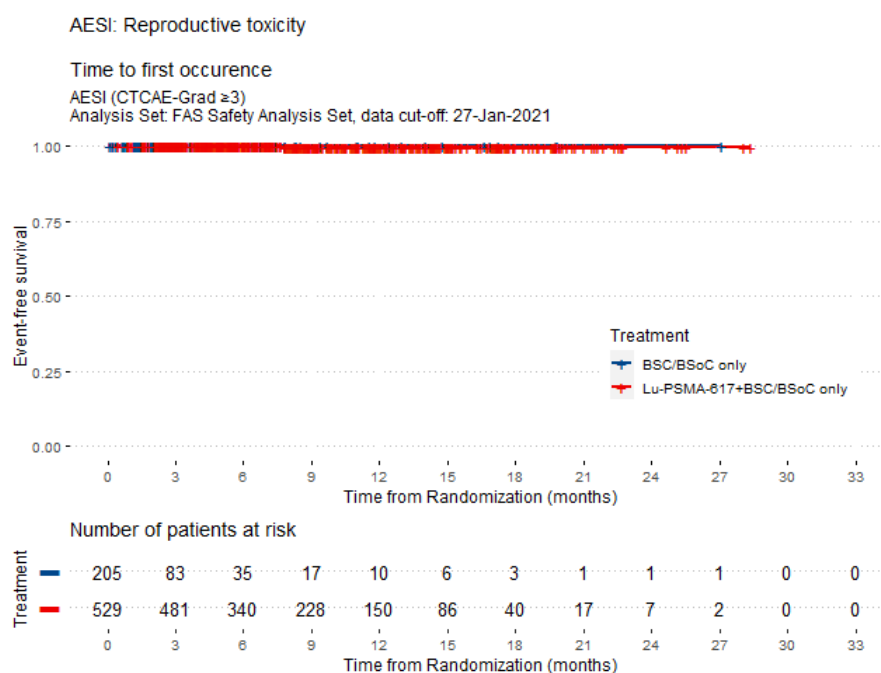


Abbildung 184: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Nausea and Vomiting

Abbildung 185: AESi (CTCAE-Grad ≥ 3): Time to first occurrence of AESi: QT prolongationAbbildung 186: AESi (CTCAE-Grad ≥ 3): Time to first occurrence of AESi: Radiotoxicity including inadvertent exposure

Abbildung 187: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Renal effectsAbbildung 188: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Reproductive toxicity

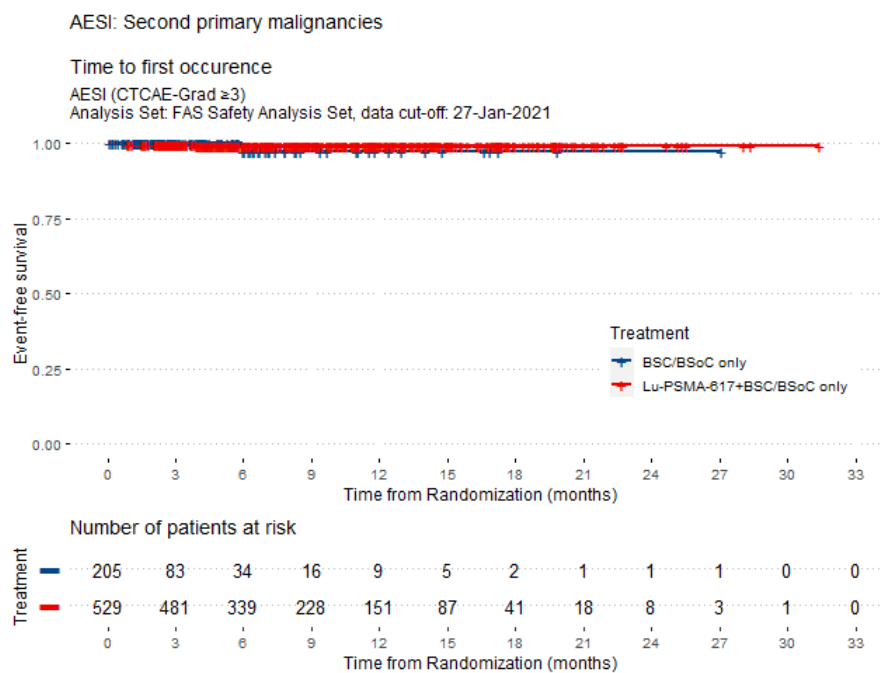


Abbildung 189: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Second primary malignancies

Anhang 4-H.2.4: Schwerwiegende UE

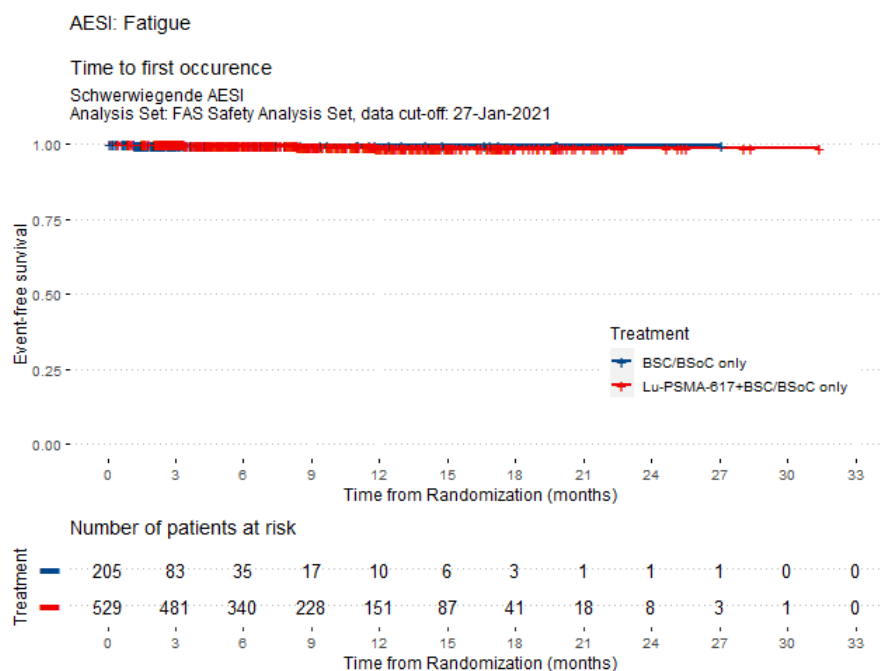


Abbildung 190: Schwerwiegende AESi: Time to first occurrence of AESi: Fatigue

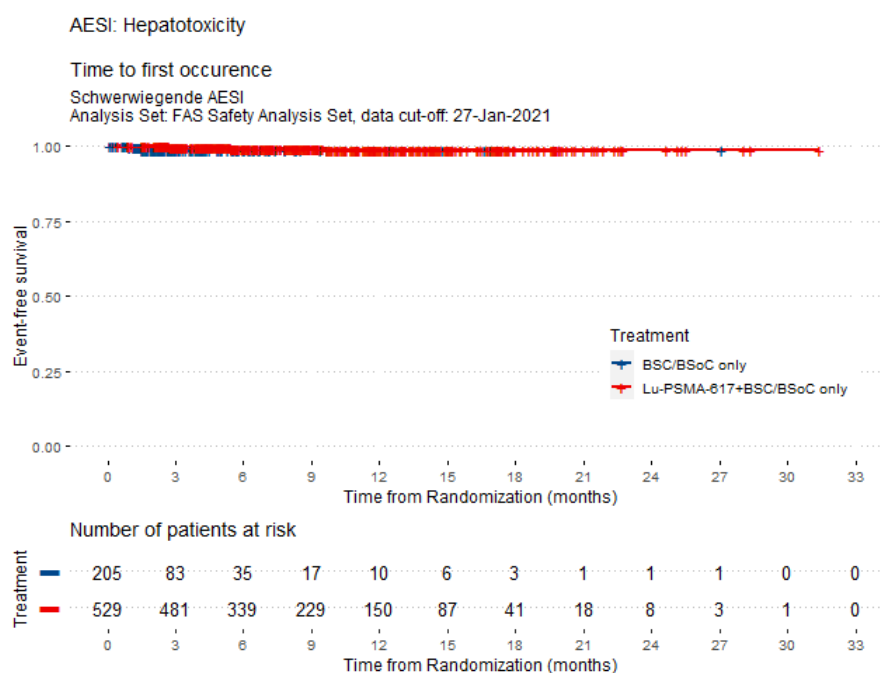


Abbildung 191: Schwerwiegende AESi: Time to first occurrence of AESi: Hepatotoxicity

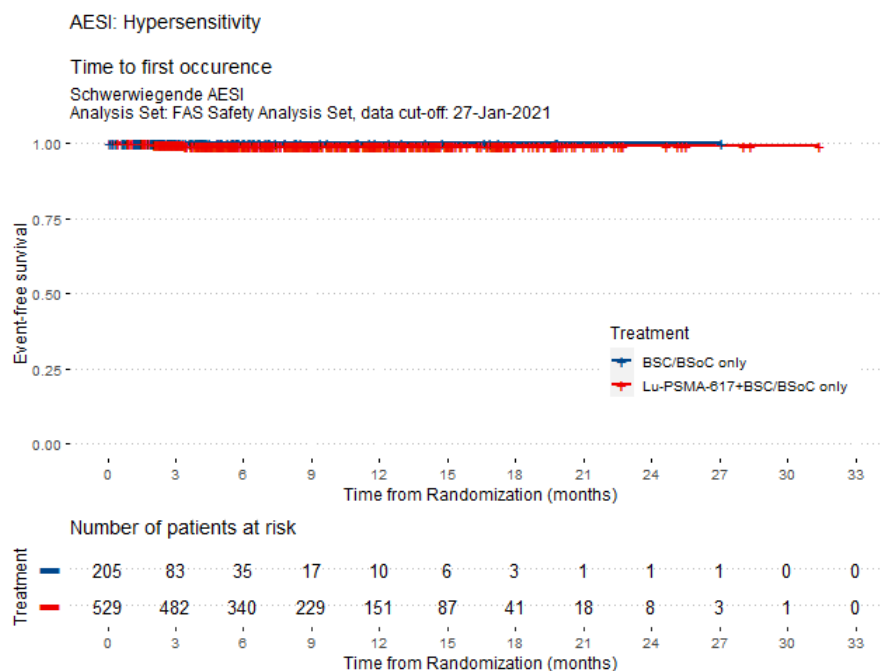


Abbildung 192: Schwerwiegende AESi: Time to first occurrence of AESi: Hypersensitivity

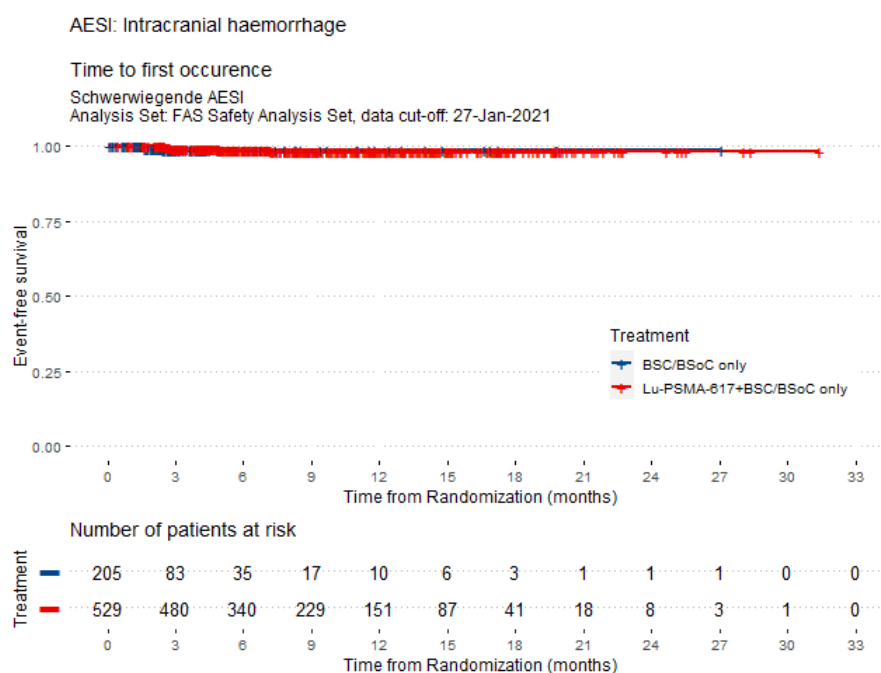


Abbildung 193: Schwerwiegende AESi: Time to first occurrence of AESi: Intracranial haemorrhage

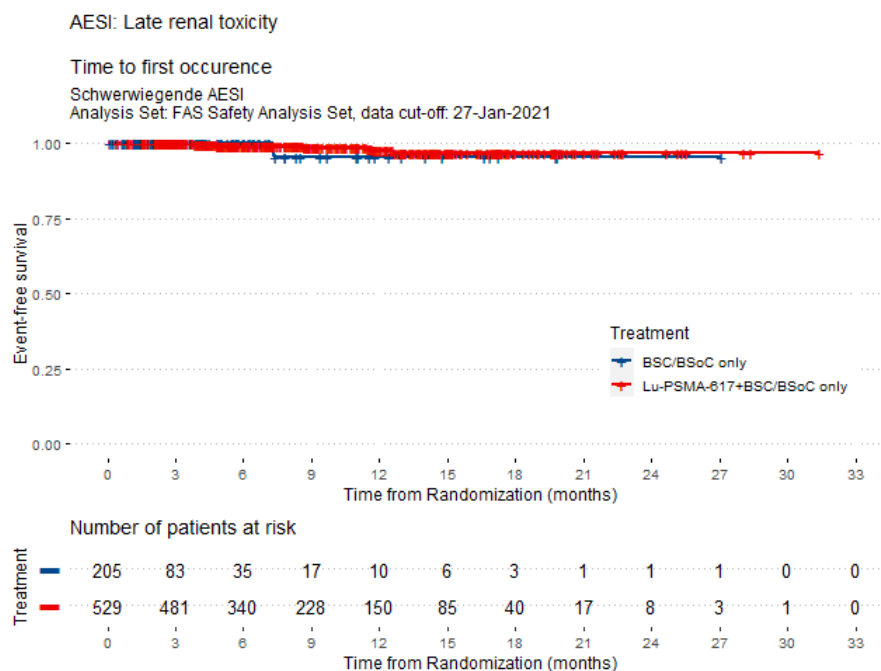


Abbildung 194: Schwerwiegende AESI: Time to first occurrence of AESI: Late renal toxicity

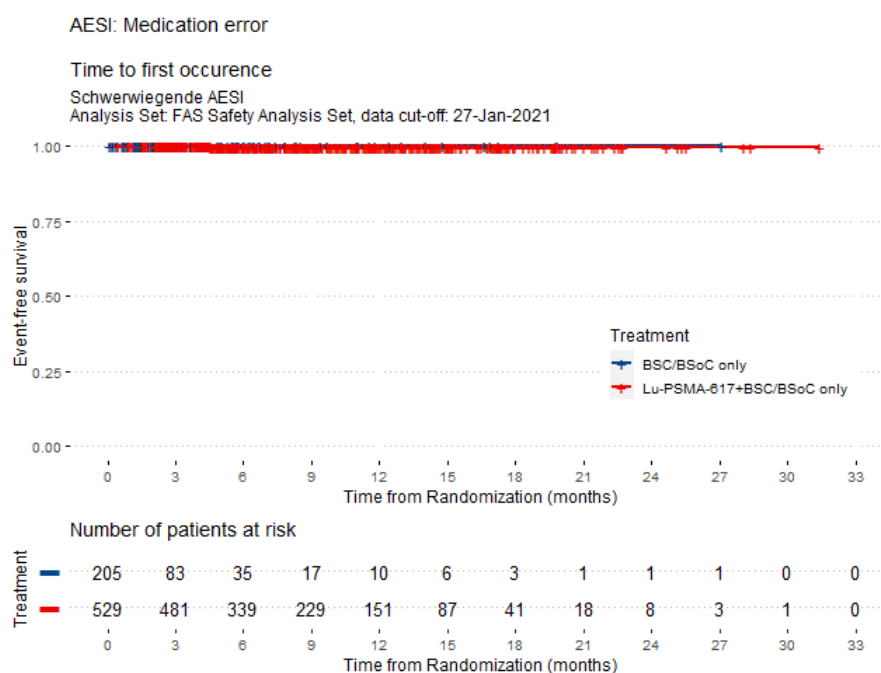


Abbildung 195: Schwerwiegende AESI: Time to first occurrence of AESI: Medication error

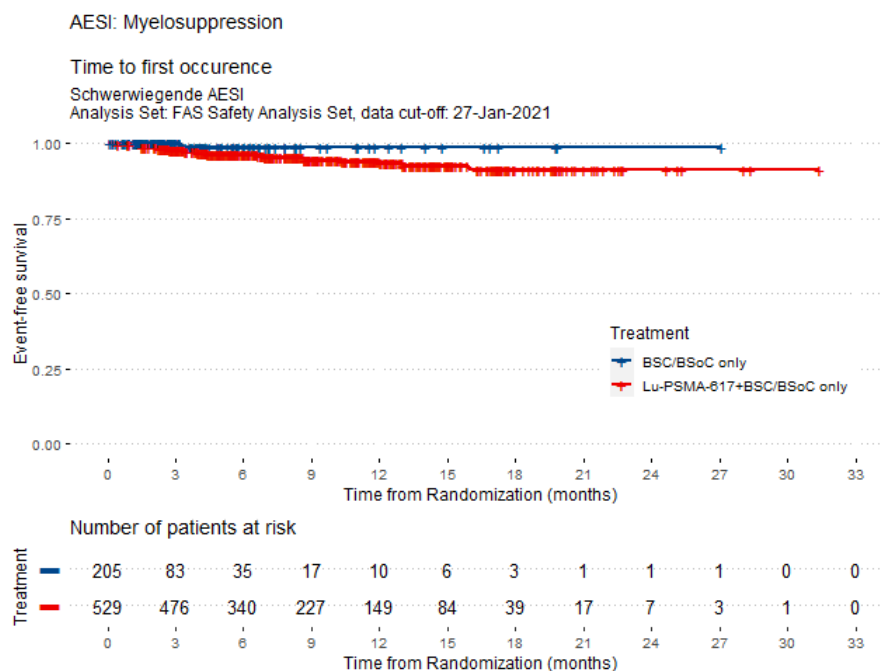


Abbildung 196: Schwerwiegende AESI: Time to first occurrence of AESI: Myelosuppression

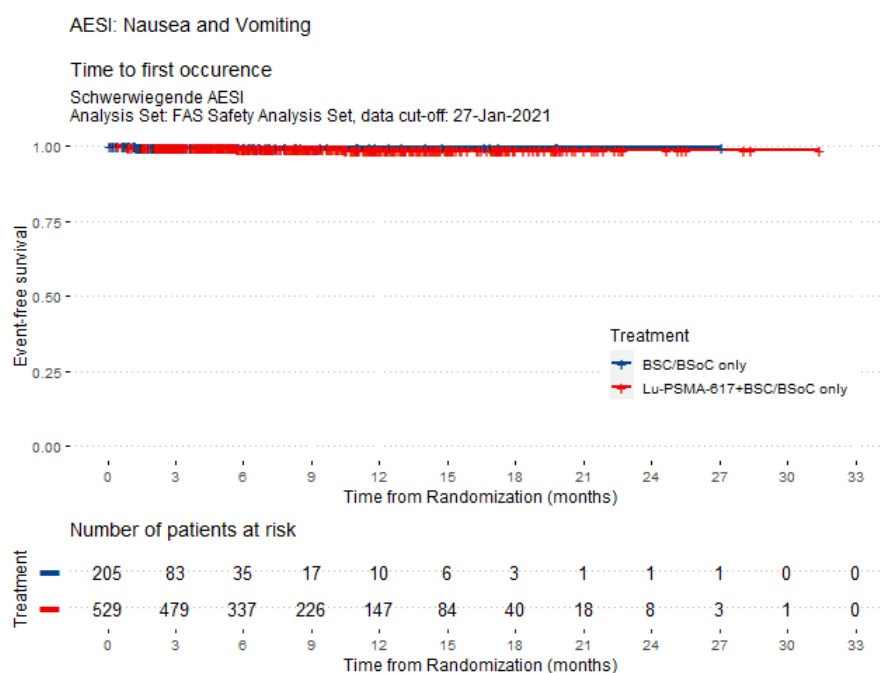


Abbildung 197: Schwerwiegende AESI: Time to first occurrence of AESI: Nausea and Vomiting

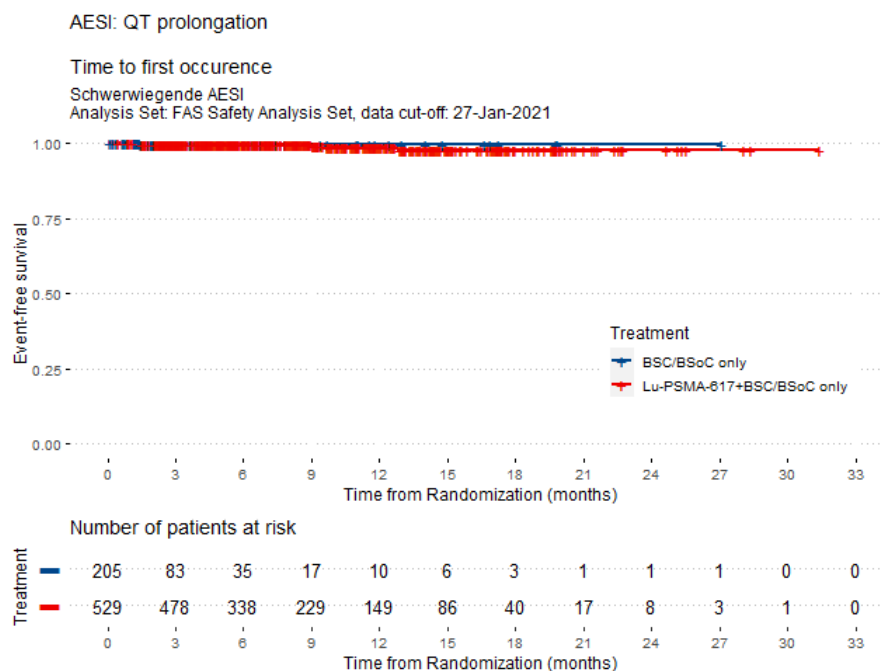


Abbildung 198: Schwerwiegende AESI: Time to first occurrence of AESI: QT prolongation

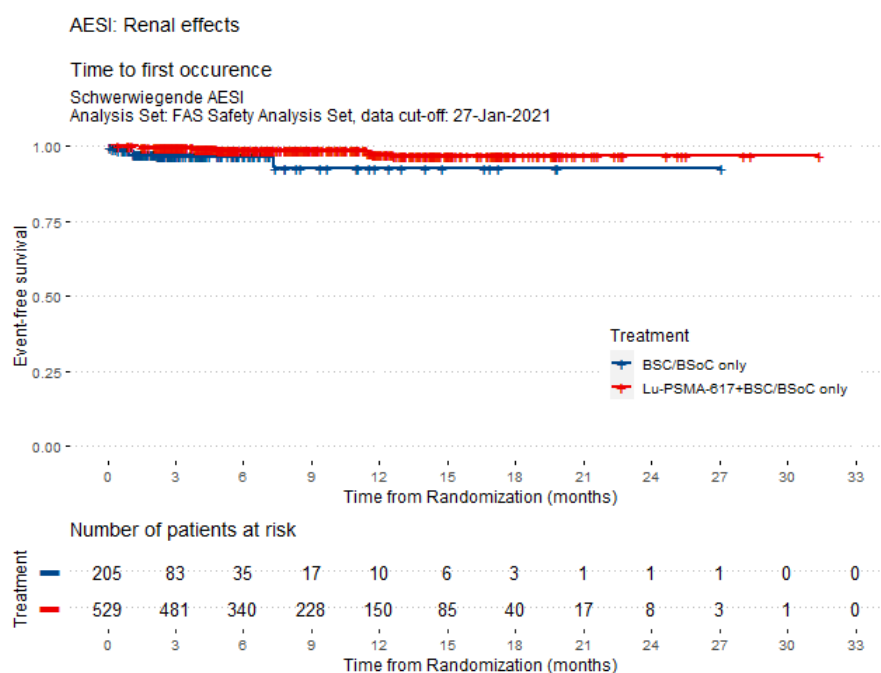


Abbildung 199: Schwerwiegende AESI: Time to first occurrence of AESI: Renal effects

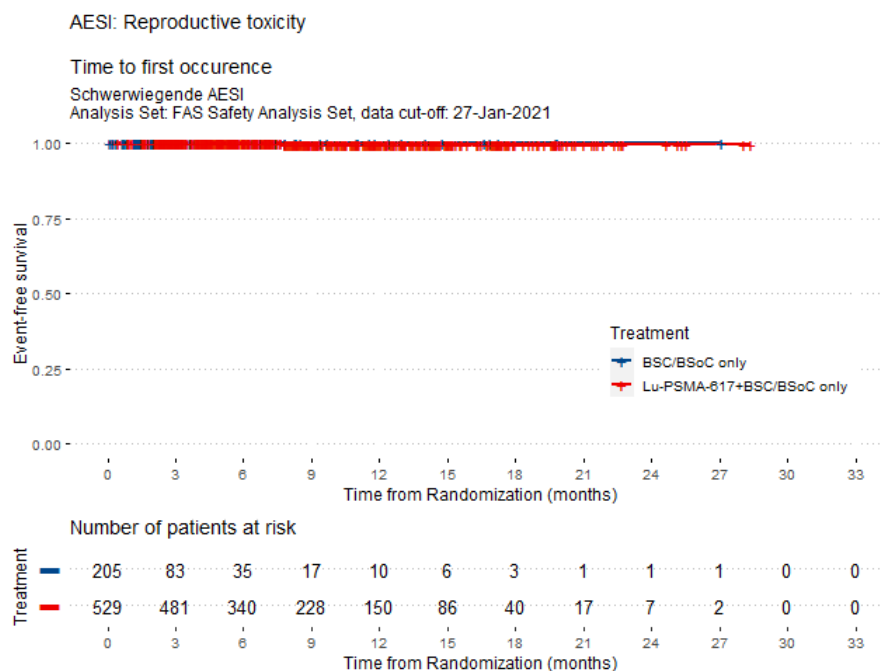


Abbildung 200: Schwerwiegende AESI: Time to first occurrence of AESI: Reproductive toxicity

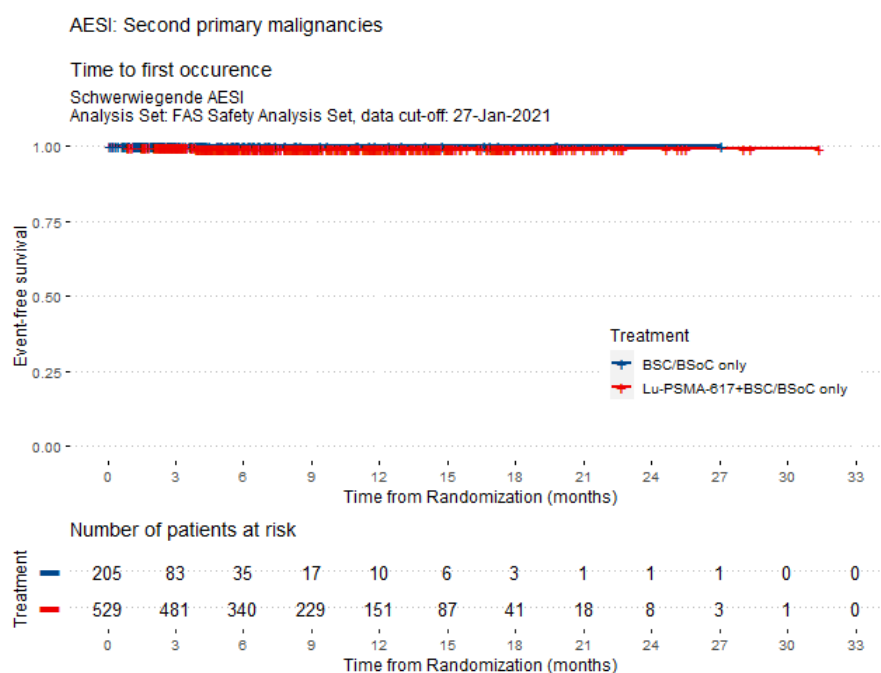


Abbildung 201: Schwerwiegende AESI: Time to first occurrence of AESI: Second primary malignancies

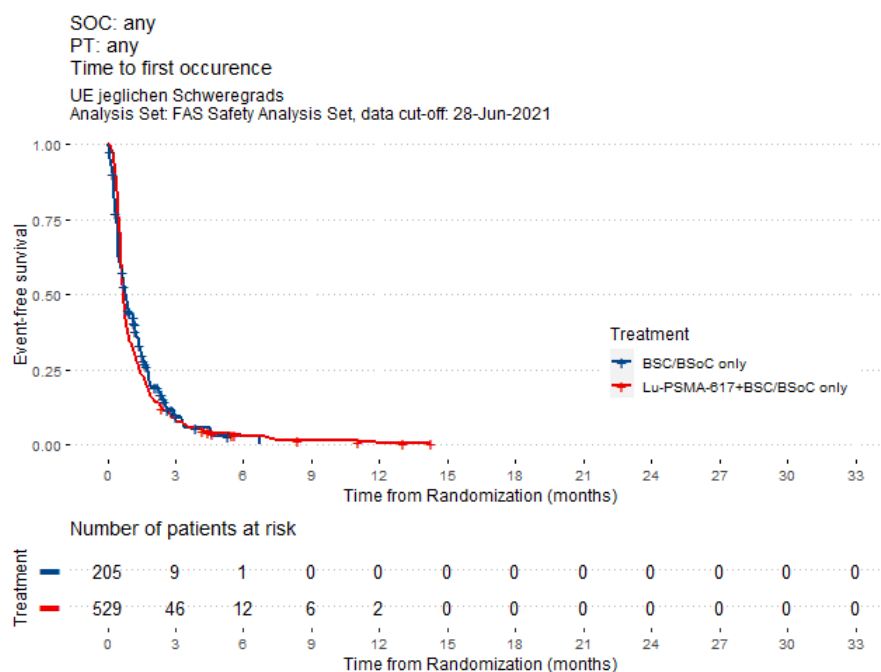
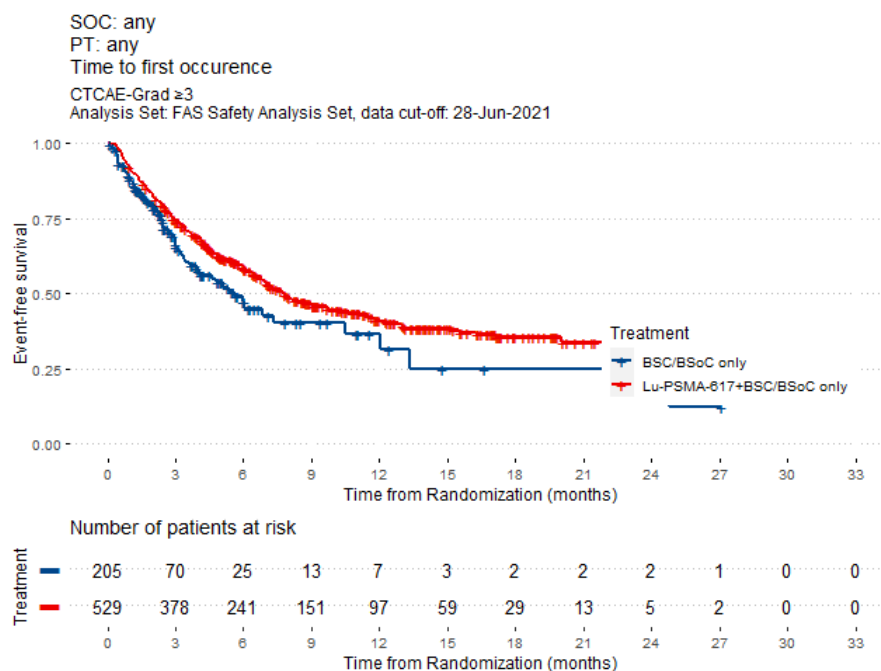
Anhang 4-H.3: Ergebnisse zum Datenschnitt vom 28. Juni 2021**Anhang 4-H.3.1: Gesamtraten UE**

Abbildung 202: UE jeglichen Schweregrads: Time to first occurrence of SOC: any; PT: any

Abbildung 203: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: any; PT: any

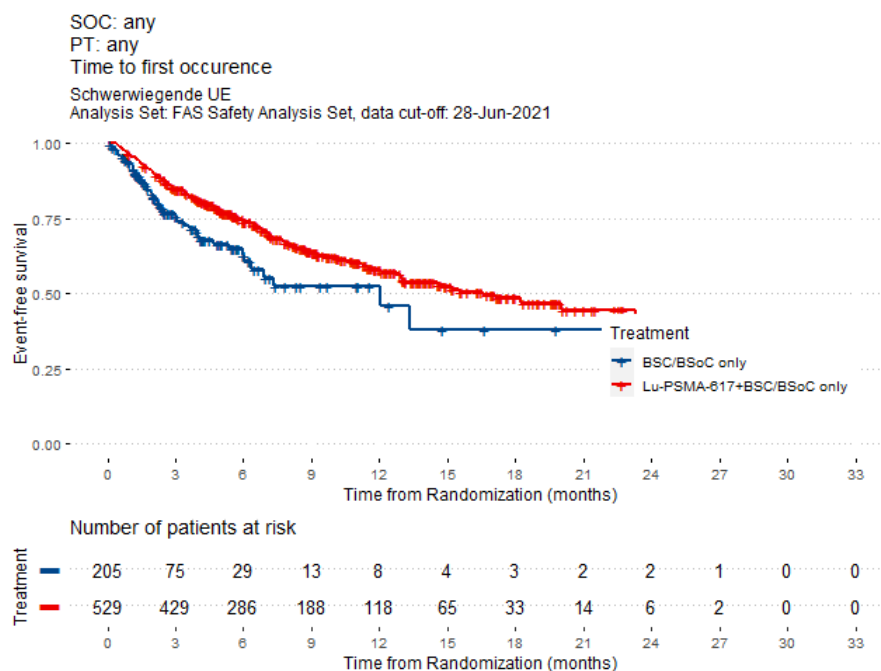


Abbildung 204: Schwerwiegende UE: Time to first occurrence of SOC: any; PT: any

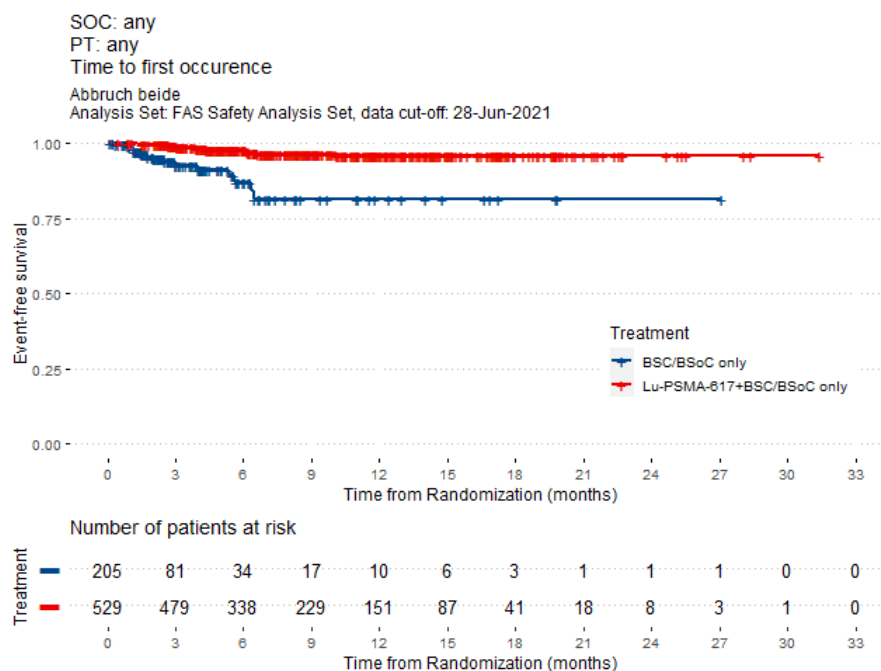


Abbildung 205: Abbruch beide: Time to first occurrence of SOC: any; PT: any

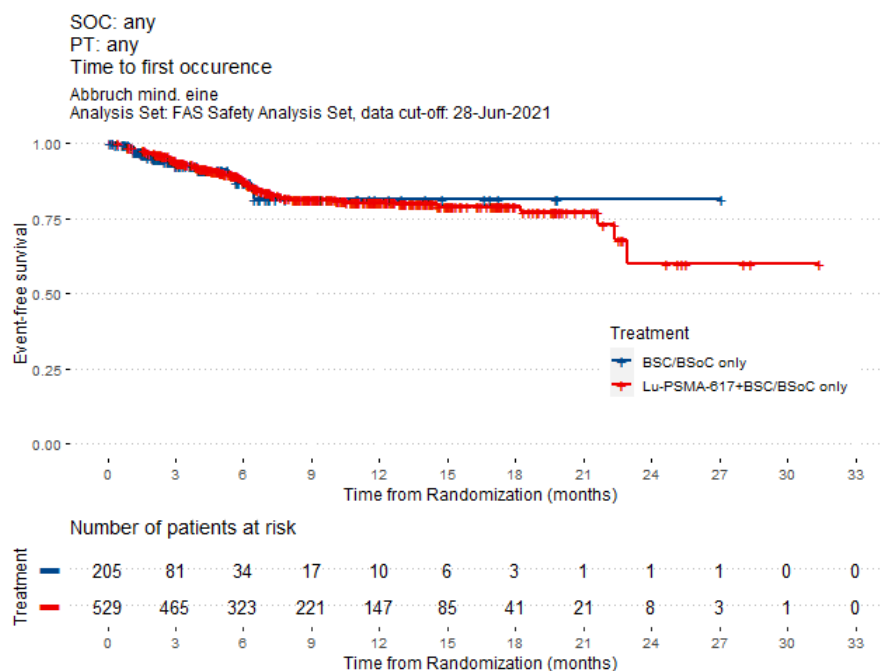


Abbildung 206: Abbruch mind. eine: Time to first occurrence of SOC: any; PT: any

Anhang 4-H.3.2: Gesamtraten UE ohne Berücksichtigung der UE, die im Rahmen eines symptomatischen skelettbezogenen Ereignisses auftraten

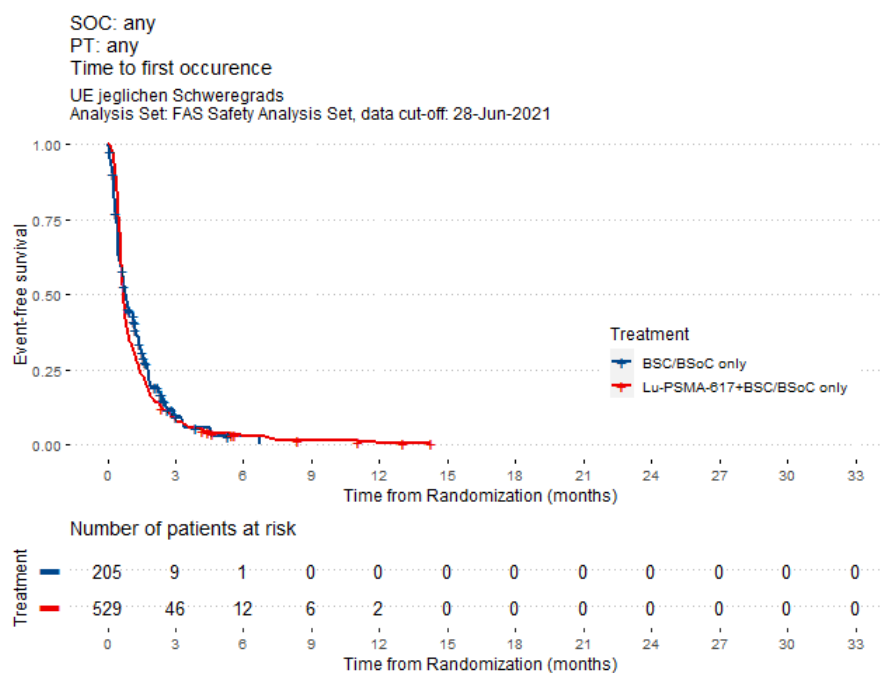
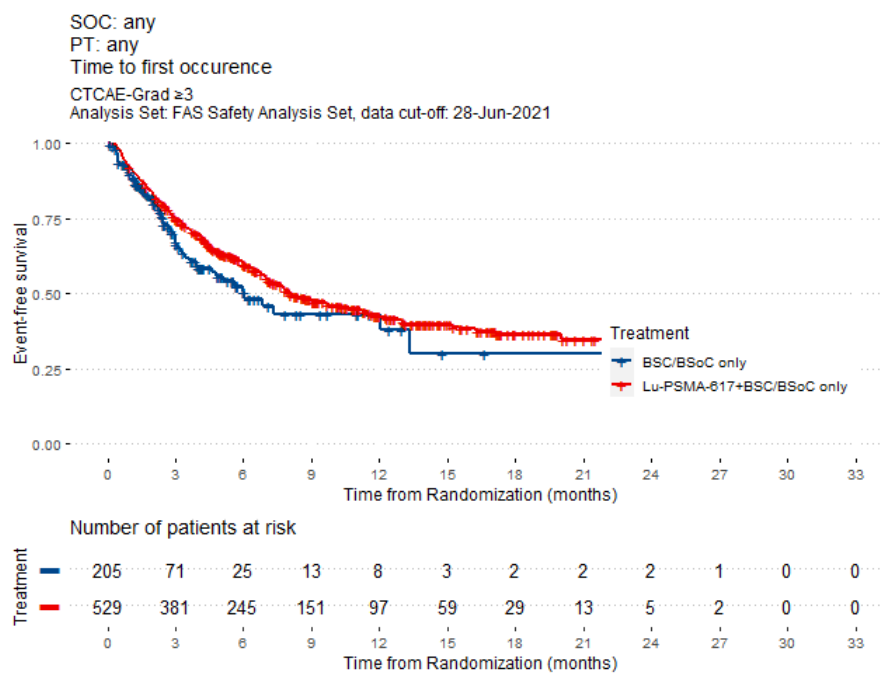


Abbildung 207: UE jeglichen Schweregrads: Time to first occurrence of SOC: any; PT: any

Abbildung 208: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: any; PT: any

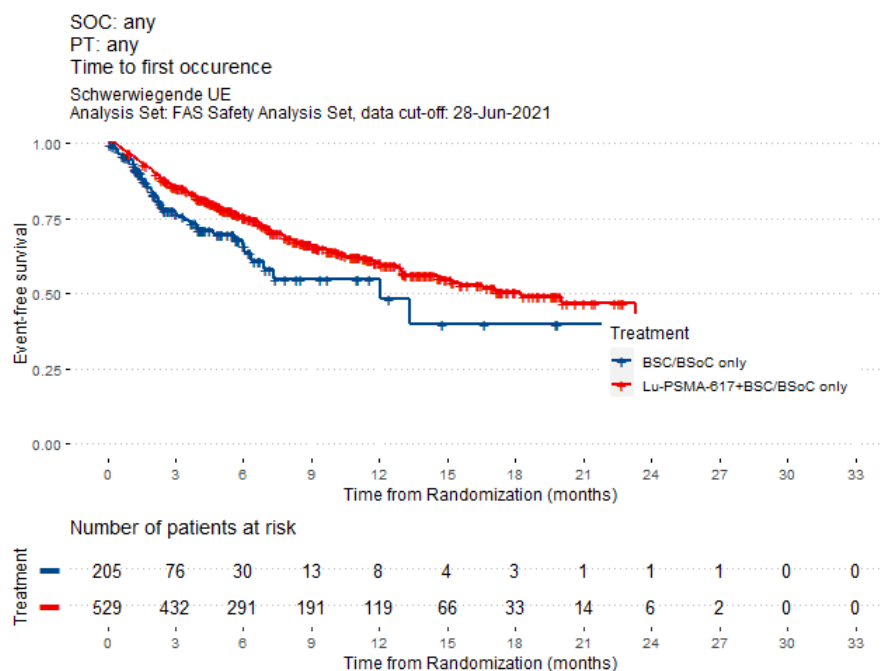


Abbildung 209: Schwerwiegende UE: Time to first occurrence of SOC: any; PT: any

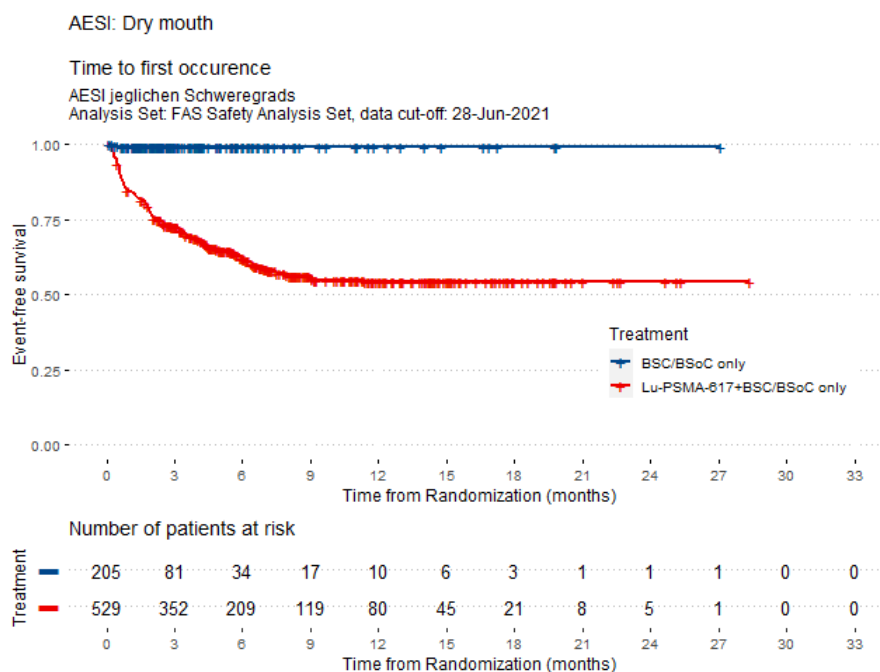
Anhang 4-H.3.3: Unerwünschte Ereignisse von besonderem Interesse**Anhang 4-H.3.3.1: UE jeglichen Schweregrads**

Abbildung 210: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Dry mouth

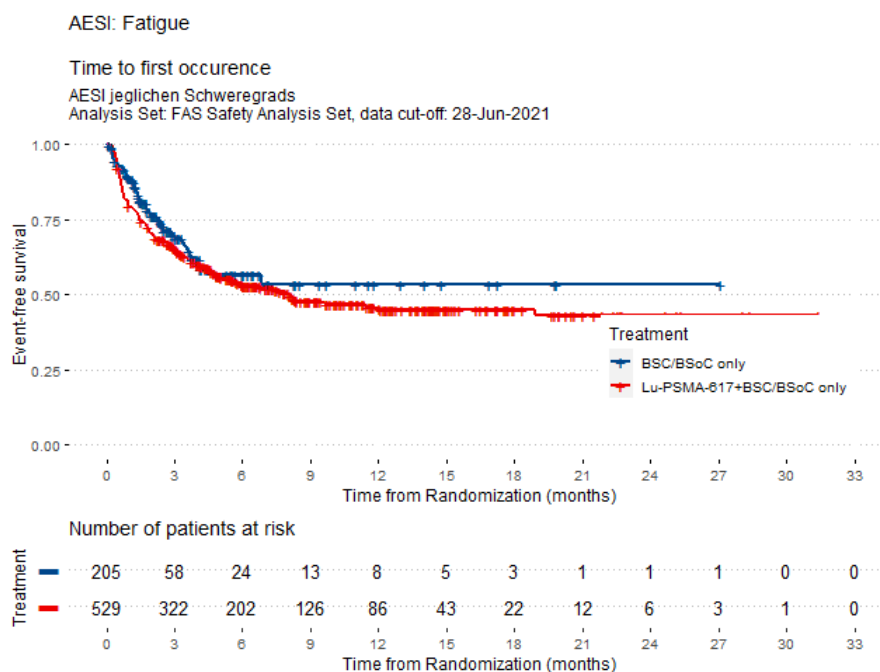


Abbildung 211: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Fatigue

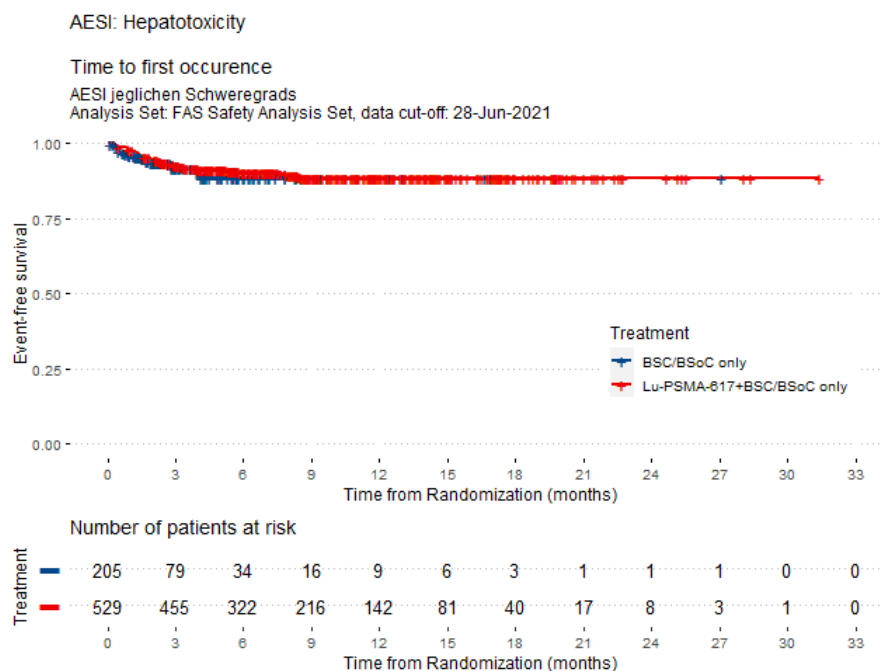


Abbildung 212: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Hepatotoxicity

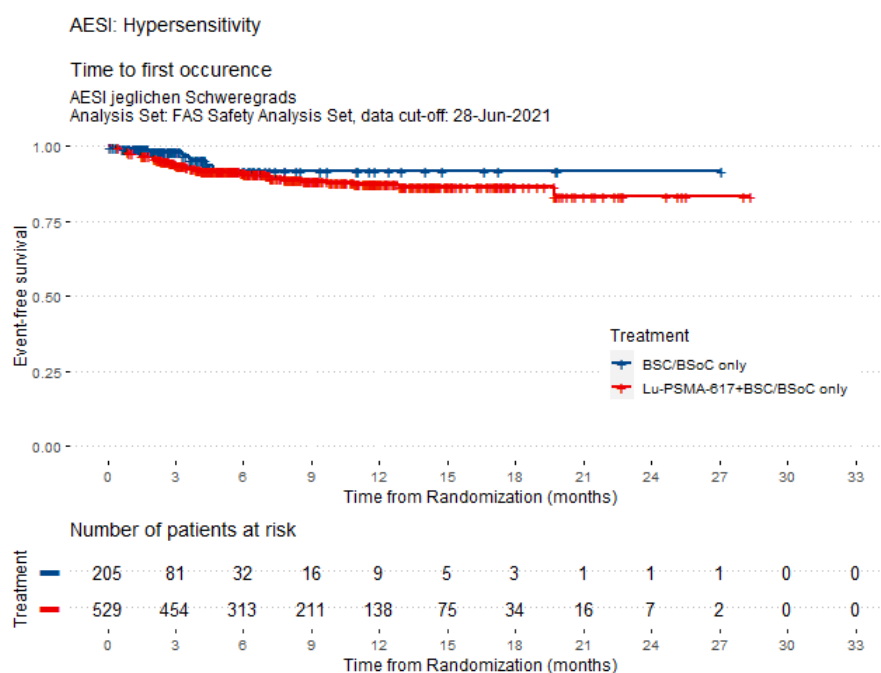


Abbildung 213: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Hypersensitivity

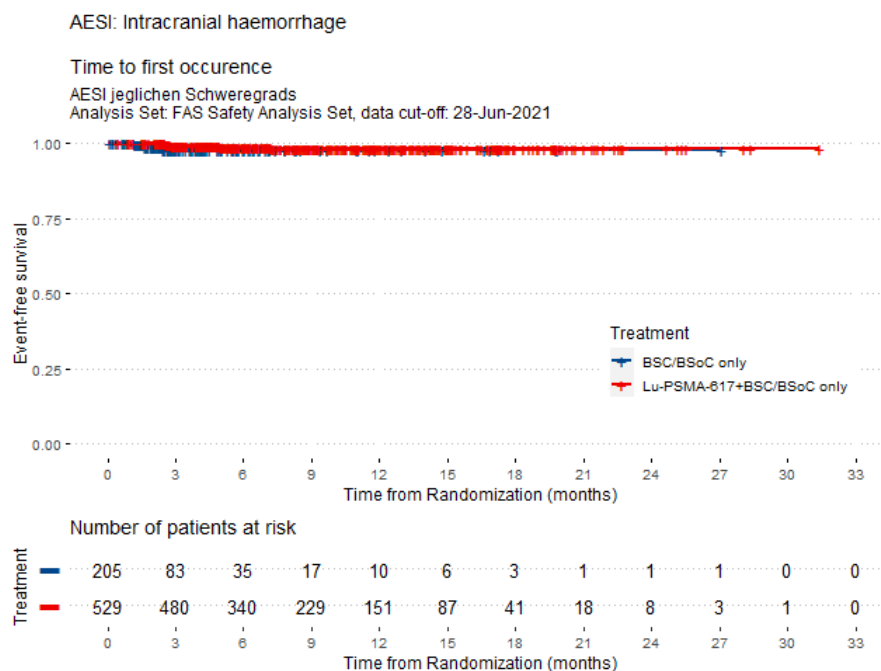


Abbildung 214: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Intracranial haemorrhage

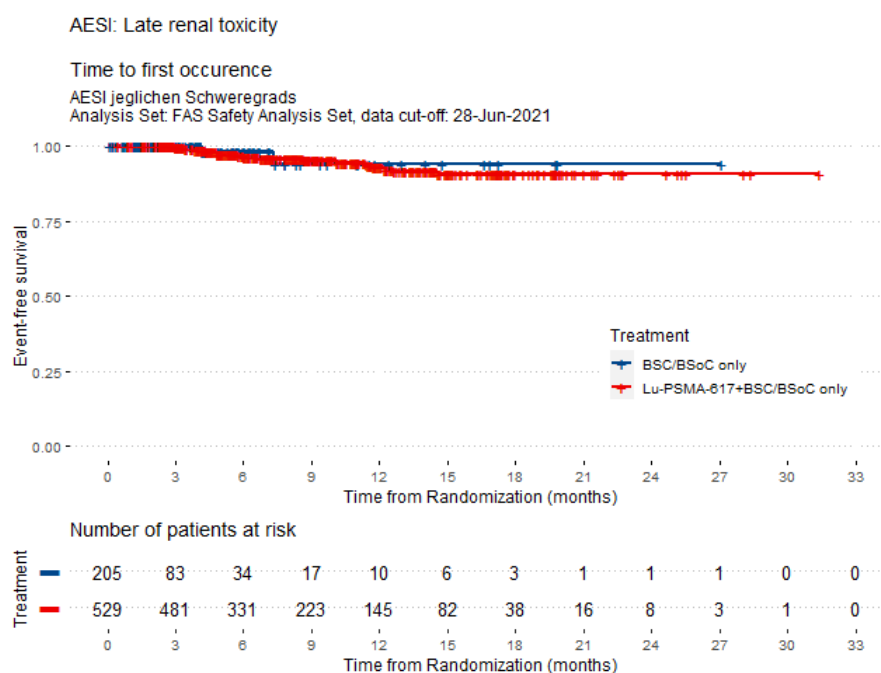


Abbildung 215: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Late renal toxicity

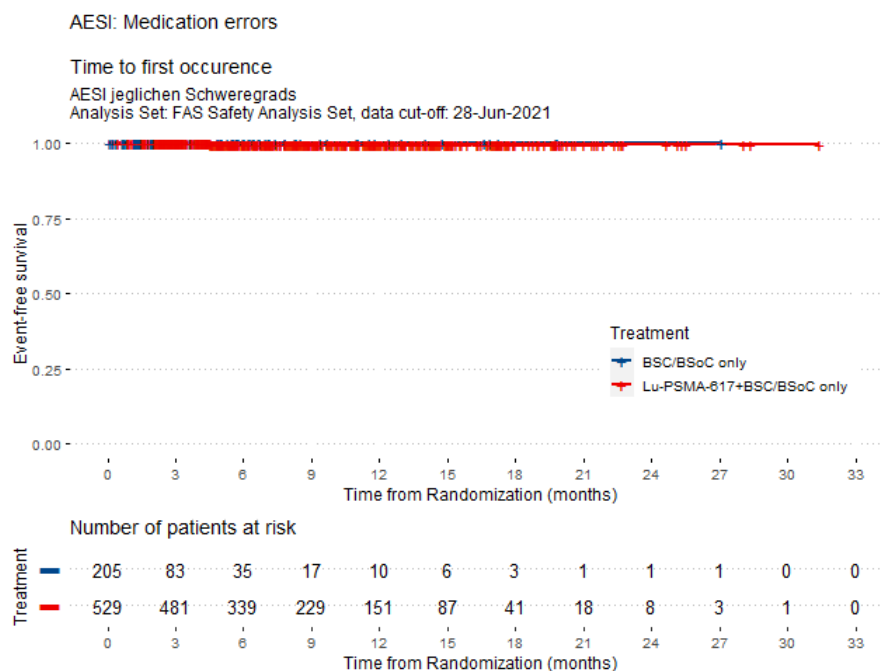


Abbildung 216: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Medication errors

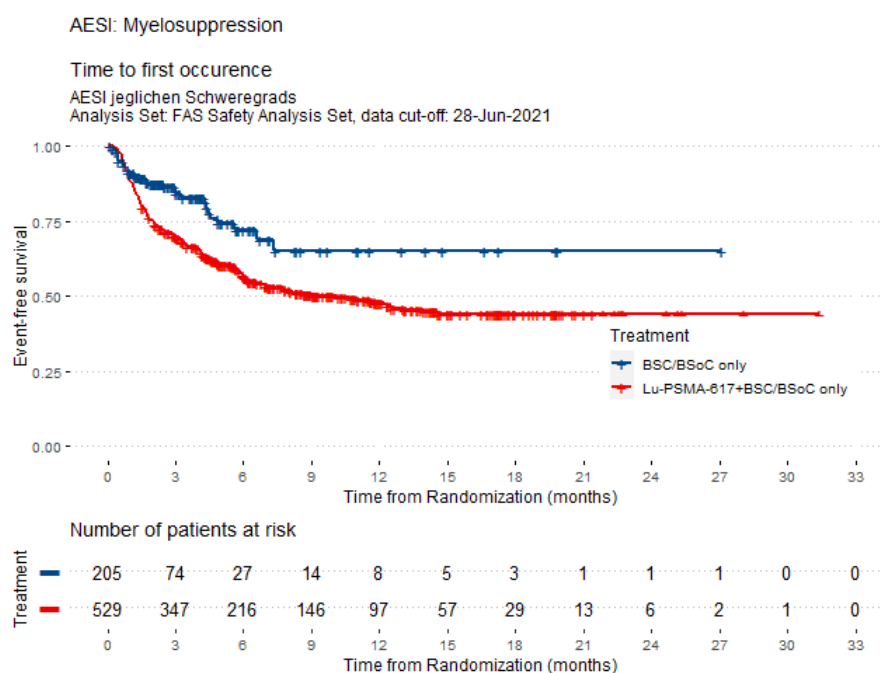


Abbildung 217: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Myelosuppression

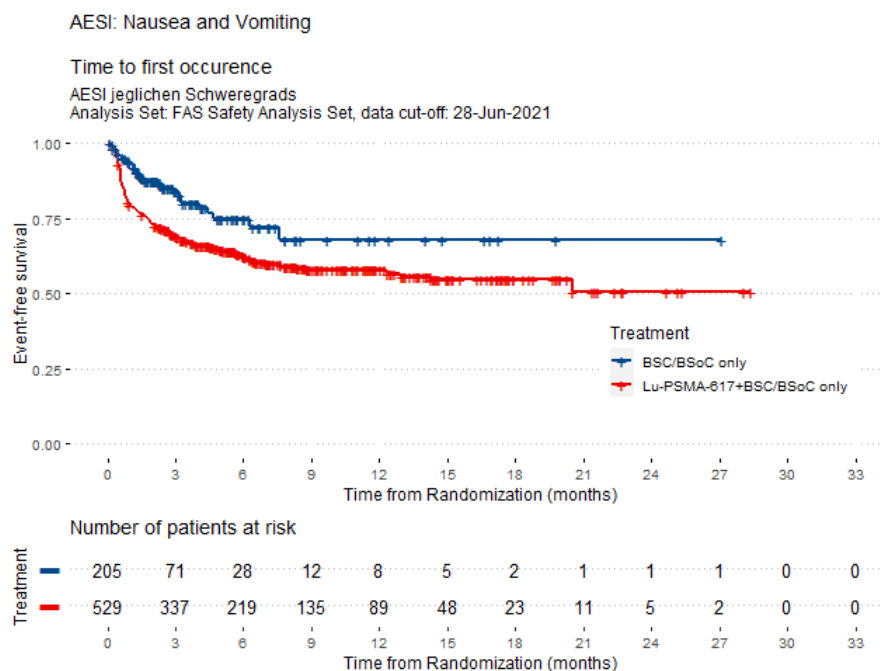


Abbildung 218: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Nausea and Vomiting

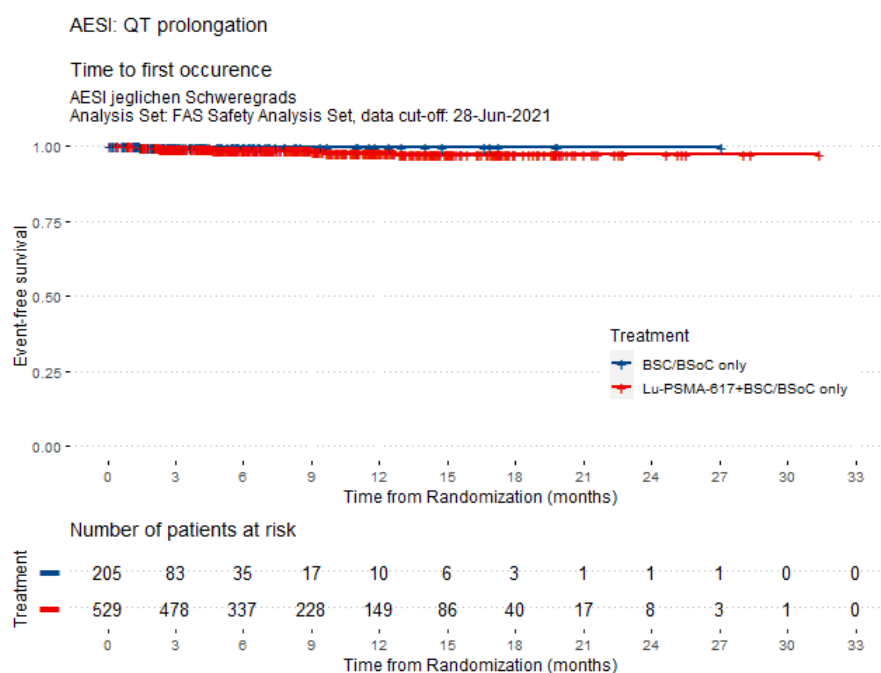


Abbildung 219: AESI jeglichen Schweregrads: Time to first occurrence of AESI: QT prolongation

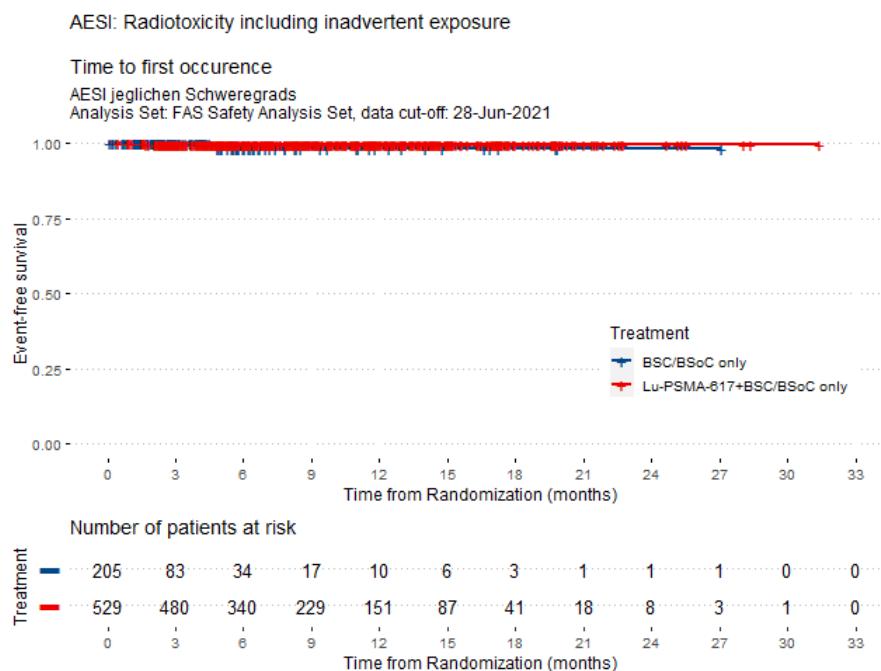


Abbildung 220: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Radiotoxicity including inadvertent exposure

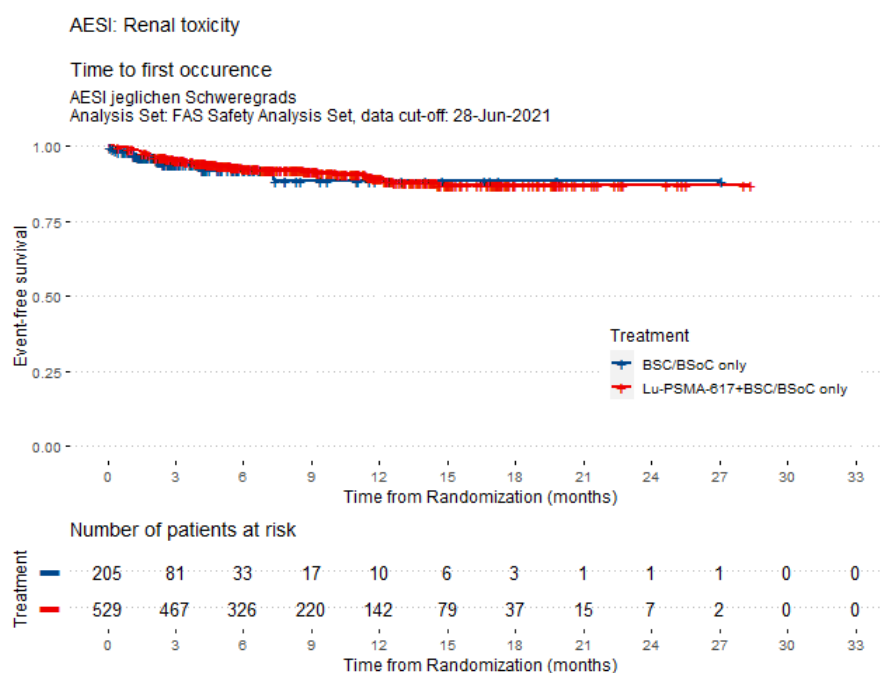


Abbildung 221: AESI jeglichen Schweregrads: Time to first occurrence of AESI: Renal toxicity

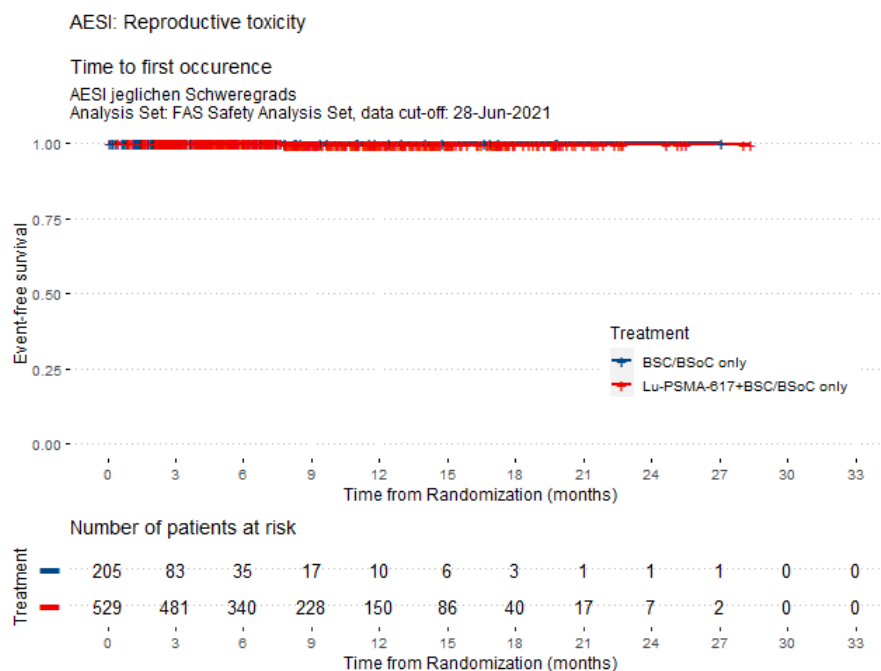


Abbildung 222: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Reproductive toxicity

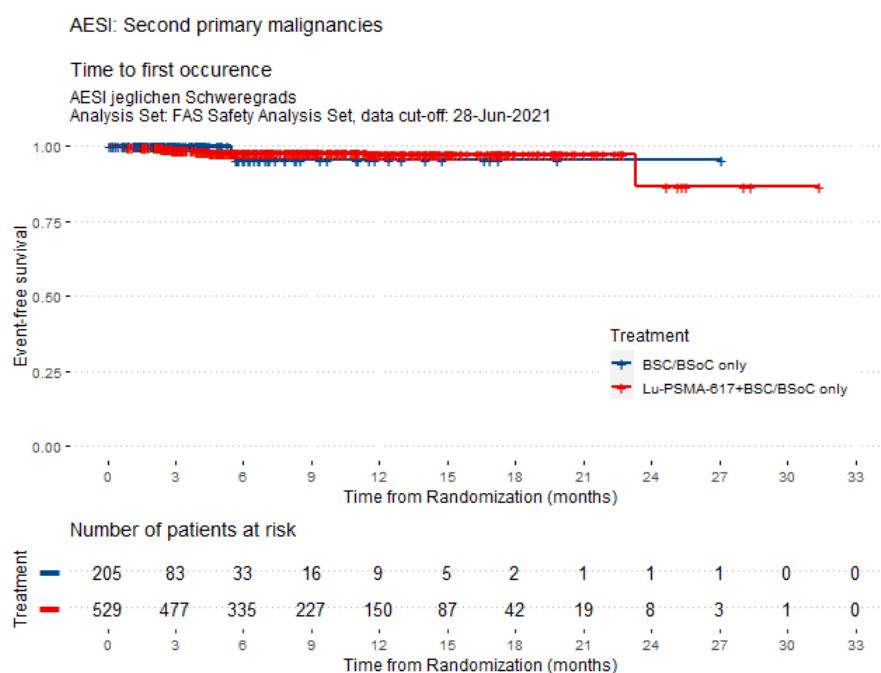


Abbildung 223: AESi jeglichen Schweregrads: Time to first occurrence of AESi: Second primary malignancies

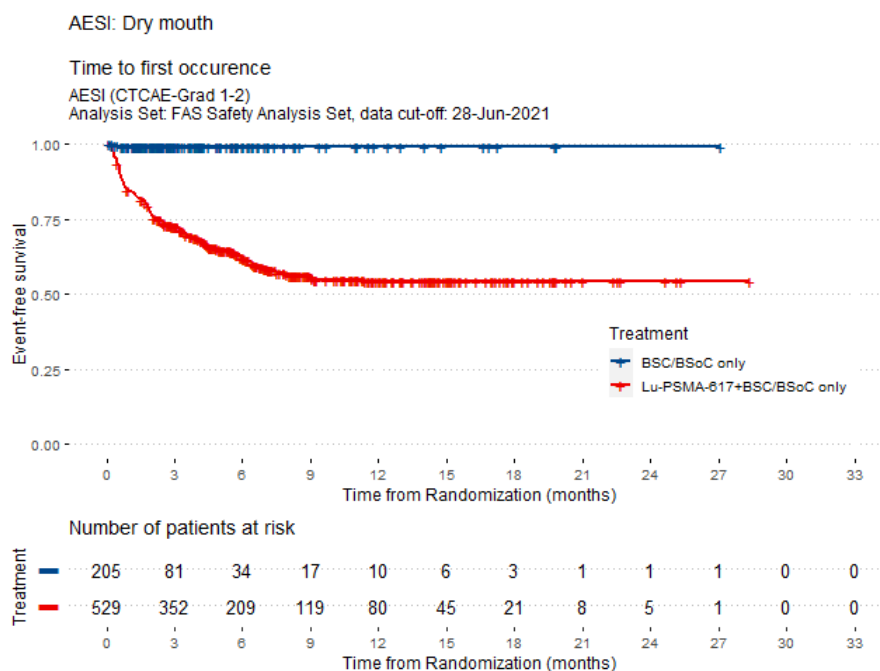
Anhang 4-H.3.3.2: Nicht-schwere UE (CTCAE-Grad 1-2)

Abbildung 224: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Dry mouth

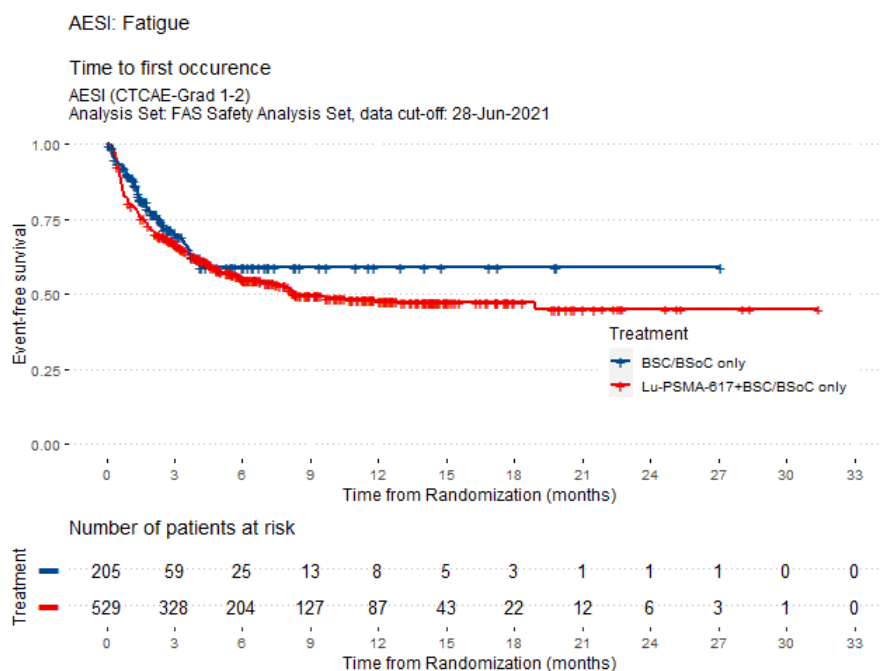


Abbildung 225: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Fatigue

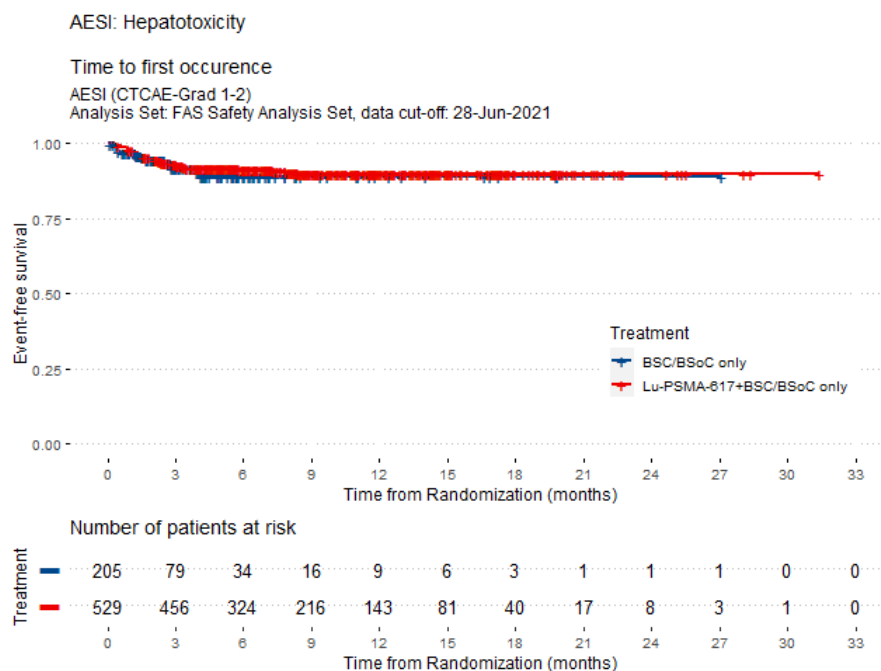


Abbildung 226: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Hepatotoxicity

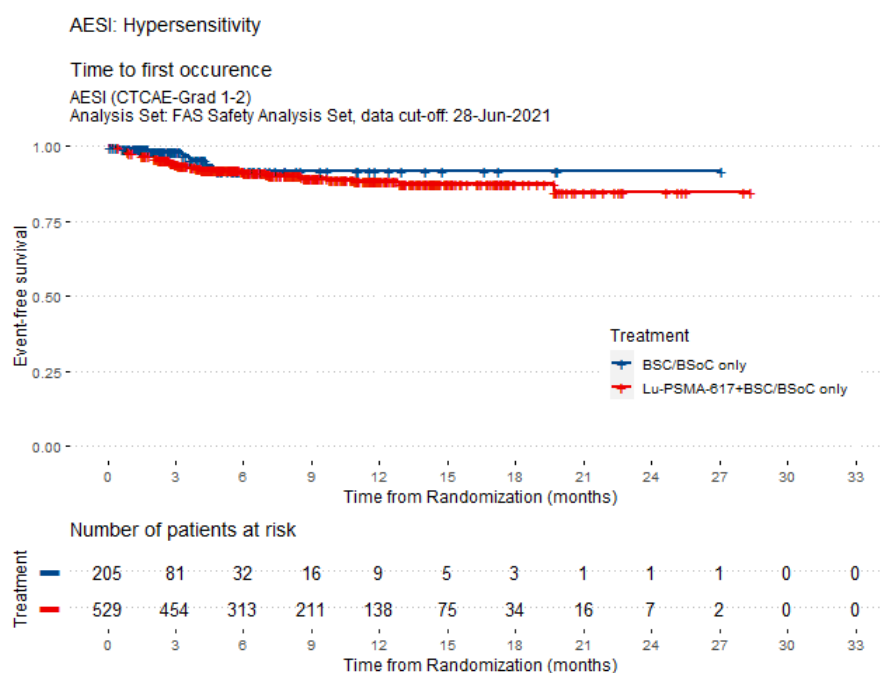


Abbildung 227: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Hypersensitivity

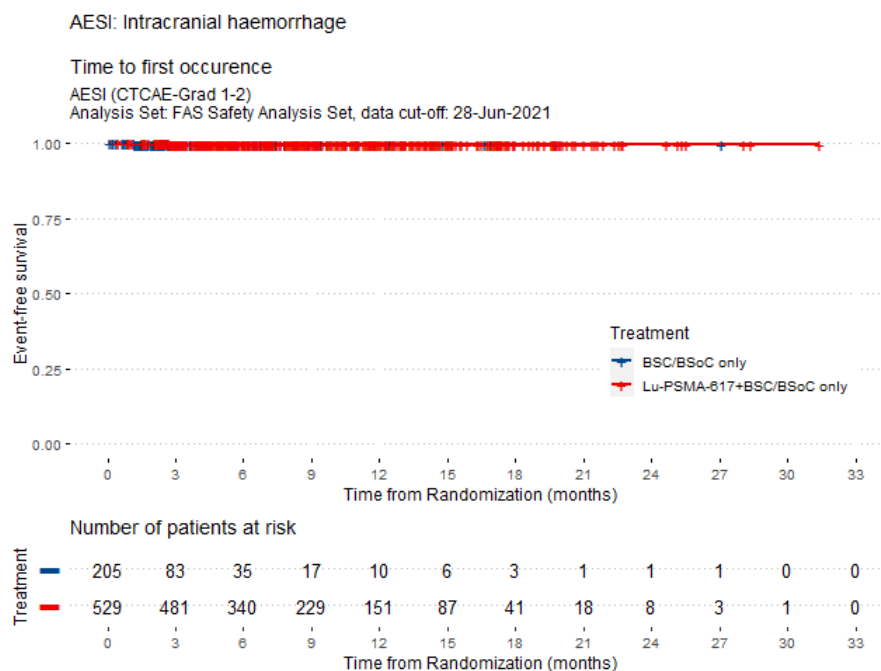


Abbildung 228: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Intracranial haemorrhage

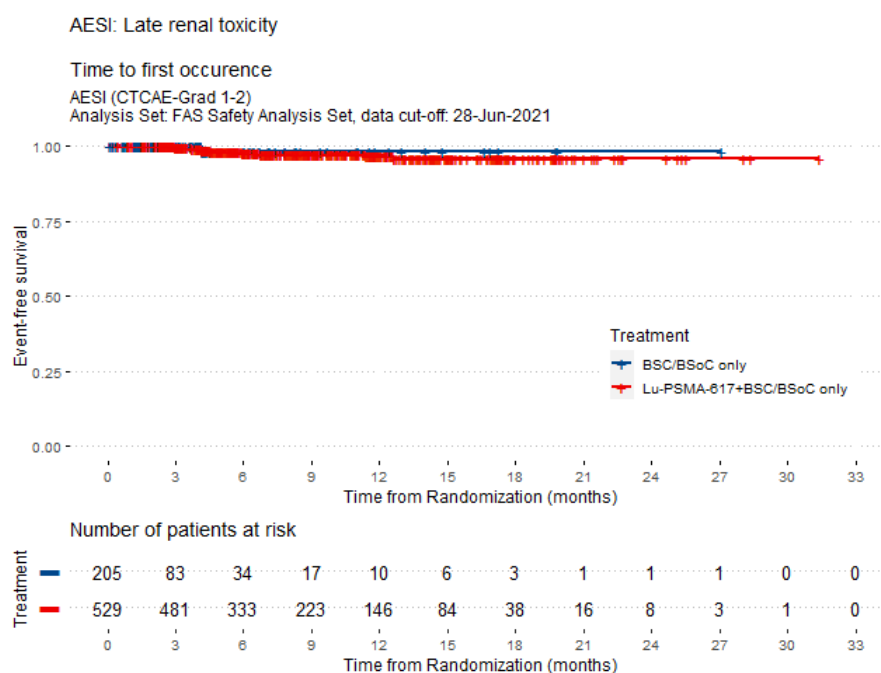


Abbildung 229: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Late renal toxicity

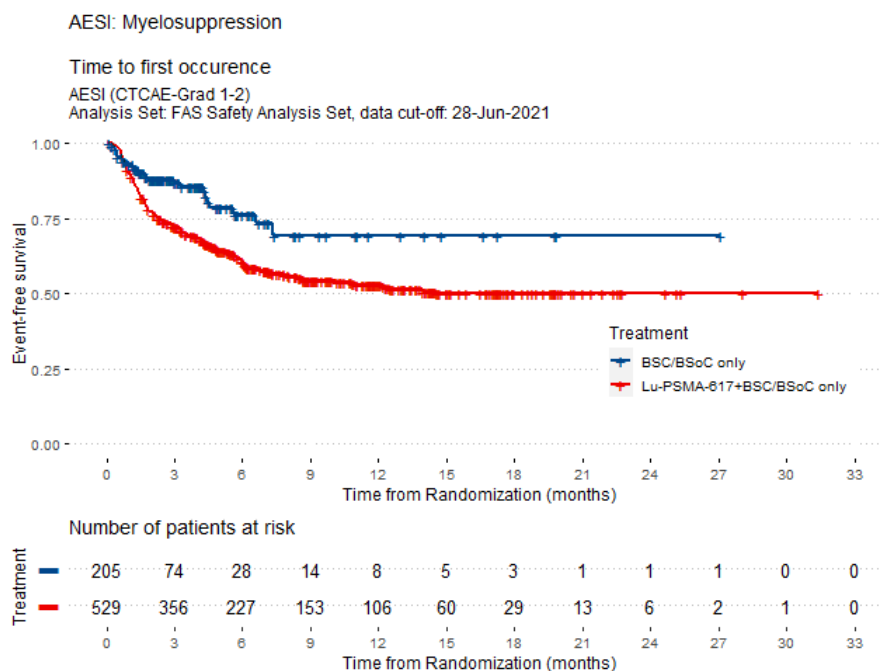


Abbildung 230: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Myelosuppression

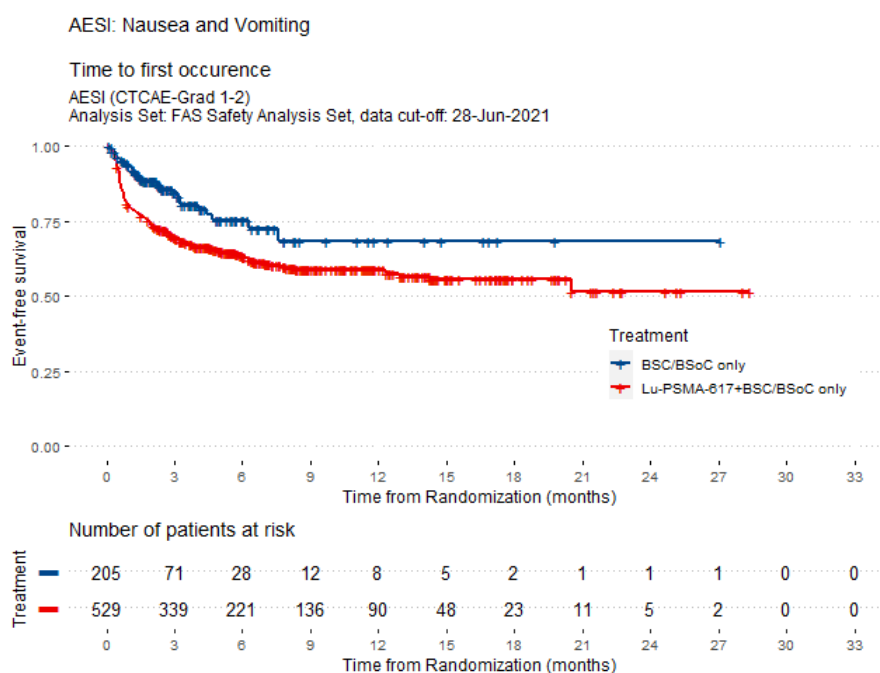


Abbildung 231: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Nausea and Vomiting

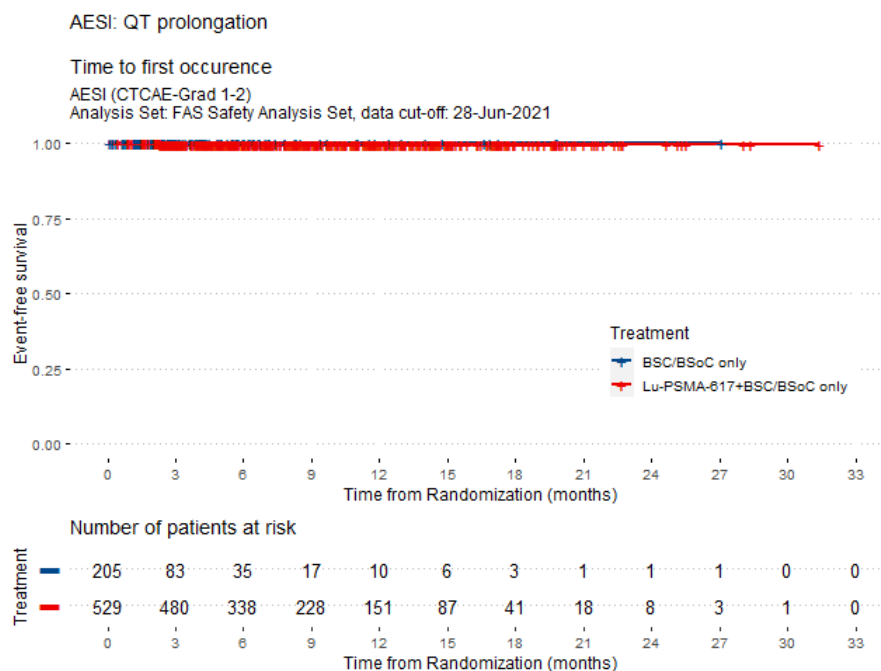


Abbildung 232: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: QT prolongation

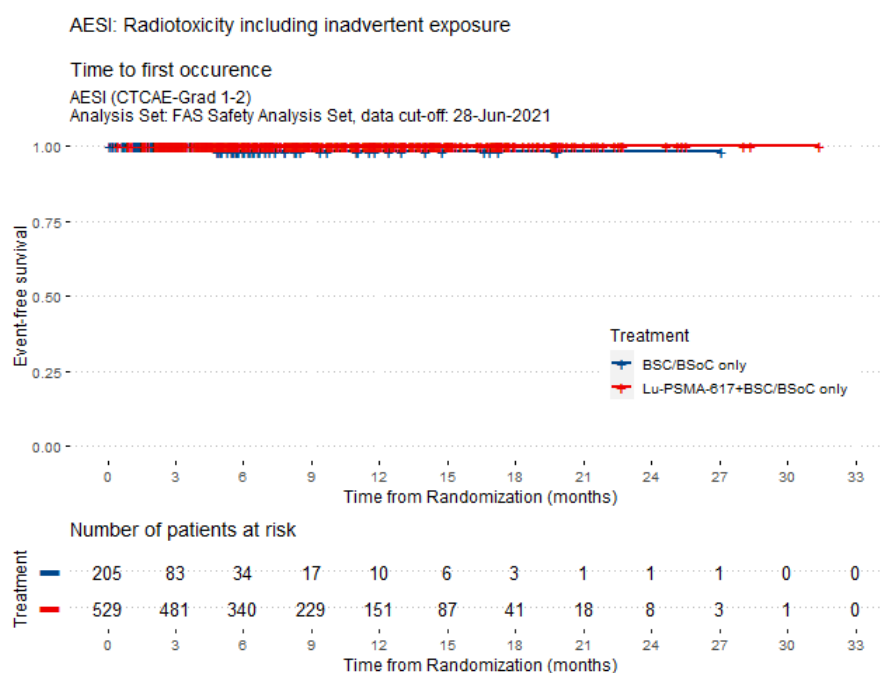


Abbildung 233: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Radiotoxicity including inadvertent exposure

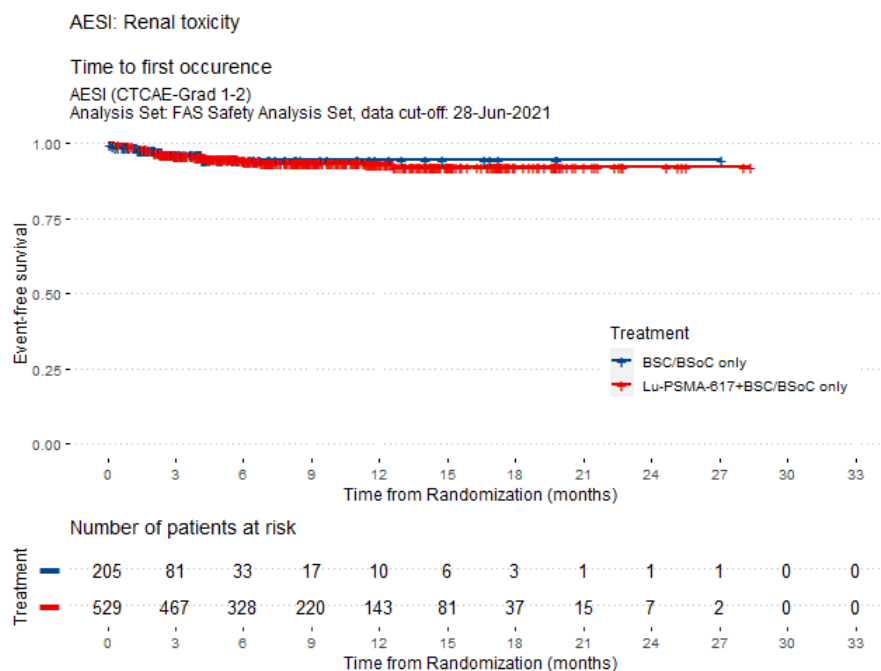


Abbildung 234: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Renal toxicity

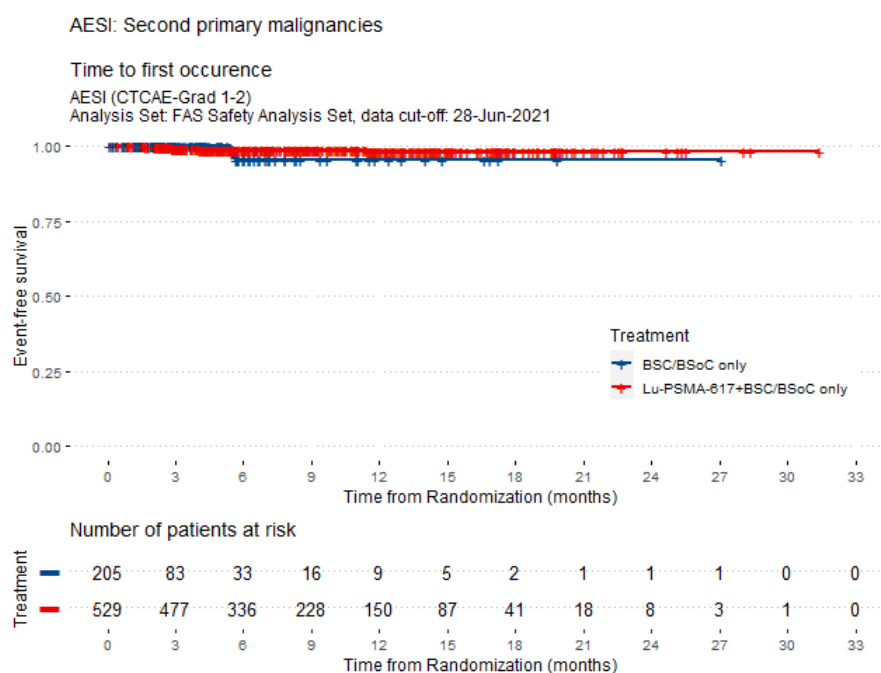
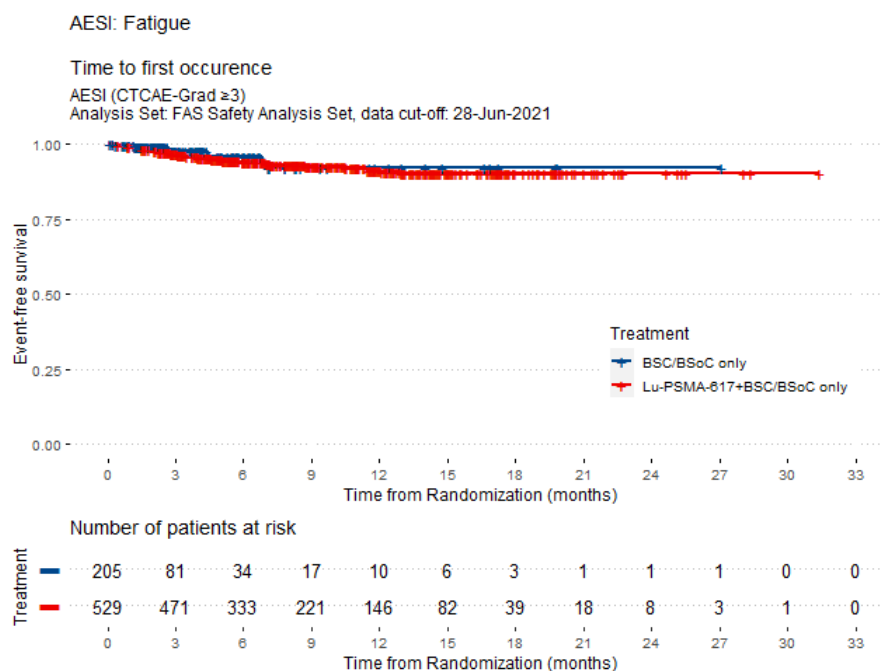
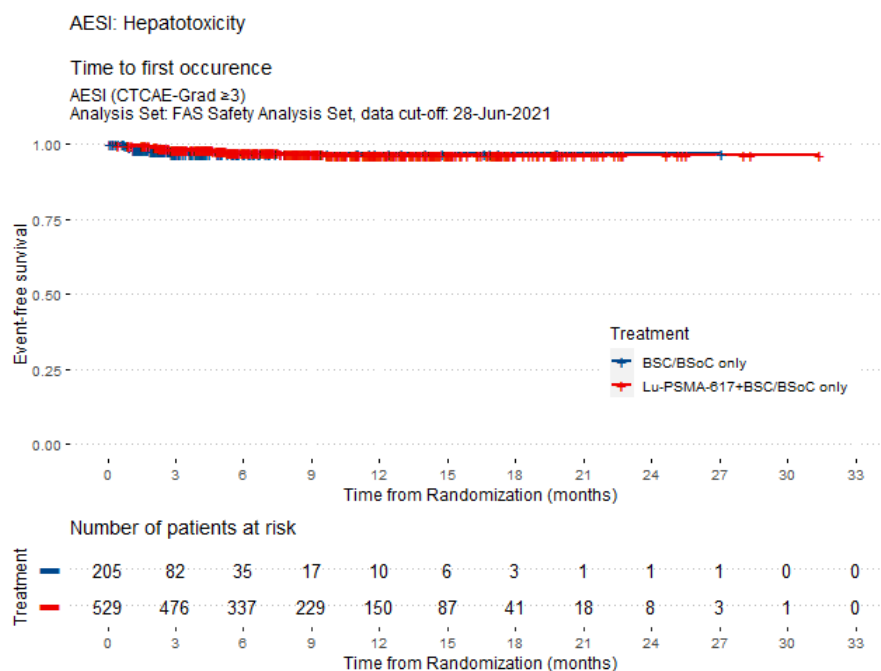
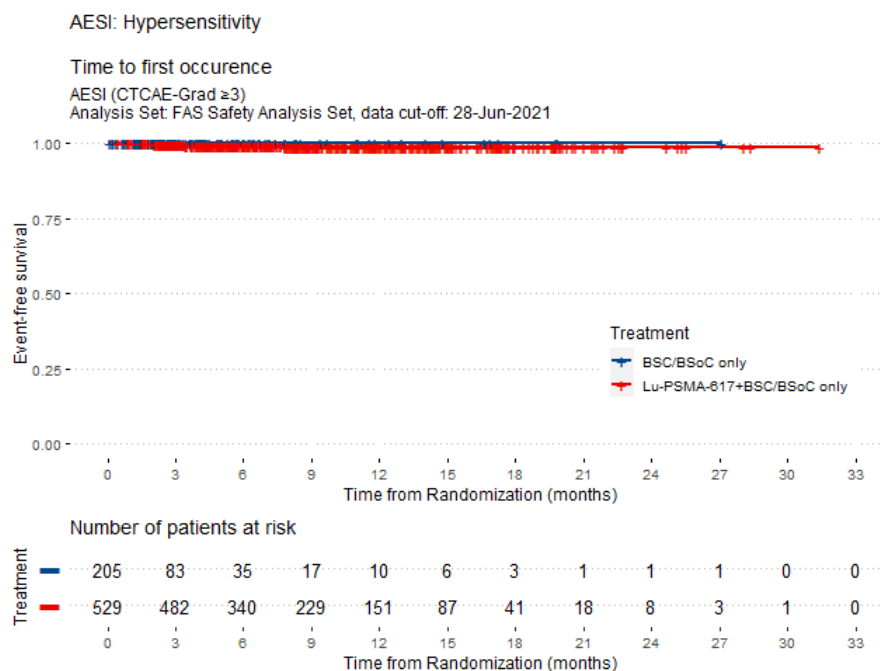
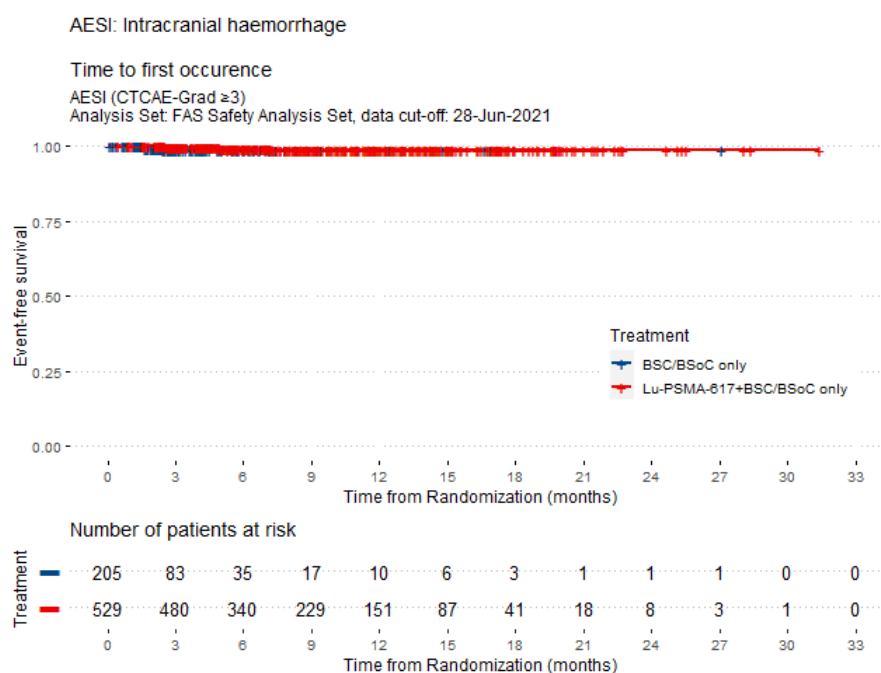


Abbildung 235: AESI (CTCAE-Grad 1-2): Time to first occurrence of AESI: Second primary malignancies

Anhang 4-H.3.3.3: Schwere UE (CTCAE-Grad ≥ 3)Abbildung 236: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: FatigueAbbildung 237: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Hepatotoxicity

Abbildung 238: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: HypersensitivityAbbildung 239: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Intracranial haemorrhage

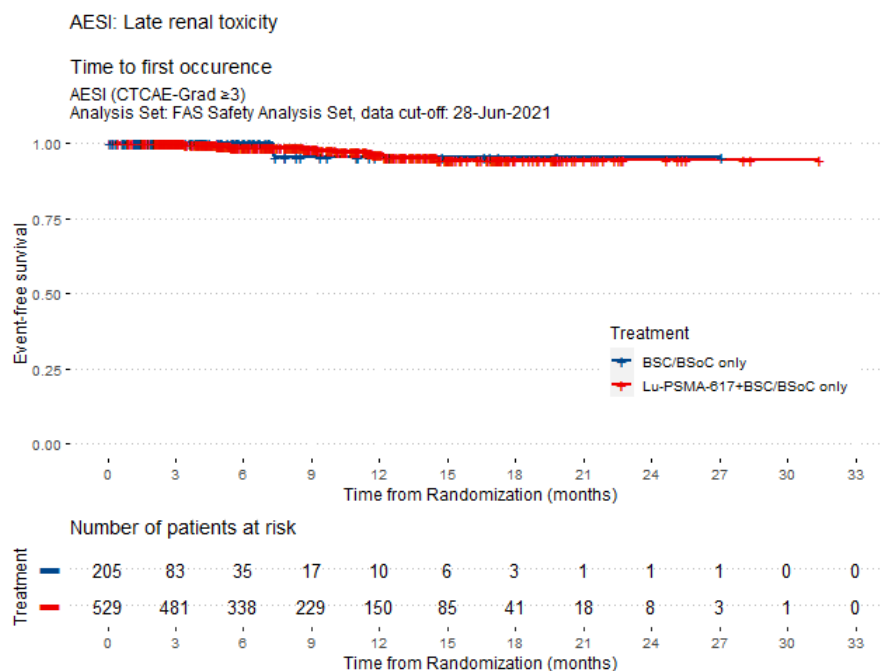


Abbildung 240: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Late renal toxicity

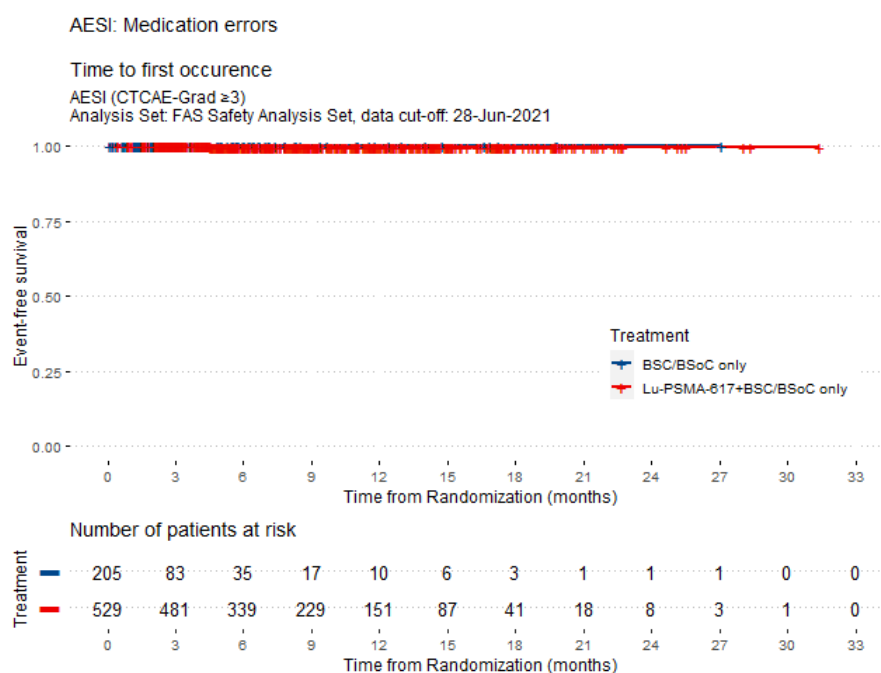


Abbildung 241: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Medication errors

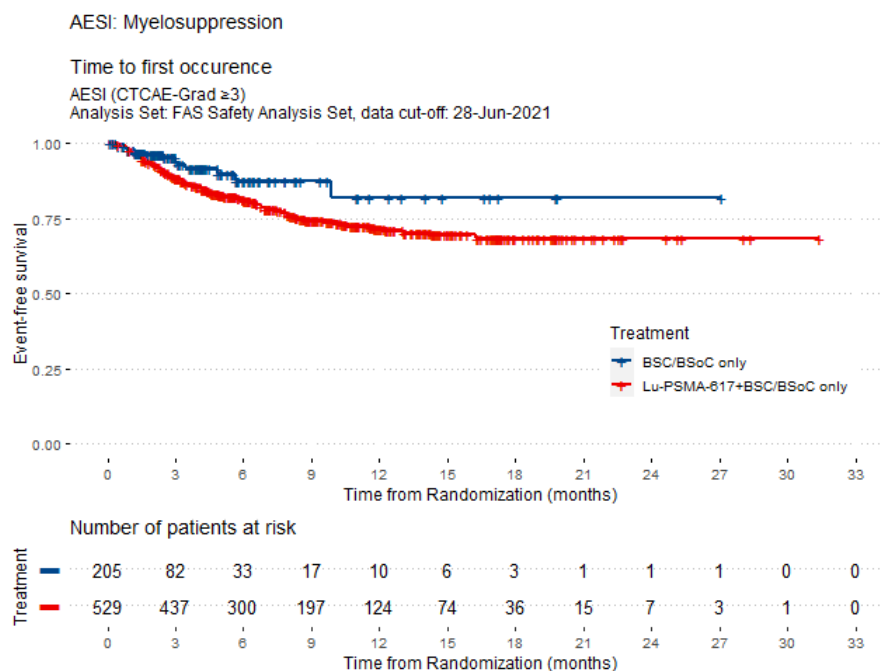


Abbildung 242: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Myelosuppression

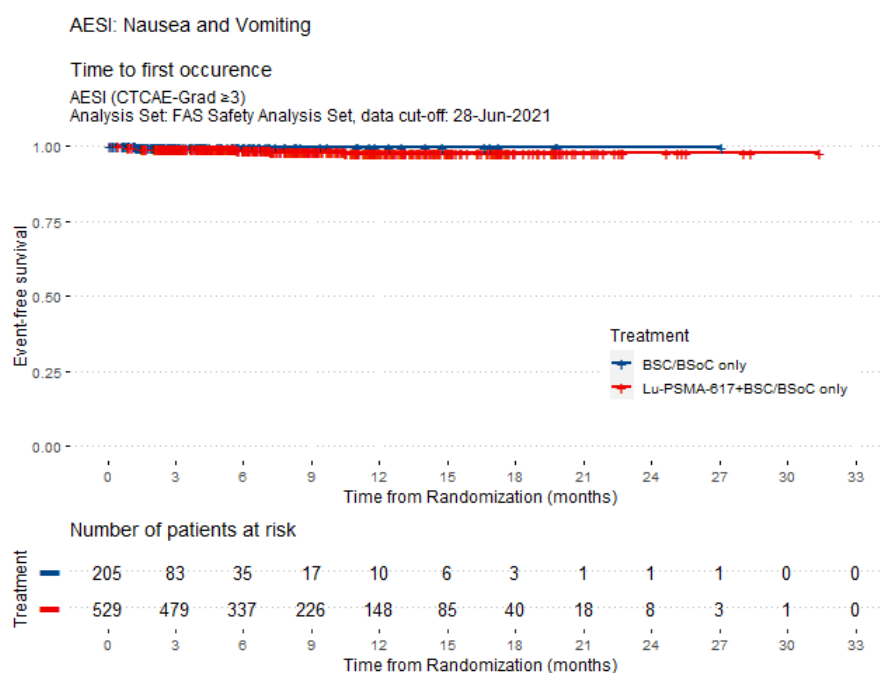
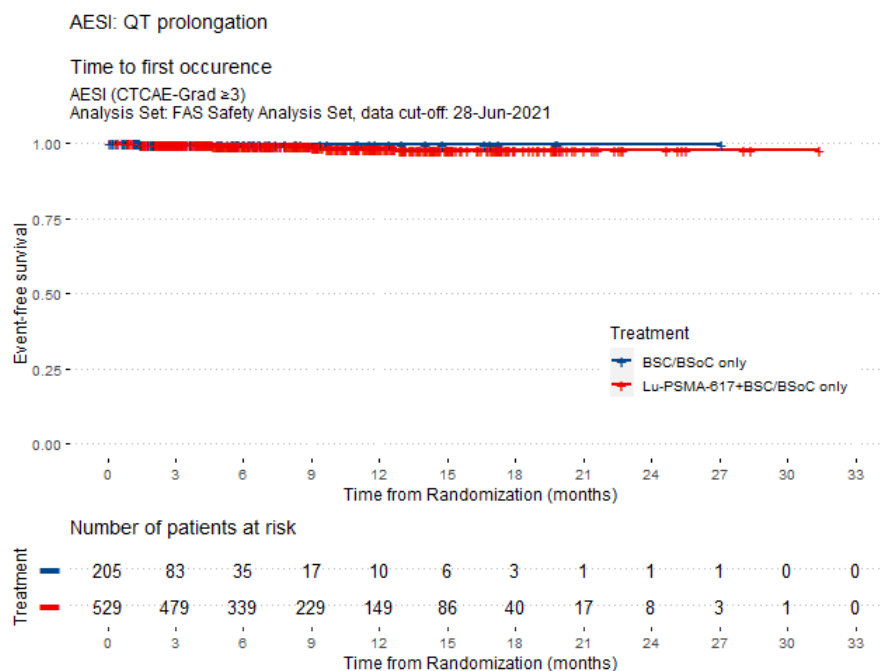
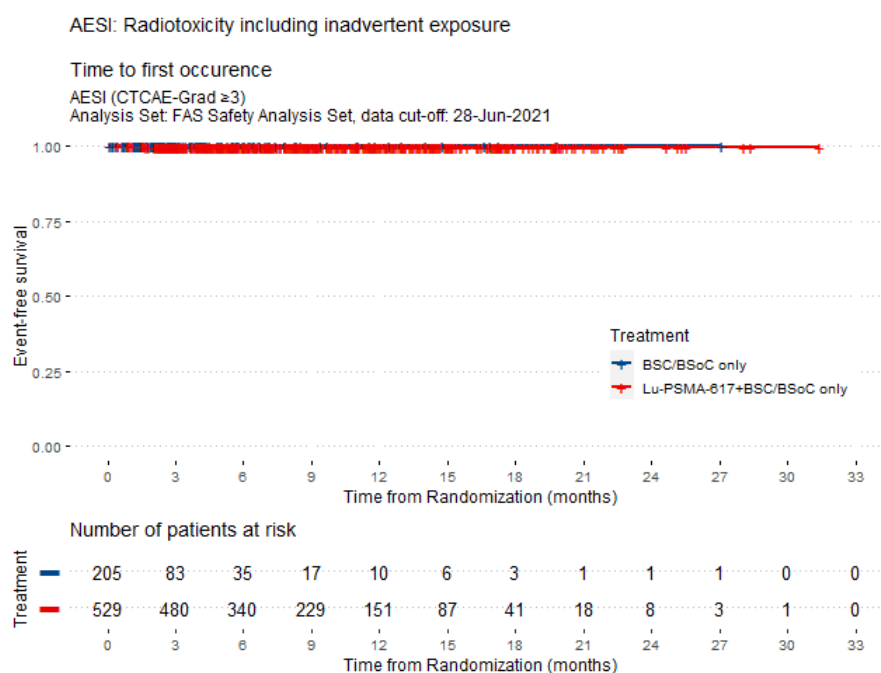
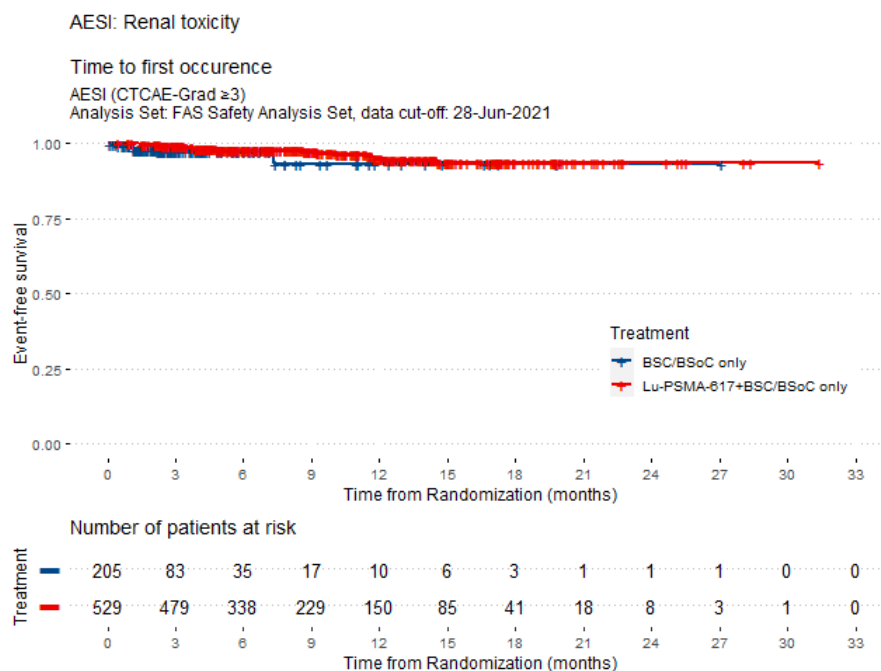
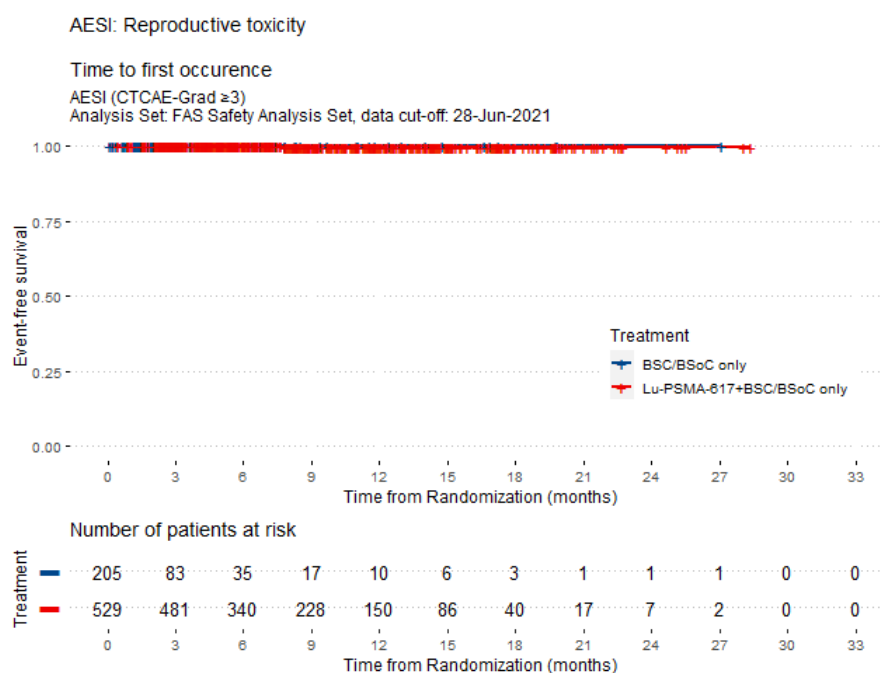


Abbildung 243: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Nausea and Vomiting

Abbildung 244: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: QT prolongationAbbildung 245: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Radiotoxicity including inadvertent exposure

Abbildung 246: AESi (CTCAE-Grad ≥ 3): Time to first occurrence of AESi: Renal toxicityAbbildung 247: AESi (CTCAE-Grad ≥ 3): Time to first occurrence of AESi: Reproductive toxicity

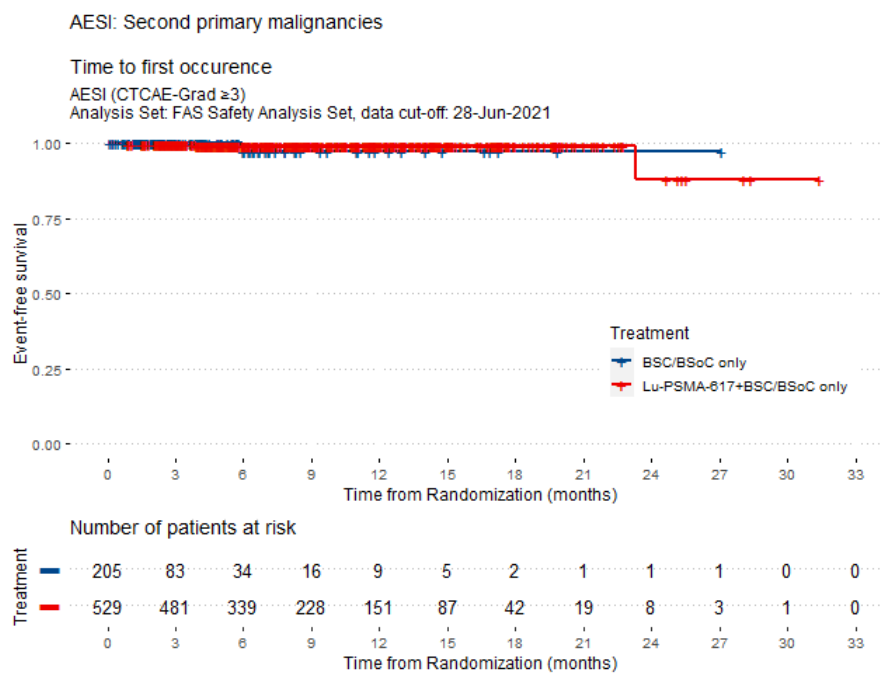


Abbildung 248: AESI (CTCAE-Grad ≥ 3): Time to first occurrence of AESI: Second primary malignancies

Anhang 4-H.3.3.4: Schwerwiegende UE

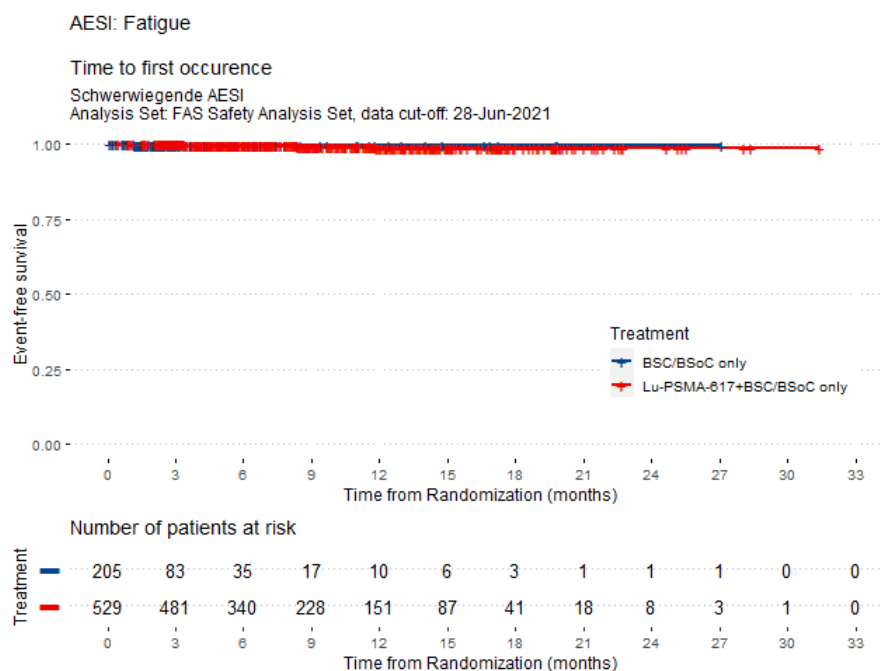


Abbildung 249: Schwerwiegende AESi: Time to first occurrence of AESi: Fatigue

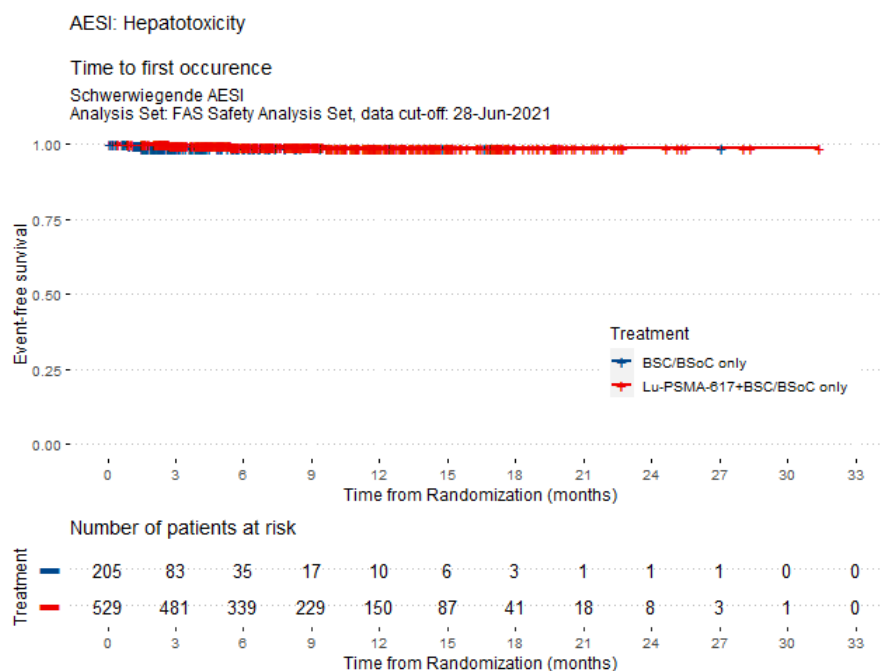


Abbildung 250: Schwerwiegende AESi: Time to first occurrence of AESi: Hepatotoxicity

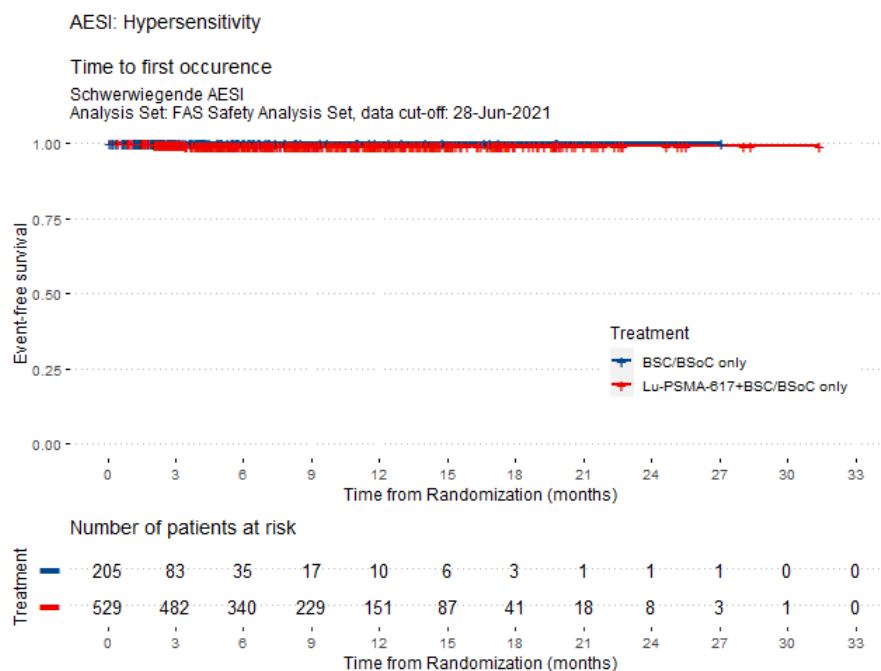


Abbildung 251: Schwerwiegende AESi: Time to first occurrence of AESi: Hypersensitivity

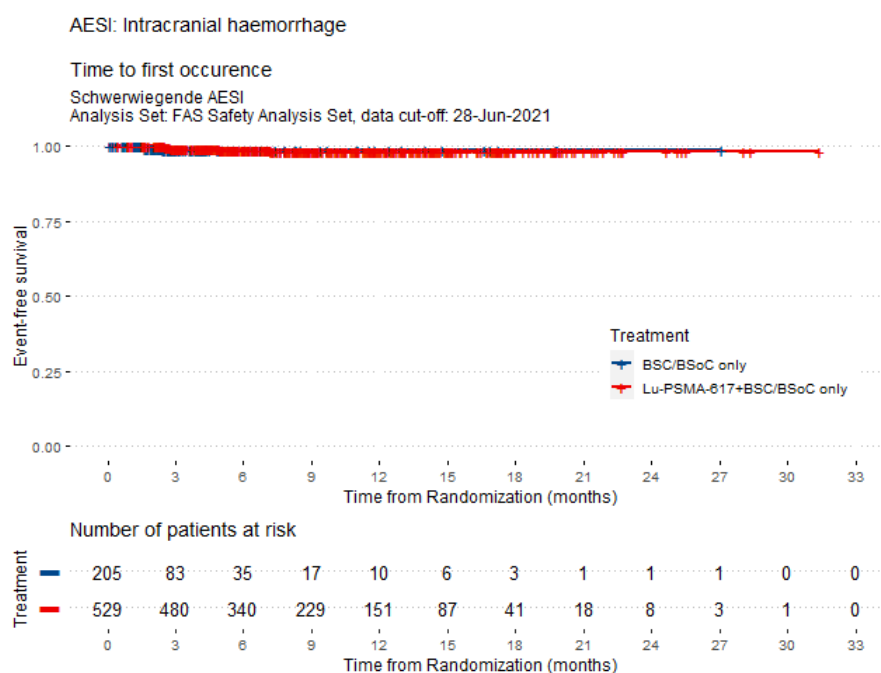


Abbildung 252: Schwerwiegende AESi: Time to first occurrence of AESi: Intracranial haemorrhage

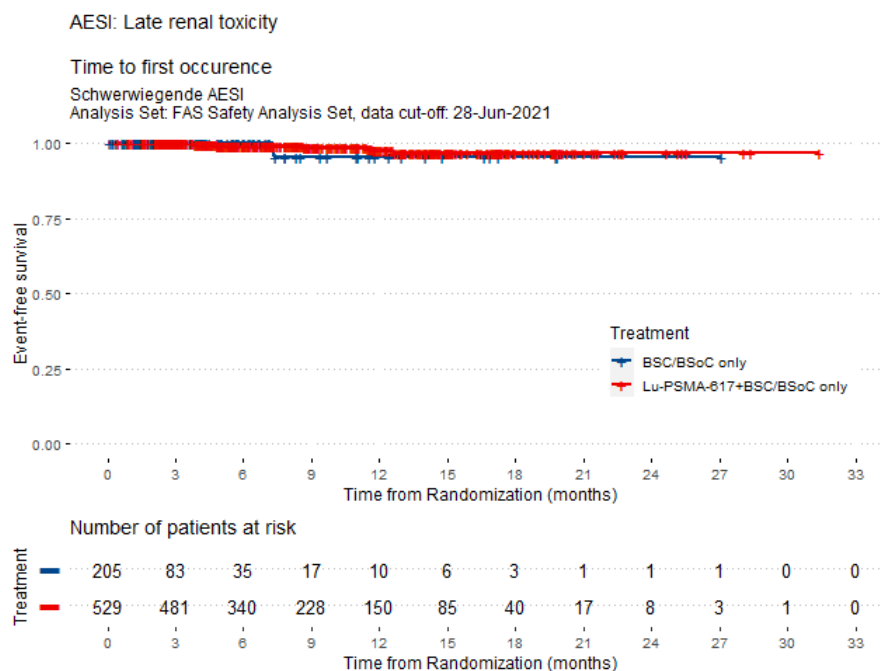


Abbildung 253: Schwerwiegende AESI: Time to first occurrence of AESI: Late renal toxicity

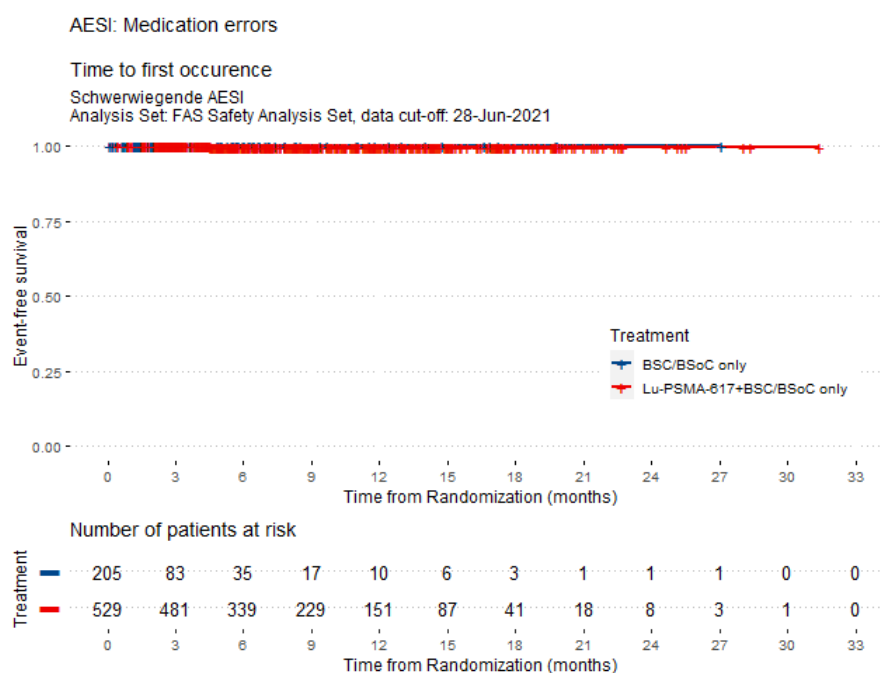


Abbildung 254: Schwerwiegende AESI: Time to first occurrence of AESI: Medication errors

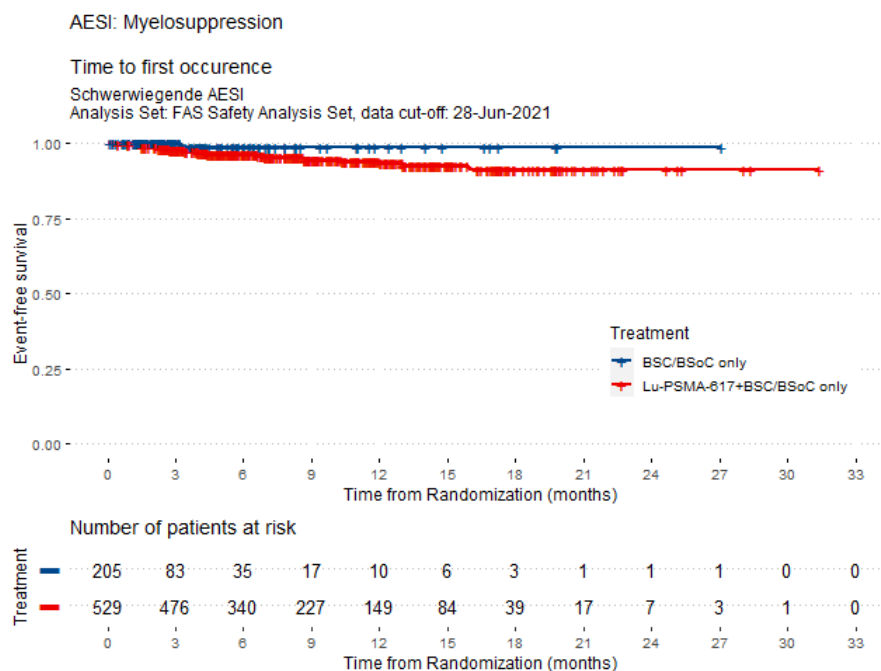


Abbildung 255: Schwerwiegende AESi: Time to first occurrence of AESi: Myelosuppression

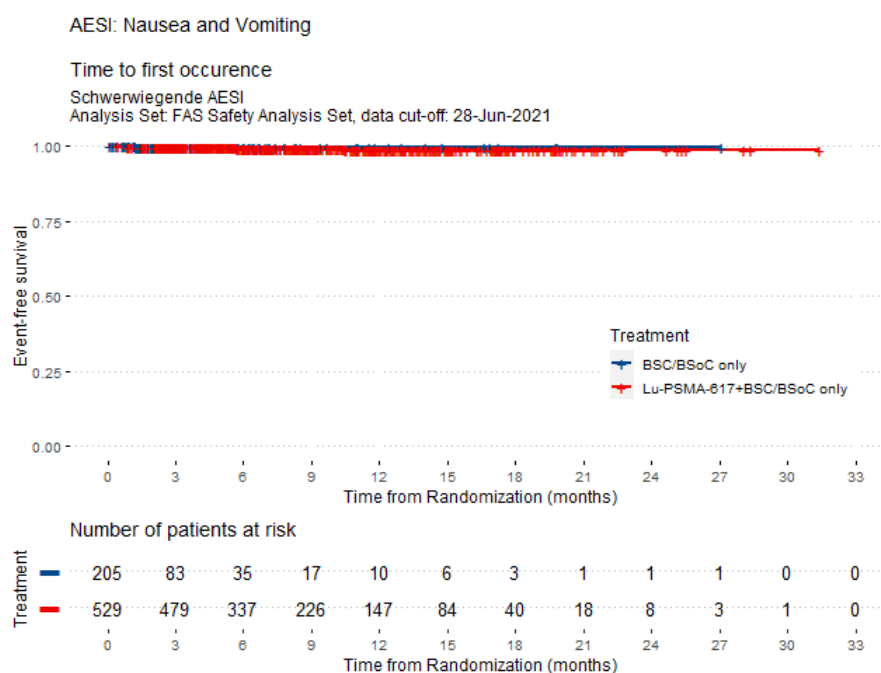


Abbildung 256: Schwerwiegende AESi: Time to first occurrence of AESi: Nausea and Vomiting

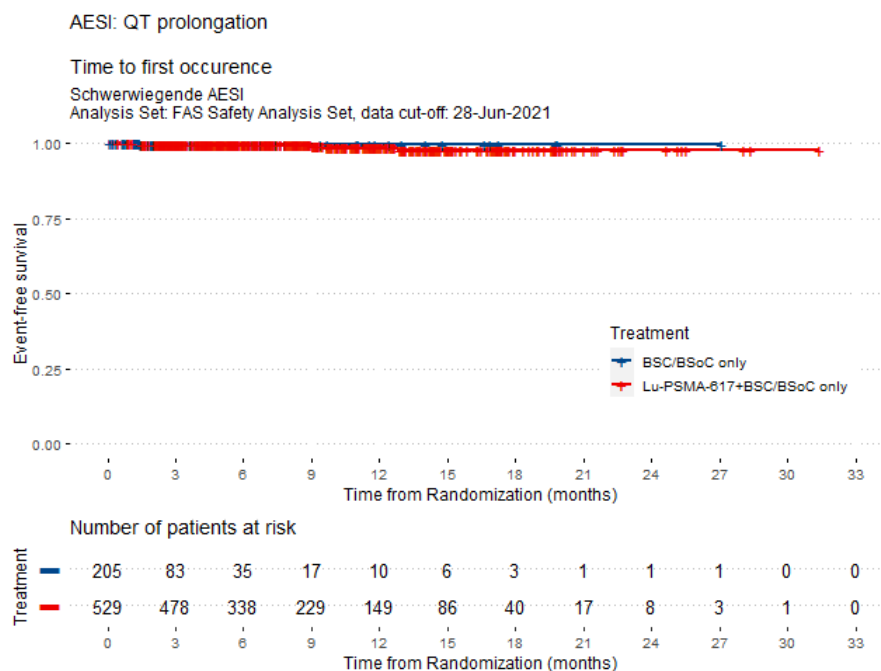


Abbildung 257: Schwerwiegende AESI: Time to first occurrence of AESI: QT prolongation

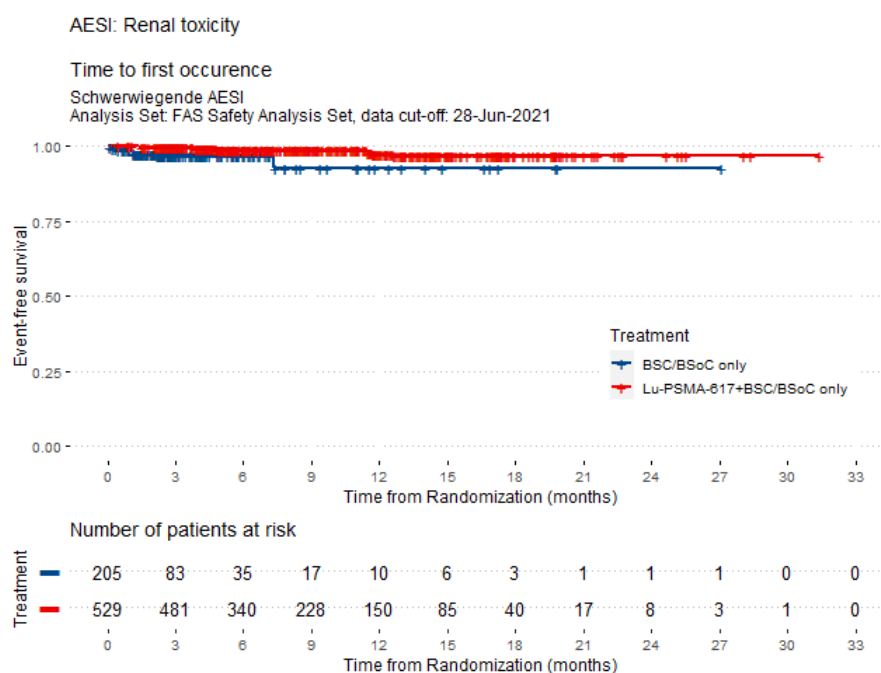


Abbildung 258: Schwerwiegende AESI: Time to first occurrence of AESI: Renal toxicity

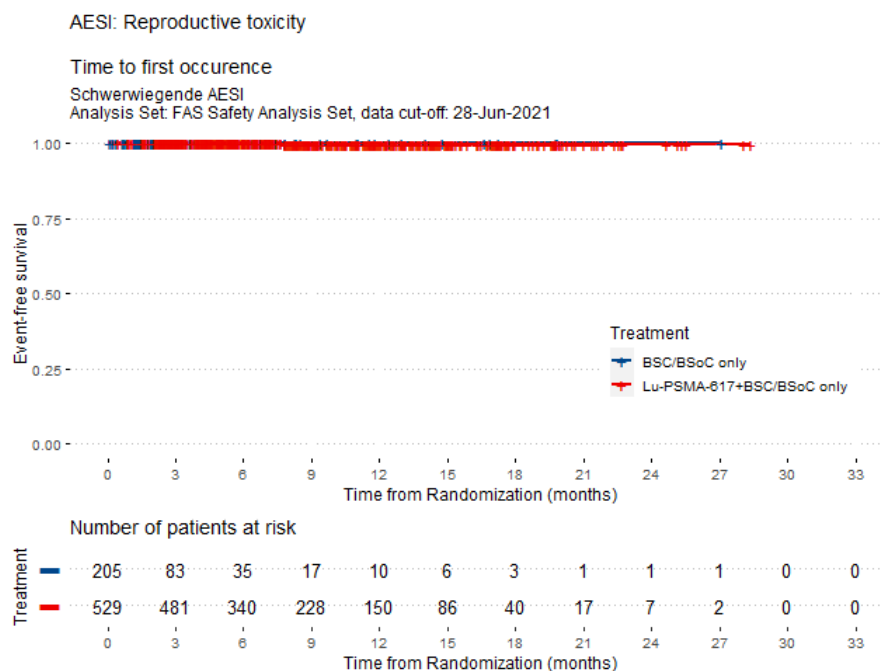


Abbildung 259: Schwerwiegende AESi: Time to first occurrence of AESi: Reproductive toxicity

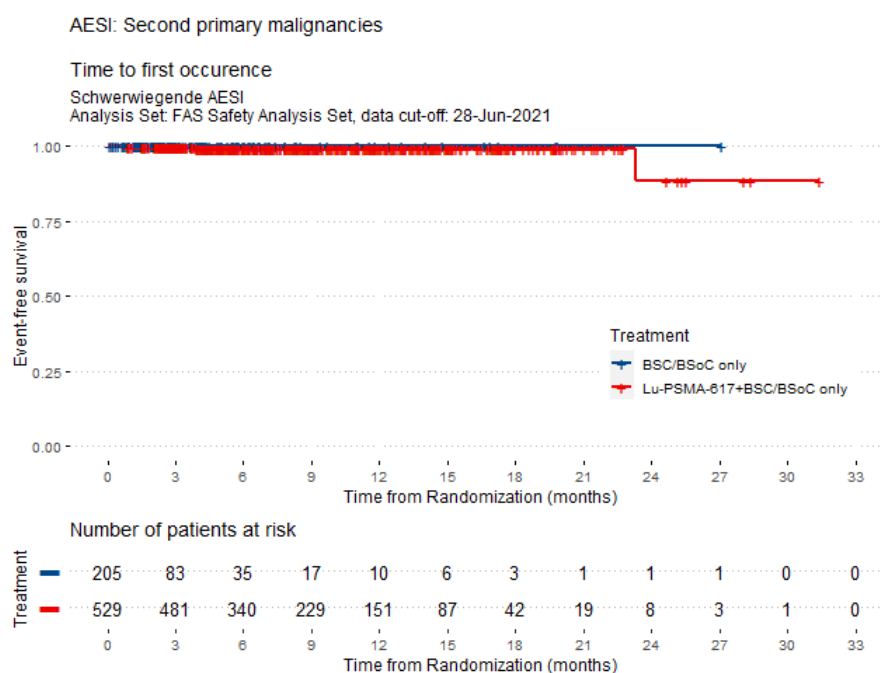


Abbildung 260: Schwerwiegende AESi: Time to first occurrence of AESi: Second primary malignancies

Anhang 4-H.3.4: Unerwünschte Ereignisse nach System Organ Class und Preferred Term

Anhang 4-H.3.4.1: UE jeglichen Schweregrads

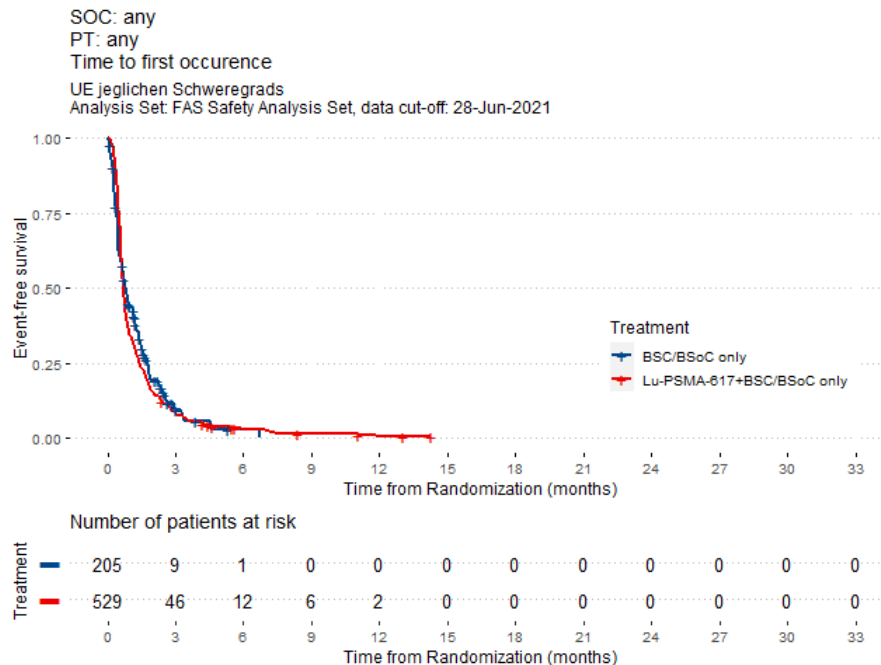


Abbildung 261: UE jeglichen Schweregrads: Time to first occurrence of SOC: any; PT: any

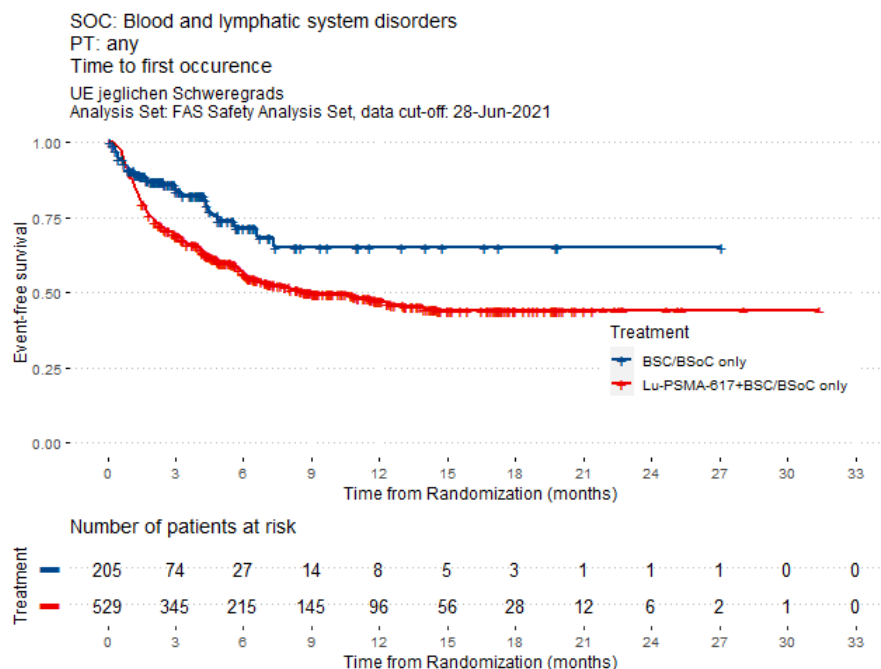


Abbildung 262: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: any

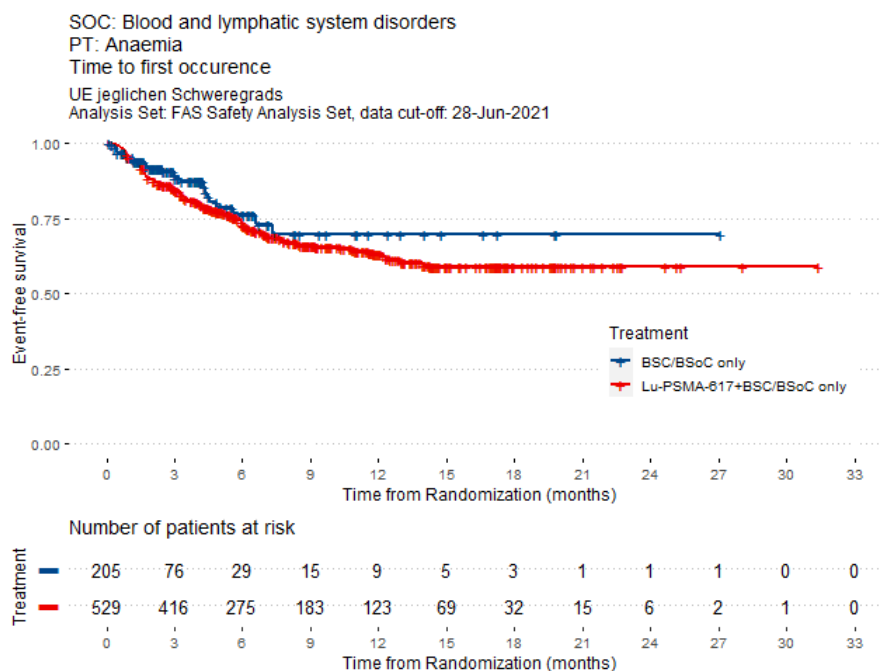


Abbildung 263: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Anaemia

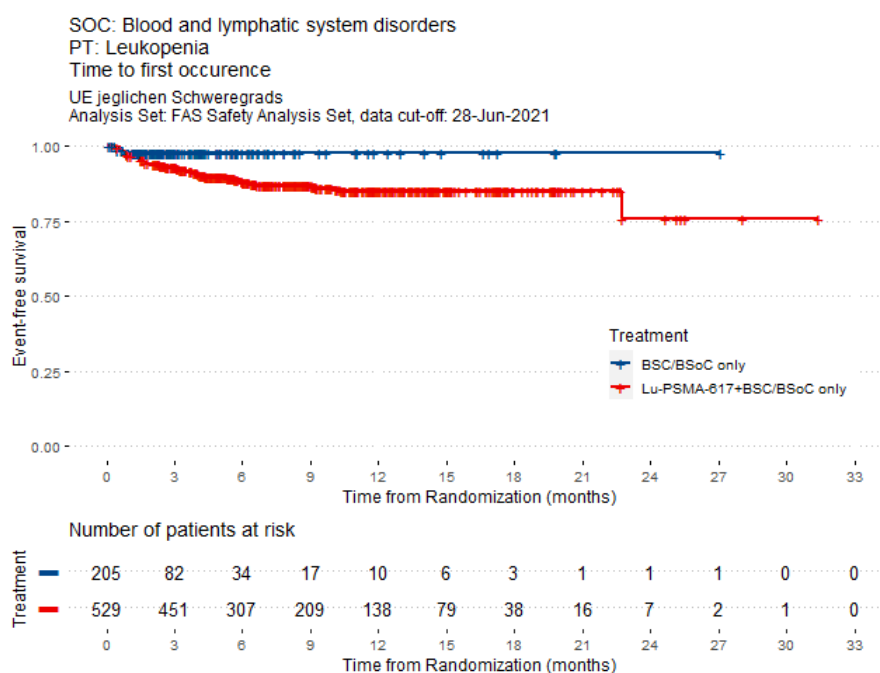


Abbildung 264: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Leukopenia

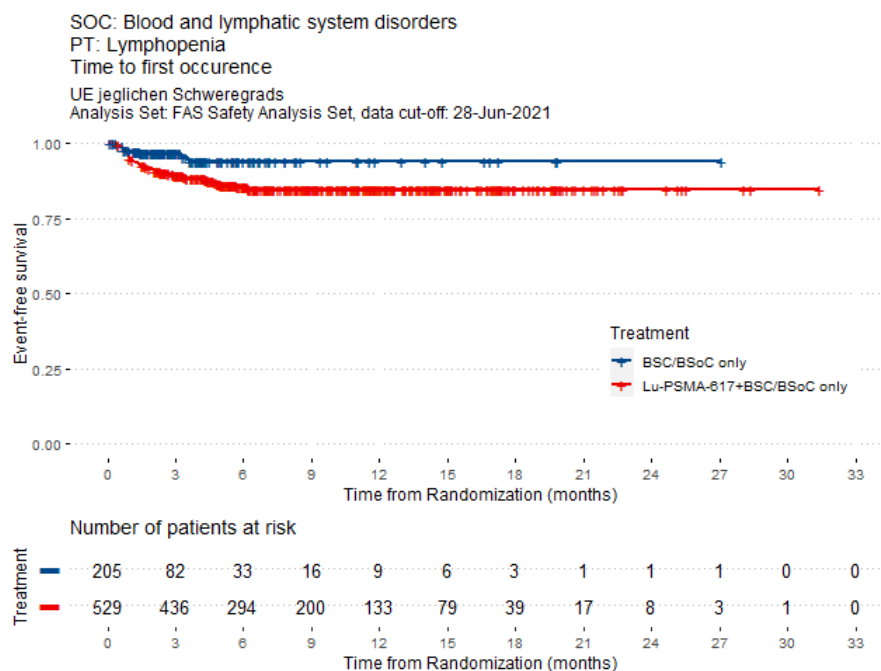


Abbildung 265: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Lymphopenia

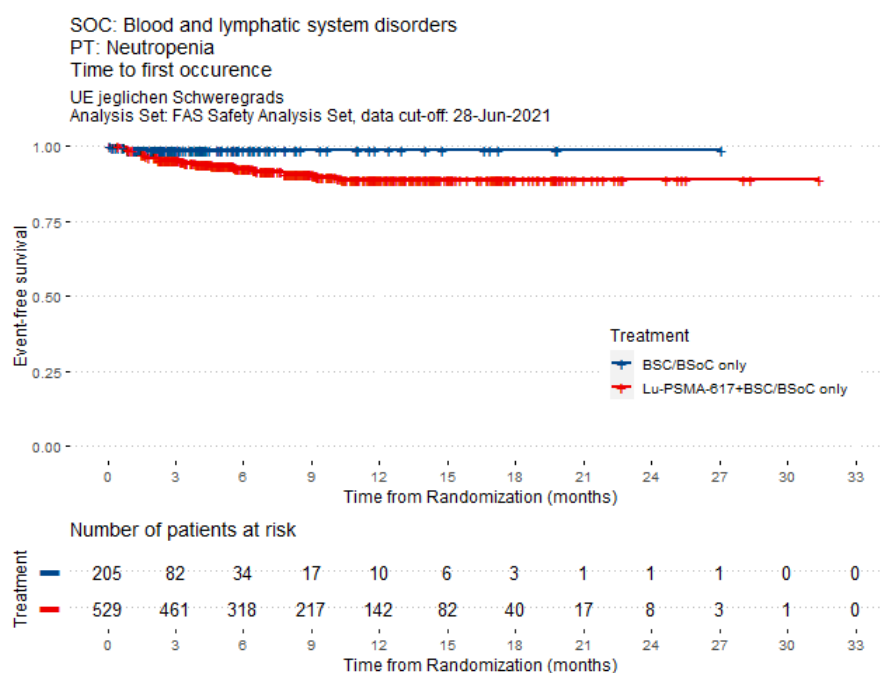


Abbildung 266: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Neutropenia

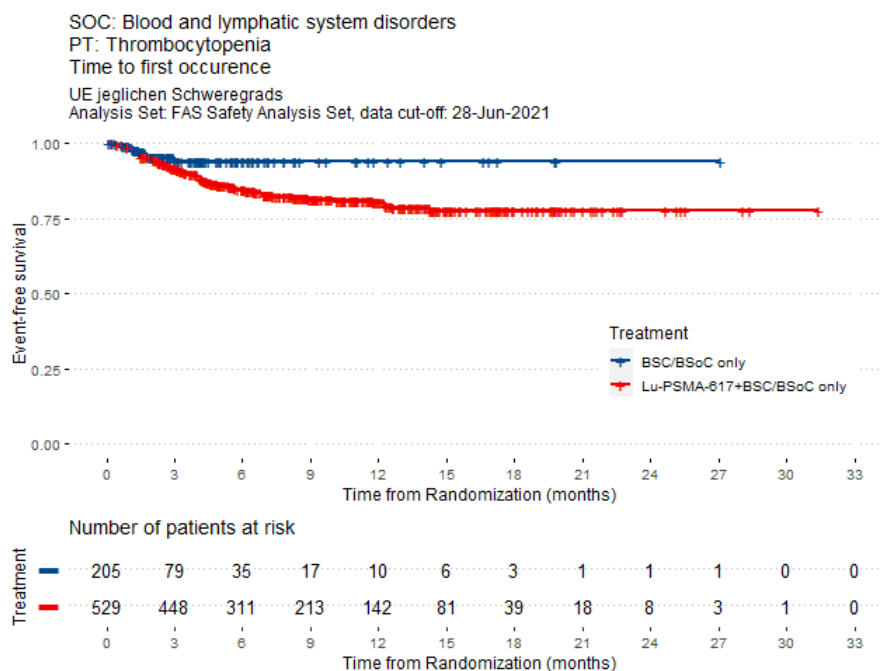


Abbildung 267: UE jeglichen Schweregrads: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Thrombocytopenia

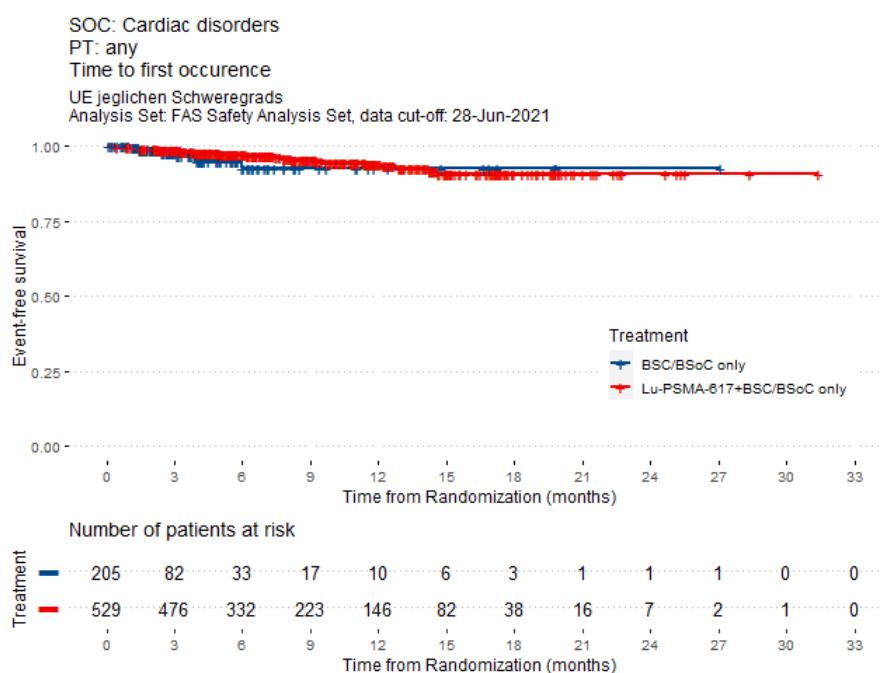


Abbildung 268: UE jeglichen Schweregrads: Time to first occurrence of SOC: Cardiac disorders; PT: any

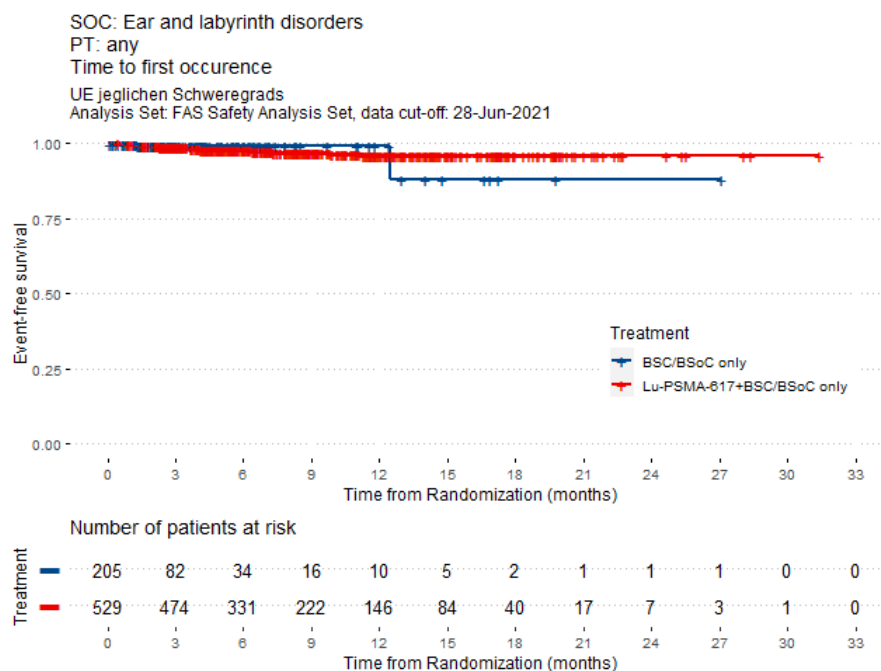


Abbildung 269: UE jeglichen Schweregrads: Time to first occurrence of SOC: Ear and labyrinth disorders; PT: any

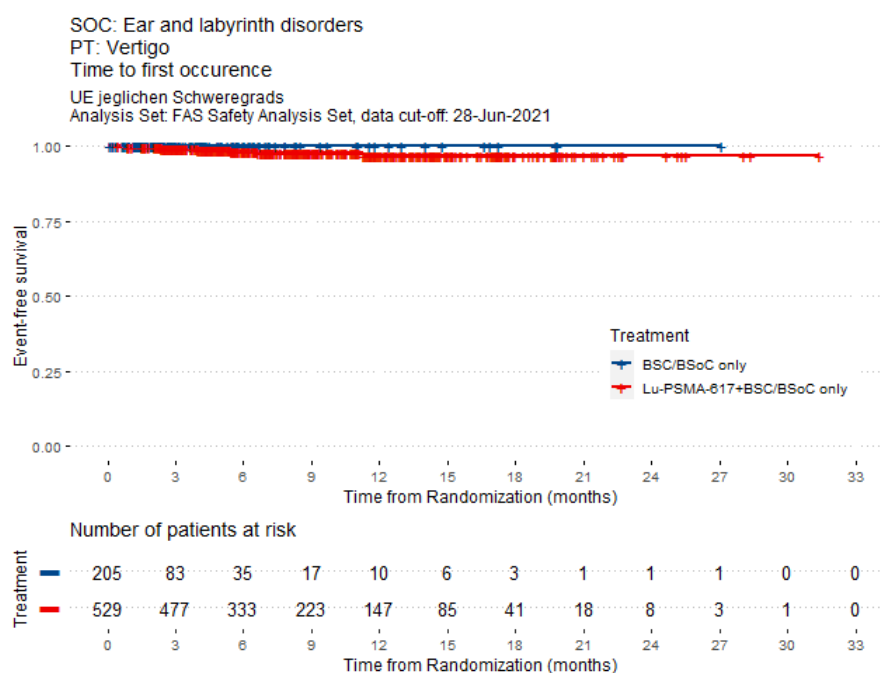


Abbildung 270: UE jeglichen Schweregrads: Time to first occurrence of SOC: Ear and labyrinth disorders; PT: Vertigo

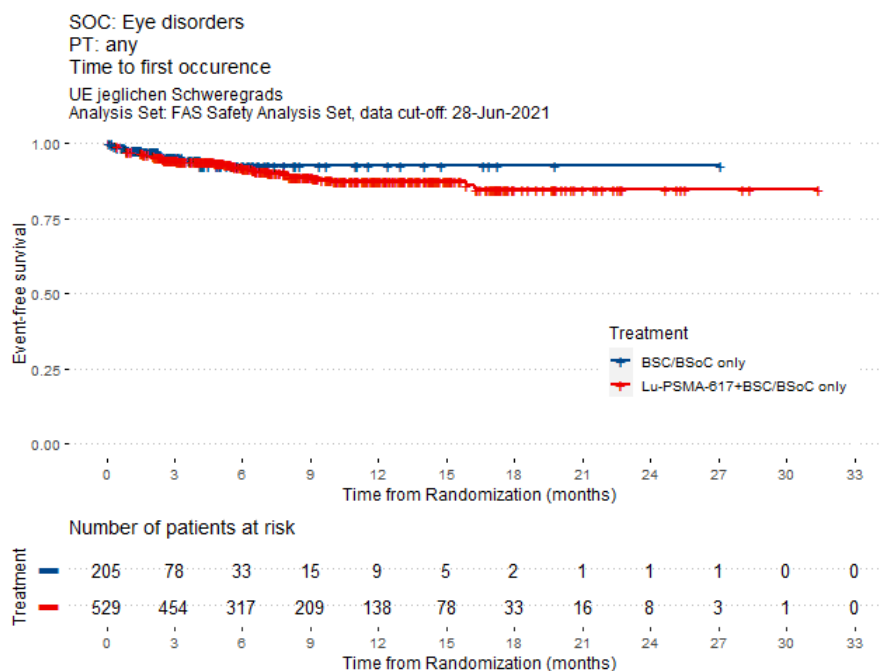


Abbildung 271: UE jeglichen Schweregrads: Time to first occurrence of SOC: Eye disorders;
PT: any

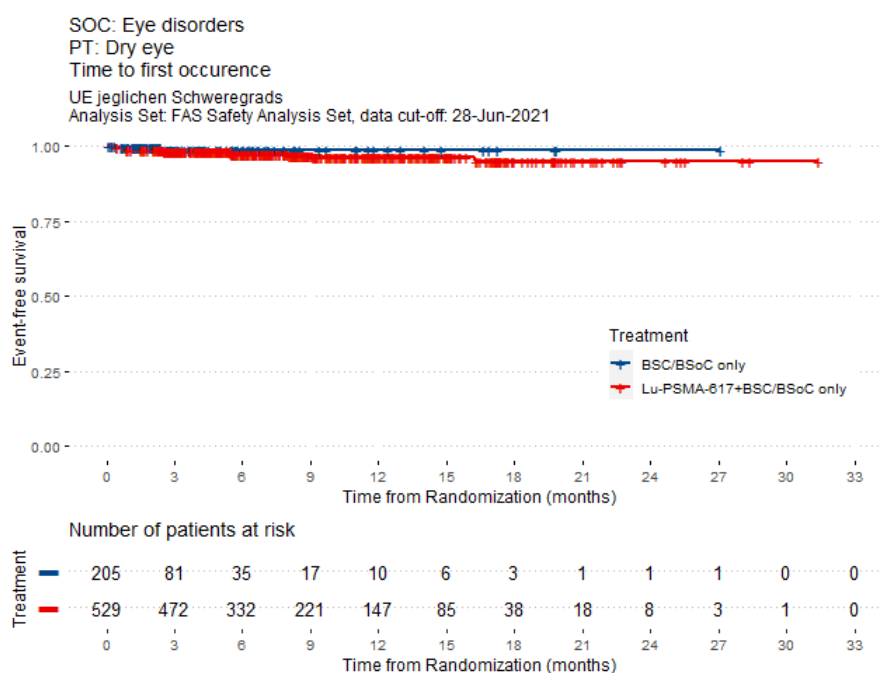


Abbildung 272: UE jeglichen Schweregrads: Time to first occurrence of SOC: Eye disorders;
PT: Dry eye

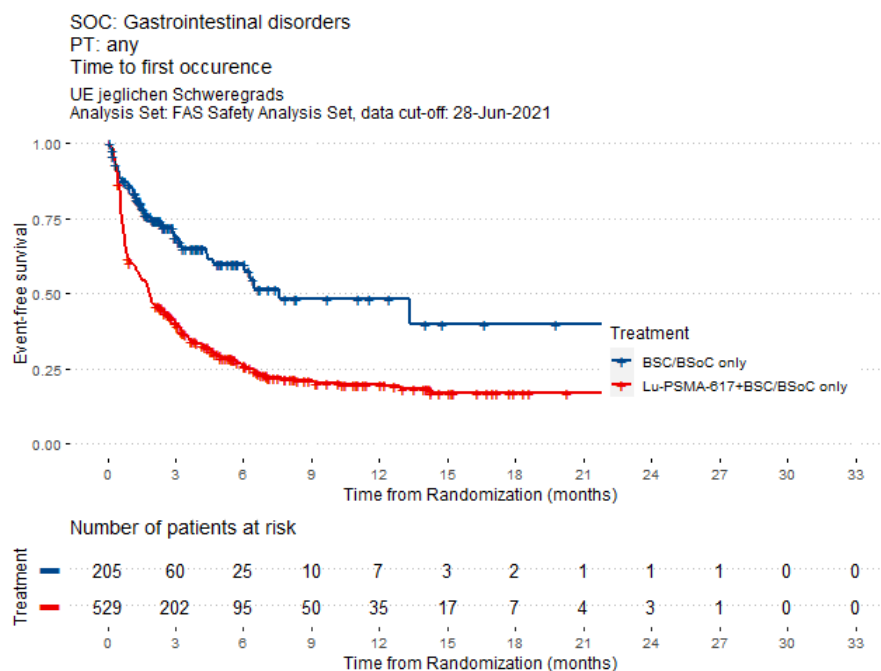


Abbildung 273: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: any

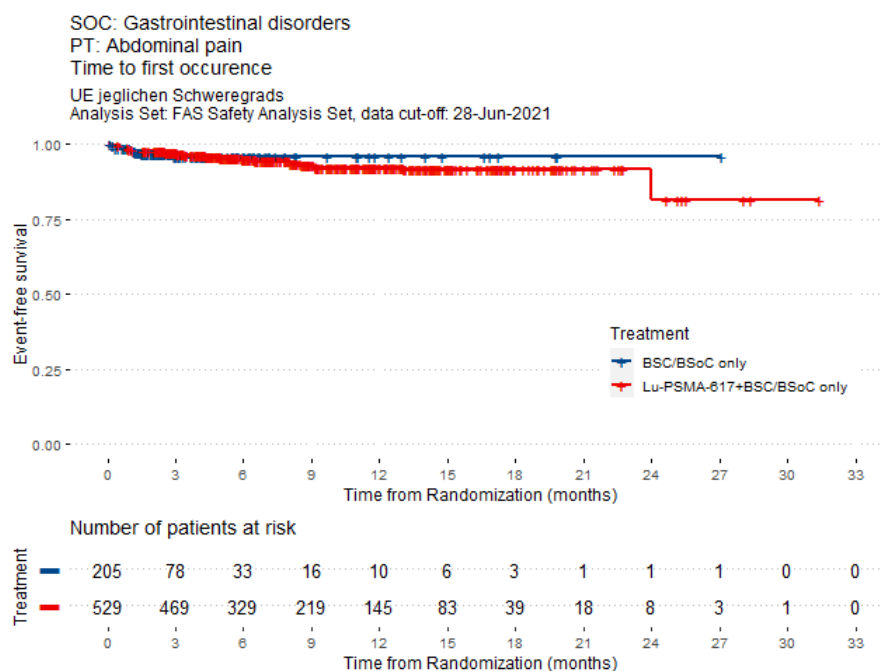


Abbildung 274: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Abdominal pain

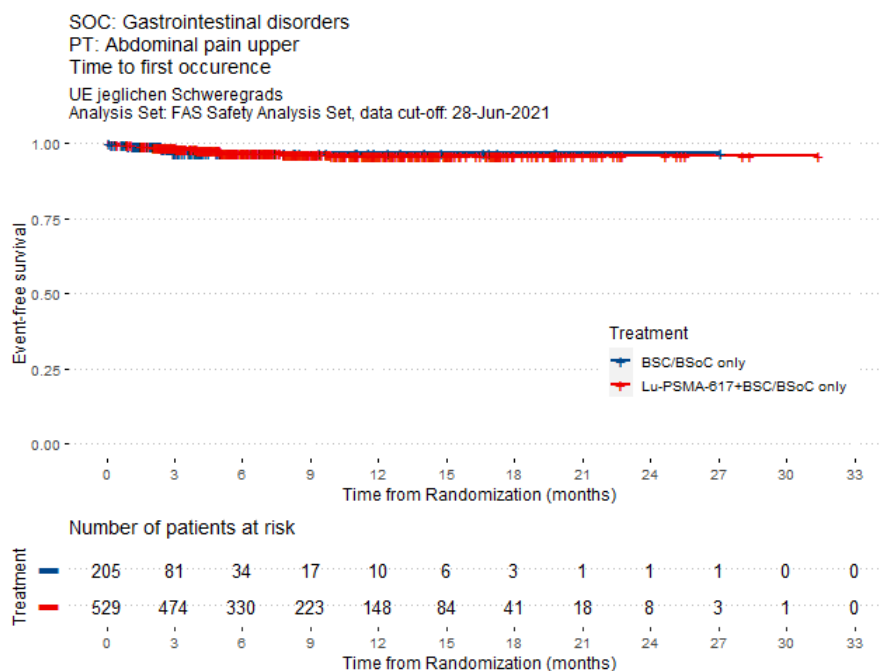


Abbildung 275: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Abdominal pain upper

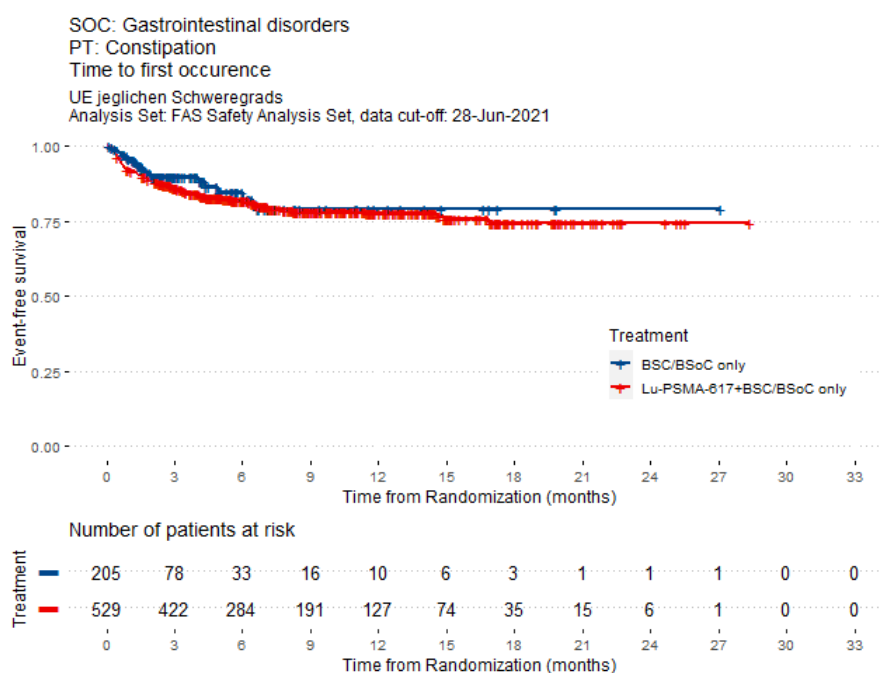


Abbildung 276: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Constipation

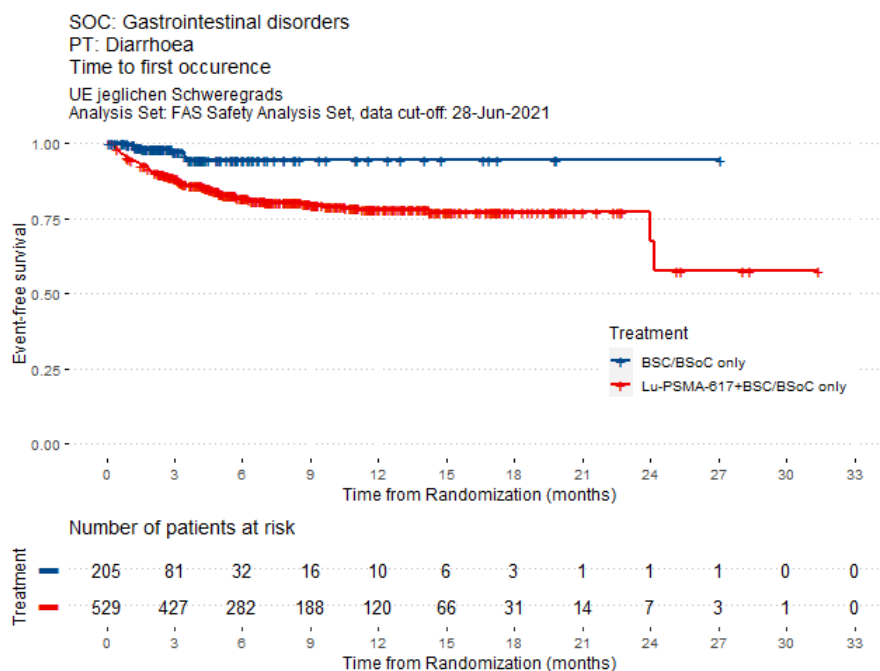


Abbildung 277: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Diarrhoea

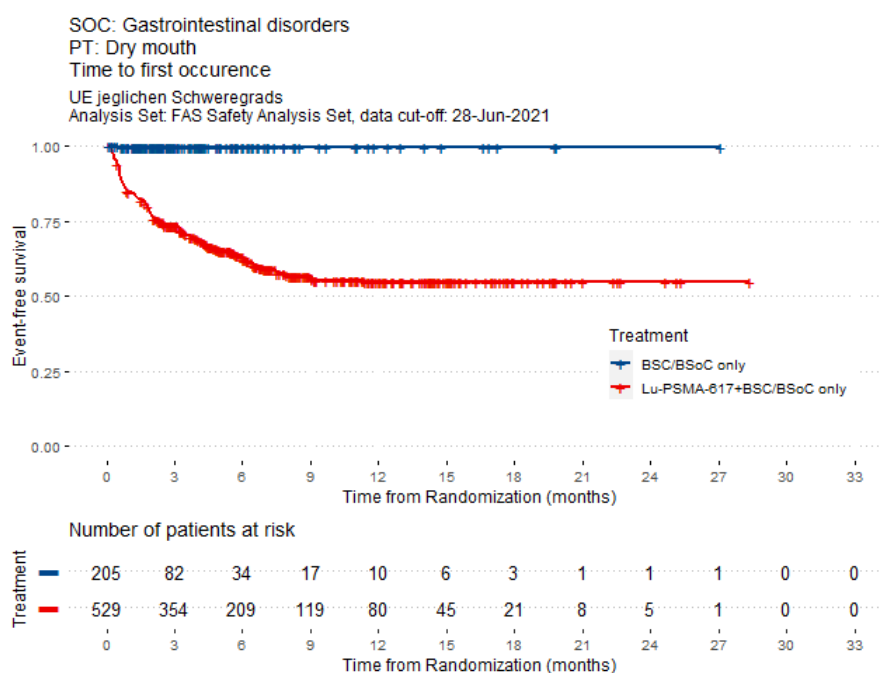


Abbildung 278: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Dry mouth

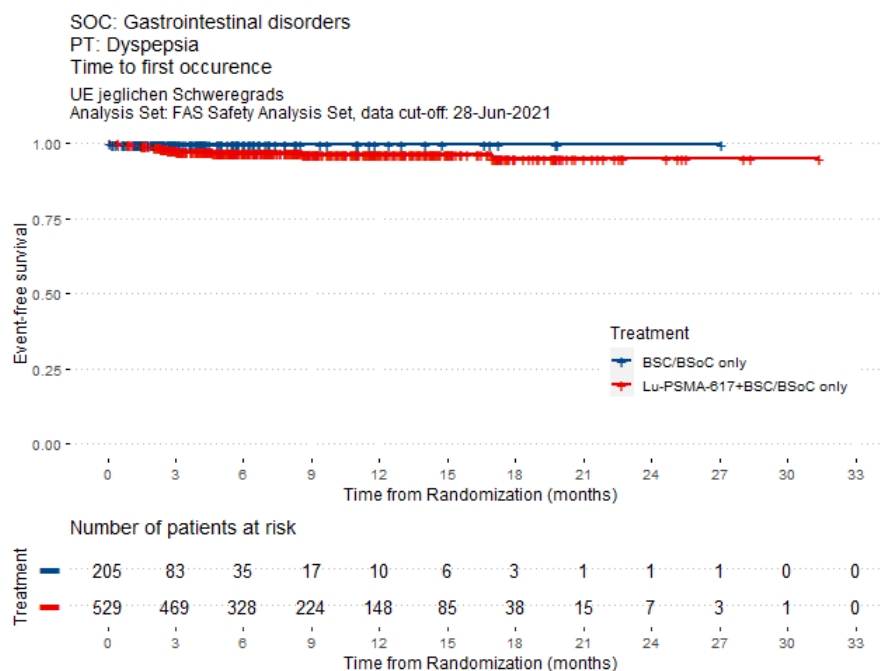


Abbildung 279: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Dyspepsia

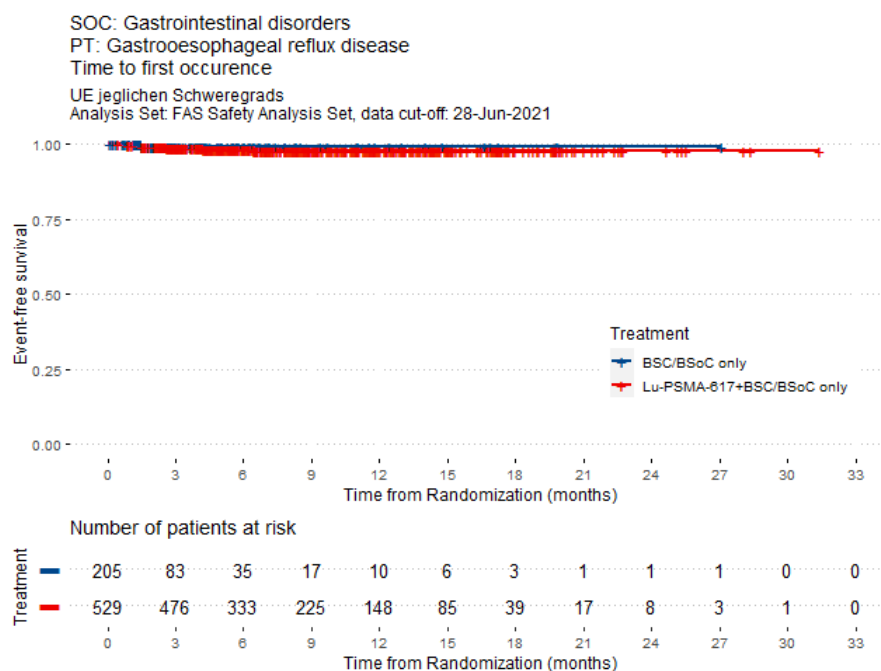


Abbildung 280: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Gastroesophageal reflux disease

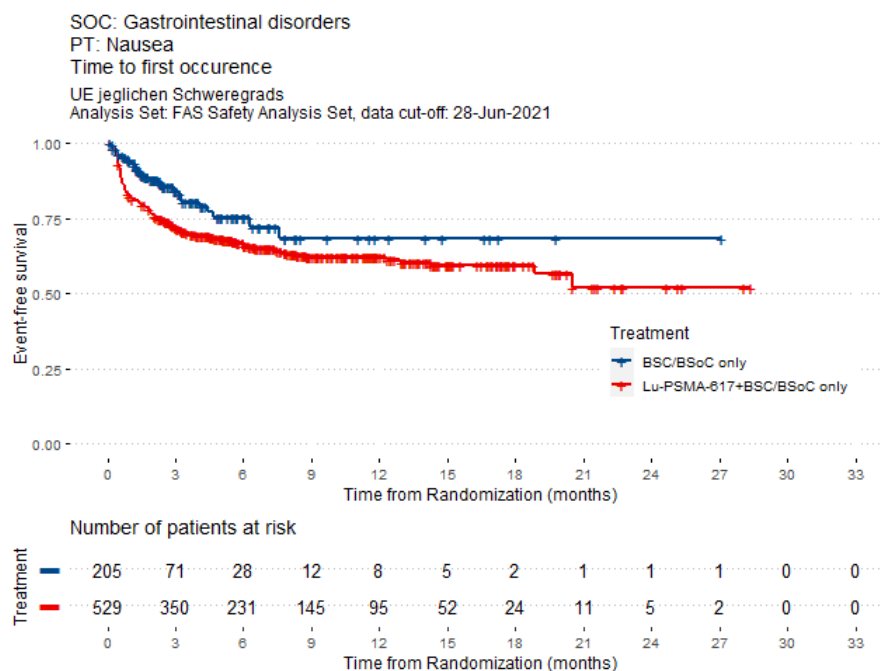


Abbildung 281: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Nausea

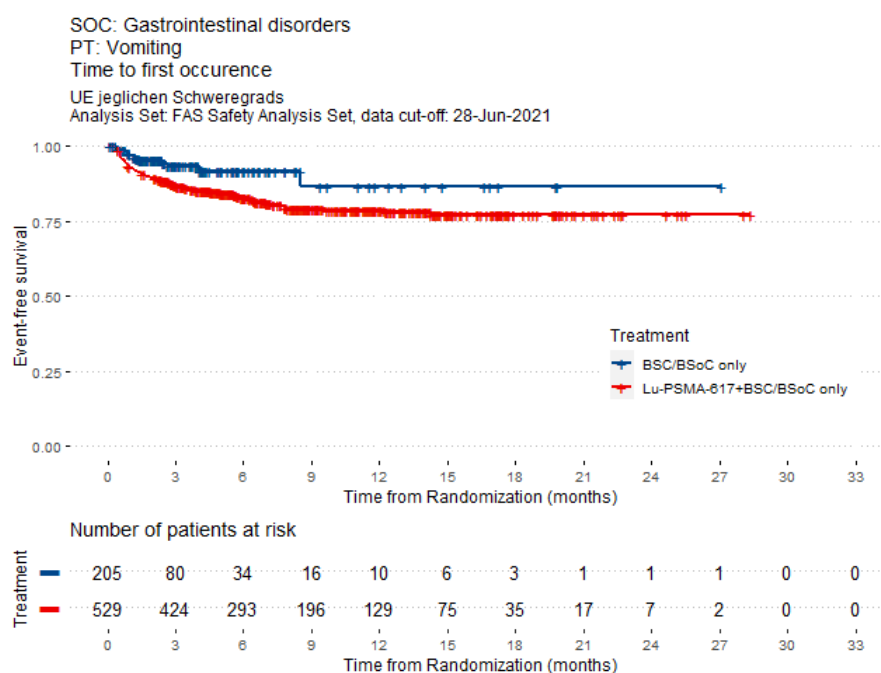


Abbildung 282: UE jeglichen Schweregrads: Time to first occurrence of SOC: Gastrointestinal disorders; PT: Vomiting

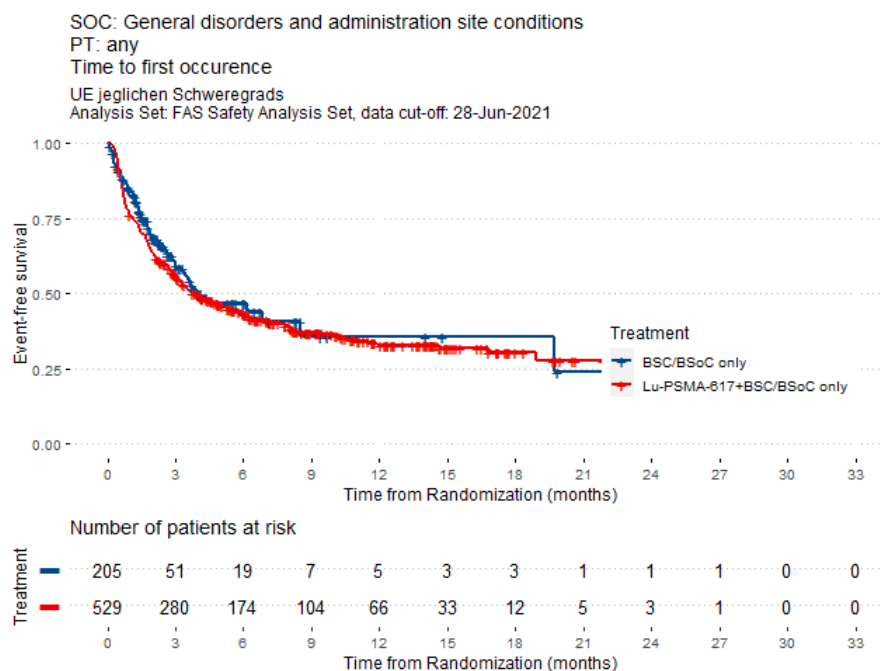


Abbildung 283: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: any

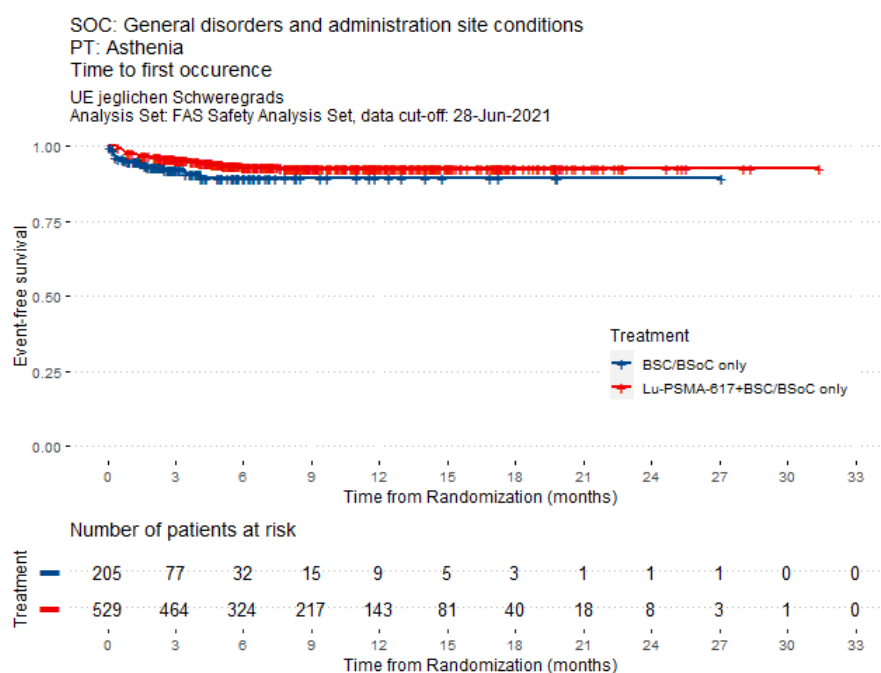


Abbildung 284: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Asthenia

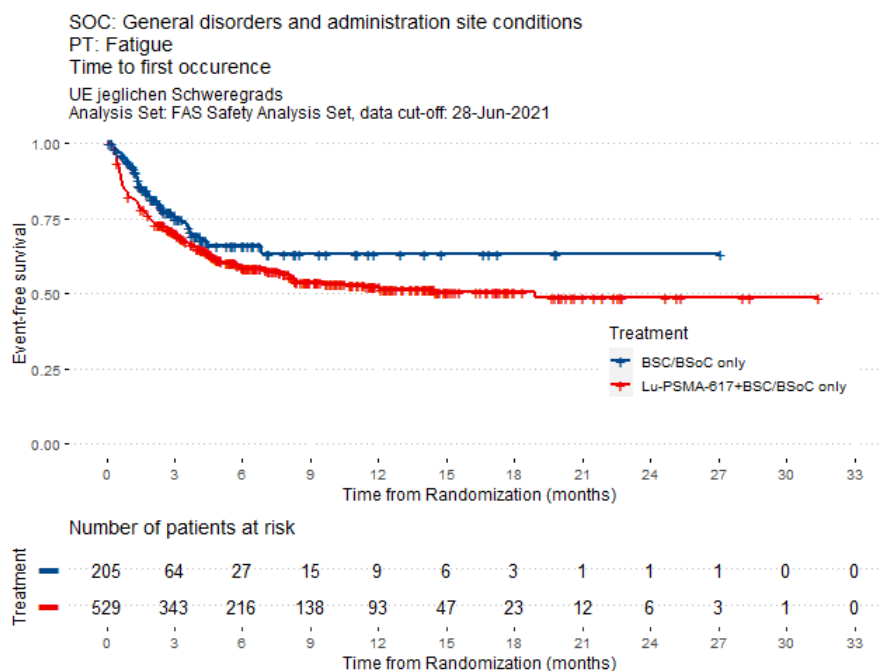


Abbildung 285: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Fatigue

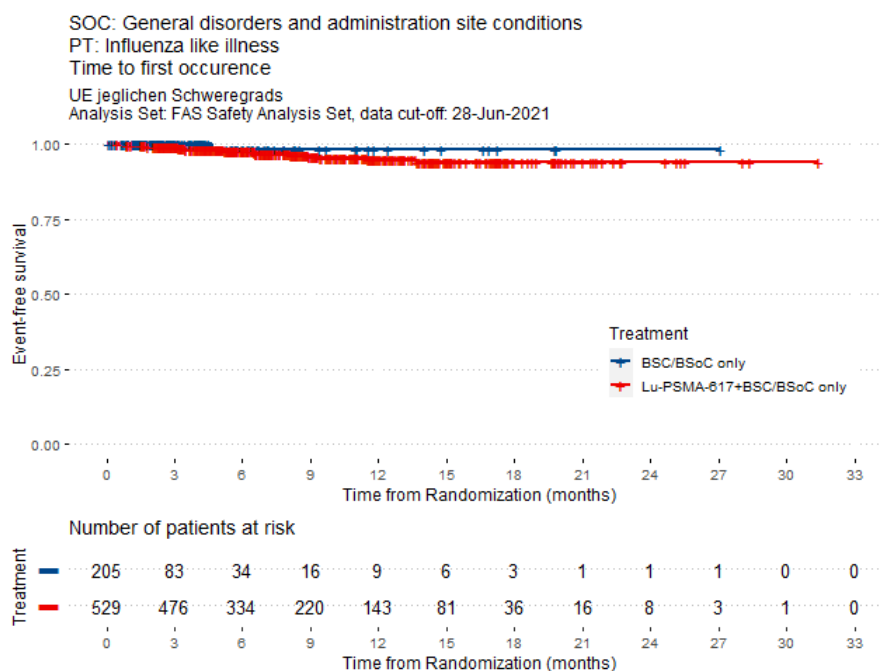


Abbildung 286: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Influenza like illness

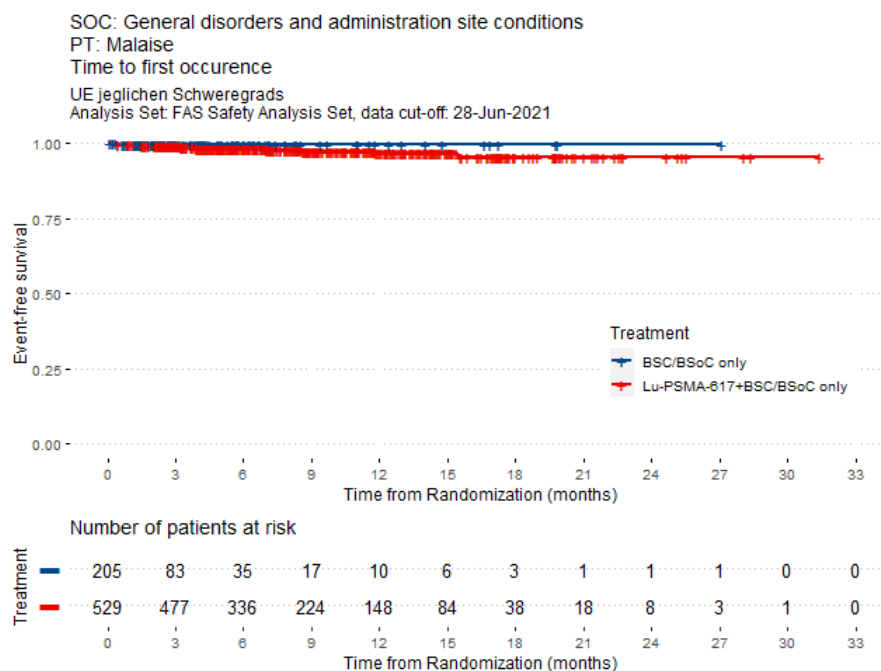


Abbildung 287: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Malaise

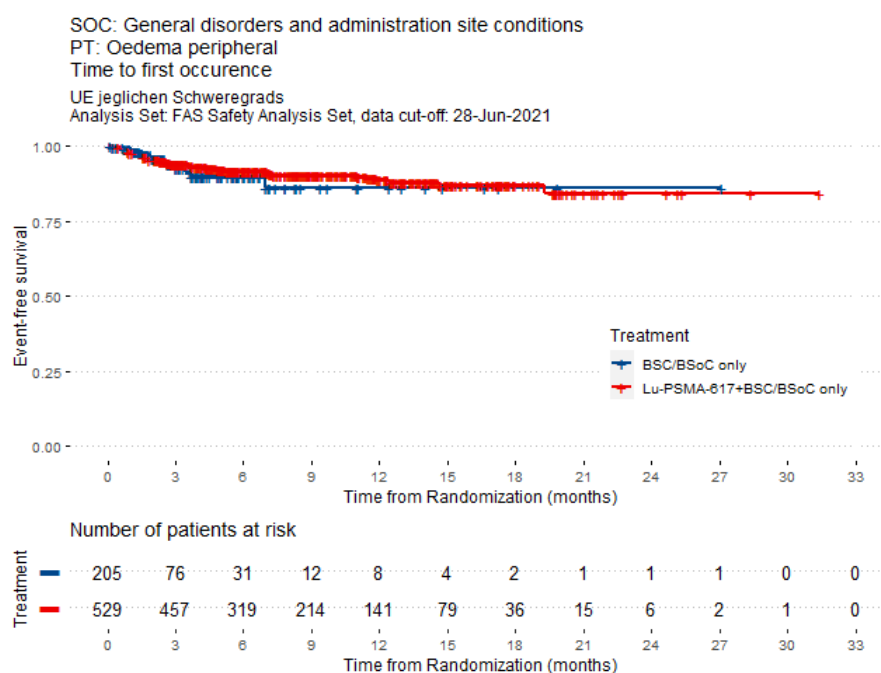


Abbildung 288: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Oedema peripheral

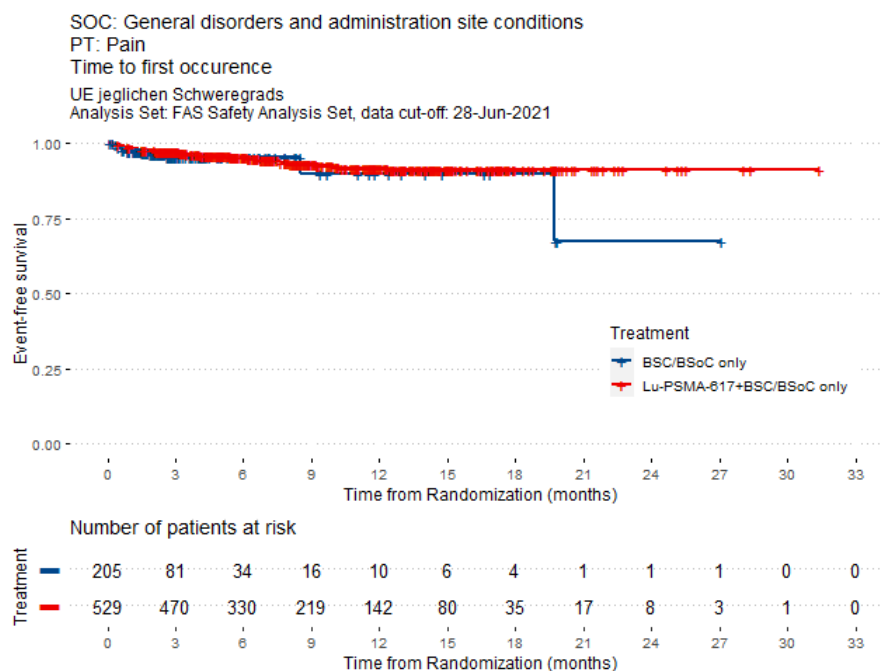


Abbildung 289: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Pain

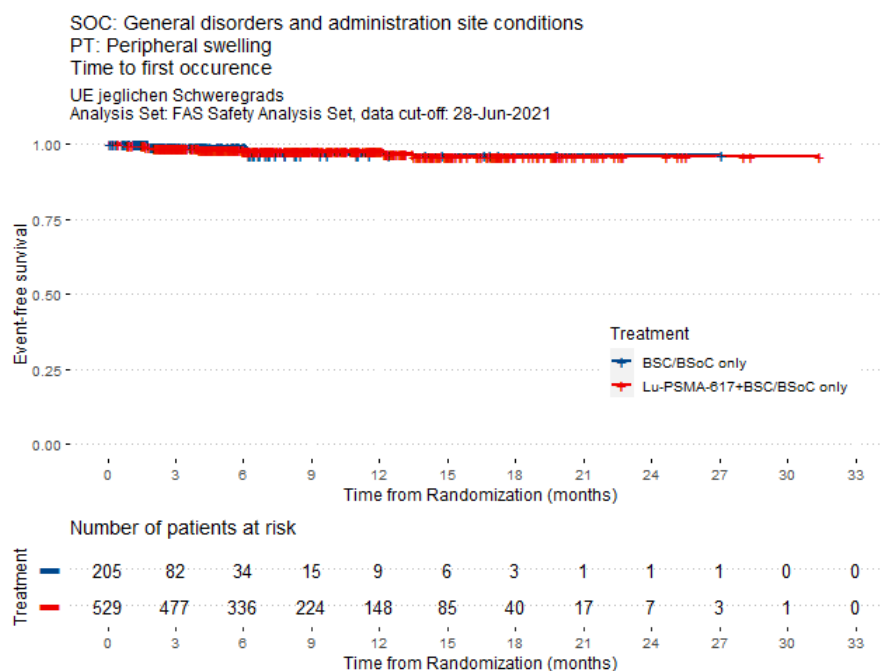


Abbildung 290: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Peripheral swelling

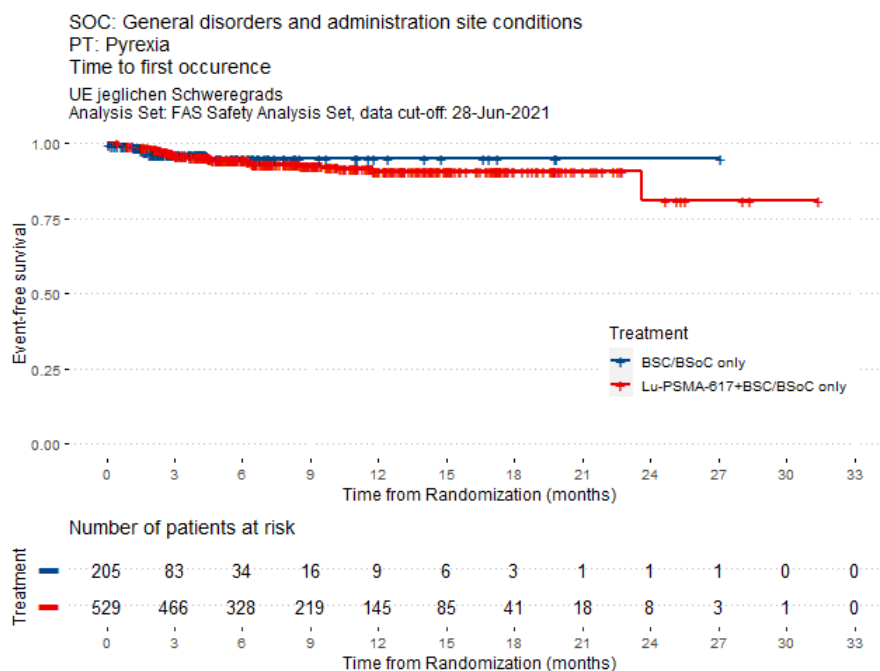


Abbildung 291: UE jeglichen Schweregrads: Time to first occurrence of SOC: General disorders and administration site conditions; PT: Pyrexia

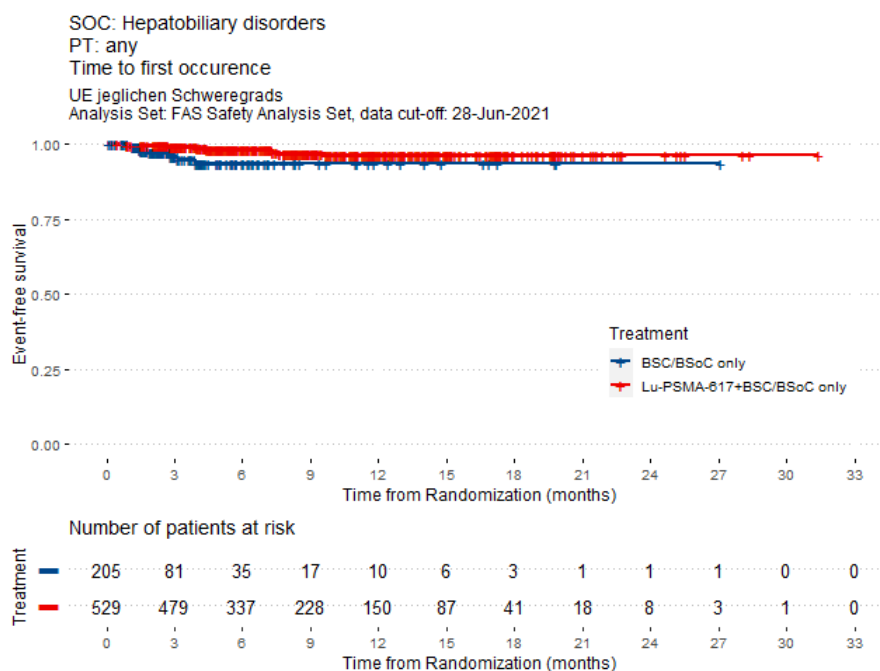


Abbildung 292: UE jeglichen Schweregrads: Time to first occurrence of SOC: Hepatobiliary disorders; PT: any

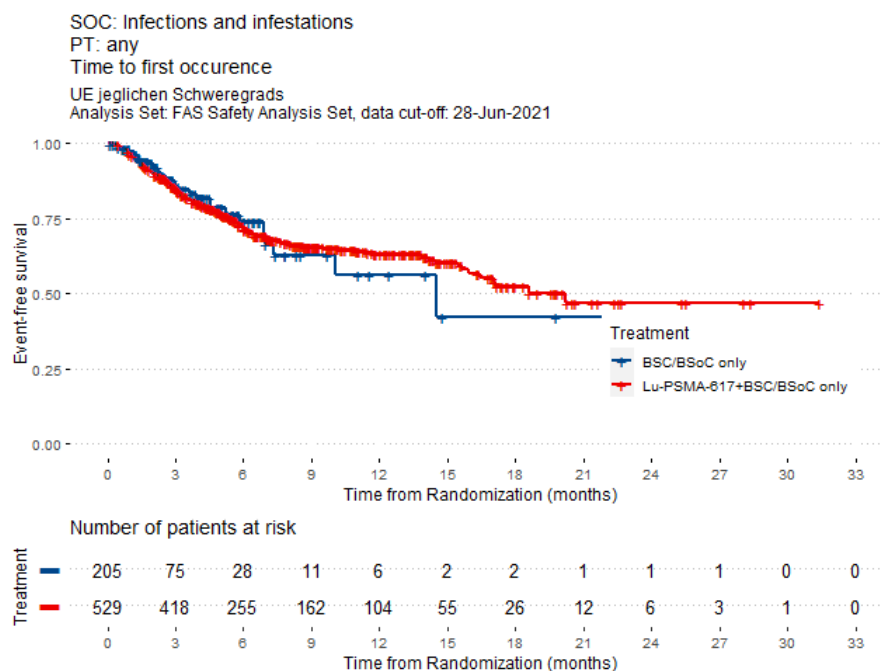


Abbildung 293: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: any

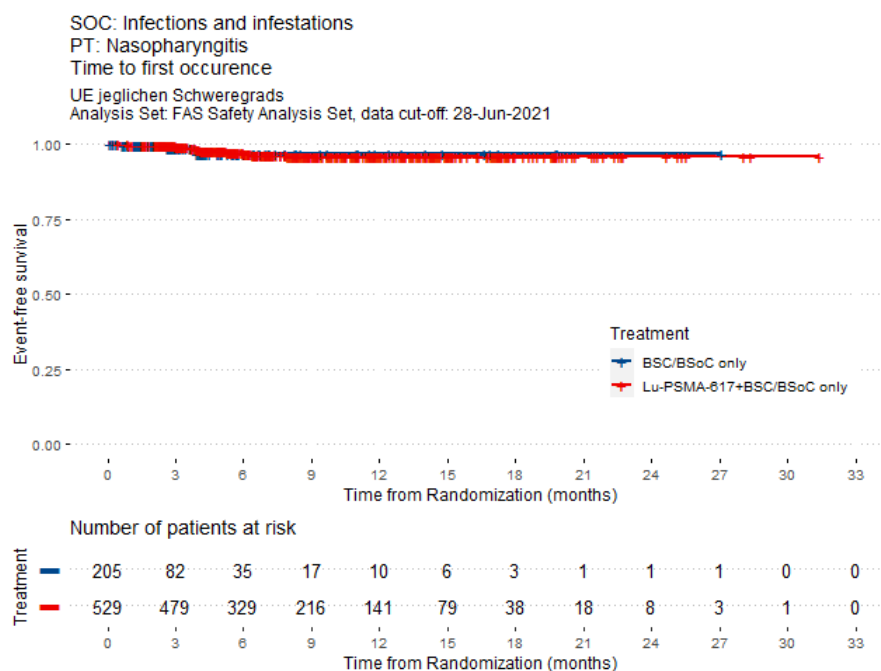


Abbildung 294: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Nasopharyngitis

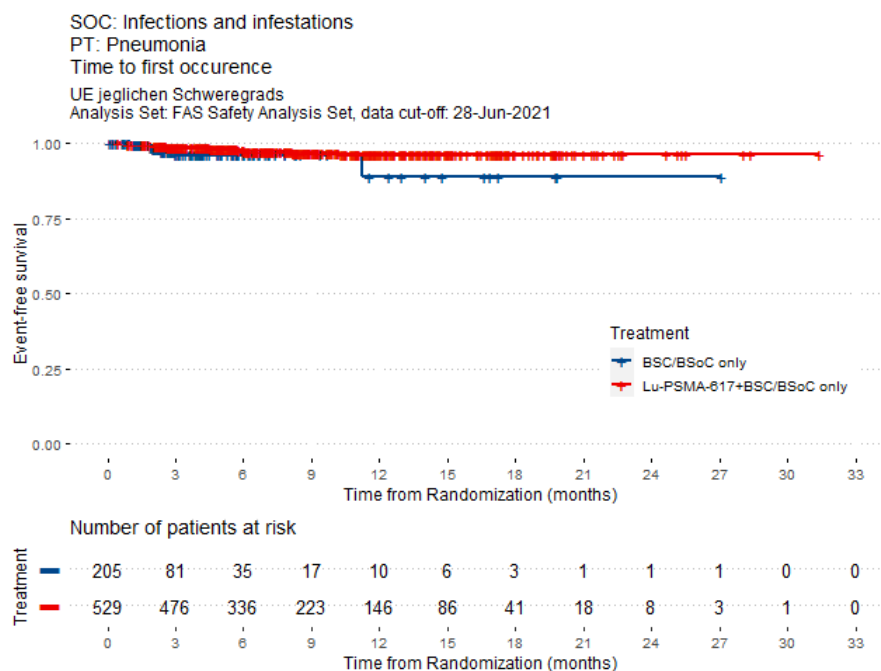


Abbildung 295: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Pneumonia

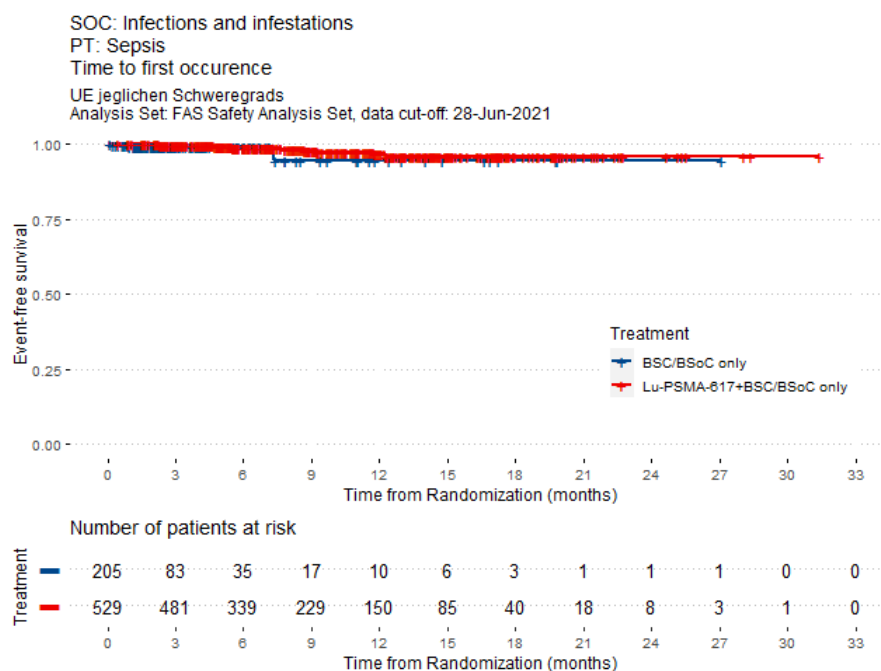


Abbildung 296: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Sepsis

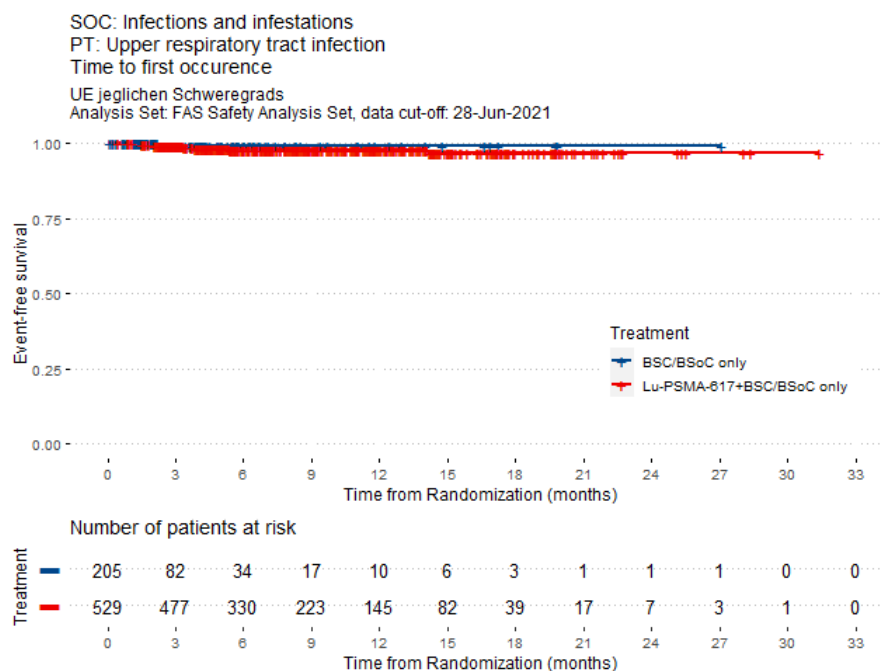


Abbildung 297: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Upper respiratory tract infection

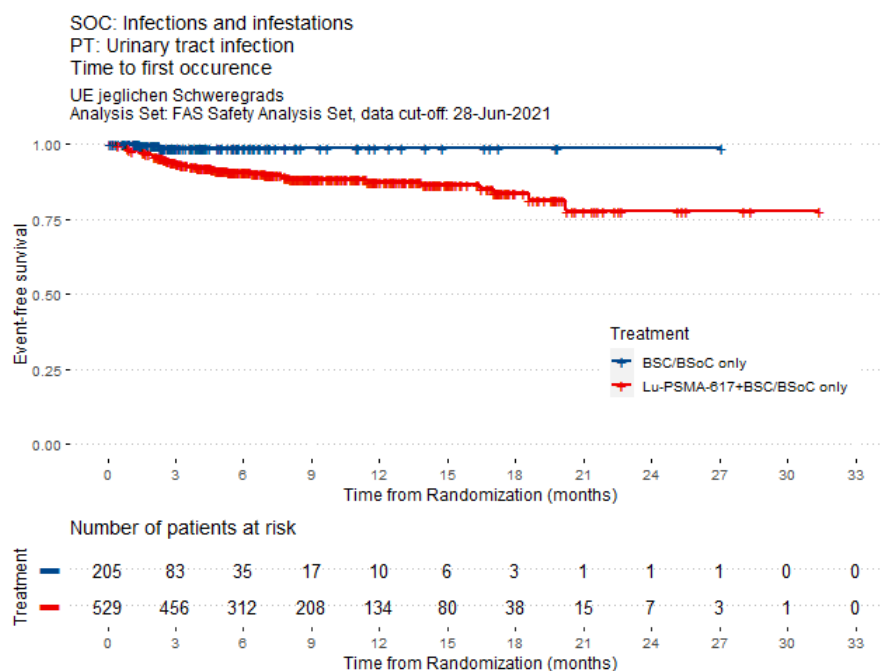


Abbildung 298: UE jeglichen Schweregrads: Time to first occurrence of SOC: Infections and infestations; PT: Urinary tract infection

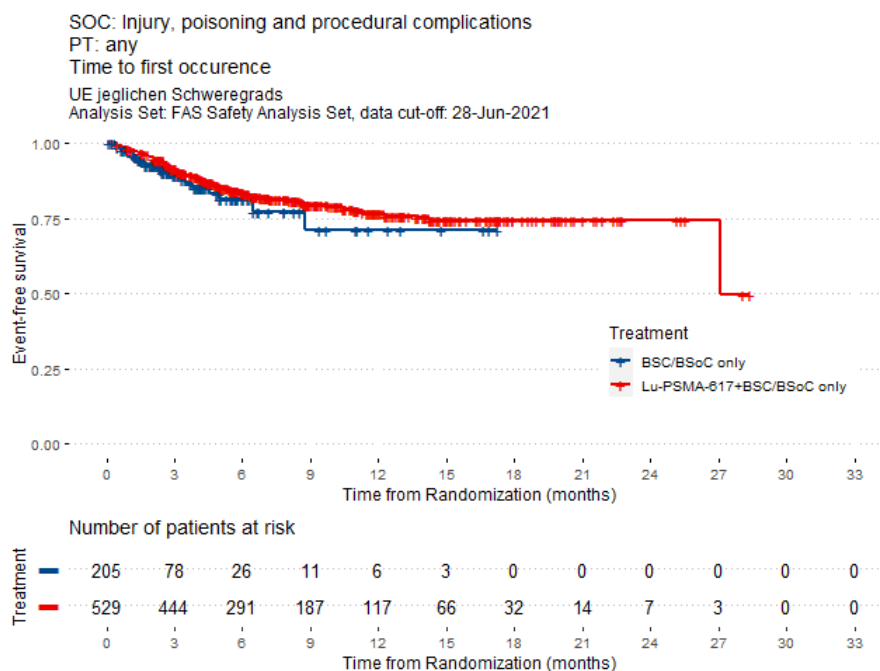


Abbildung 299: UE jeglichen Schweregrads: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: any

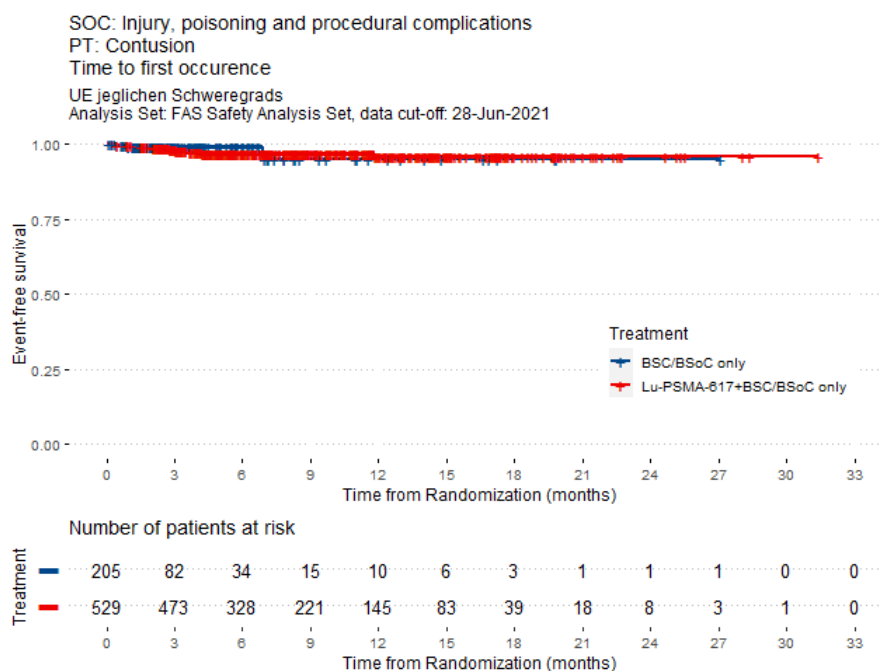


Abbildung 300: UE jeglichen Schweregrads: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: Contusion

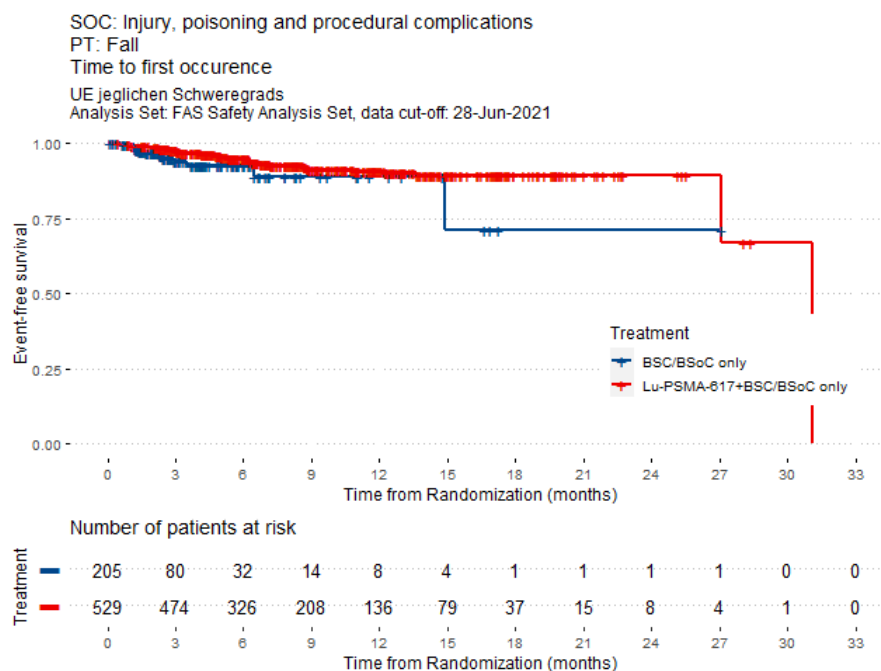


Abbildung 301: UE jeglichen Schweregrads: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: Fall

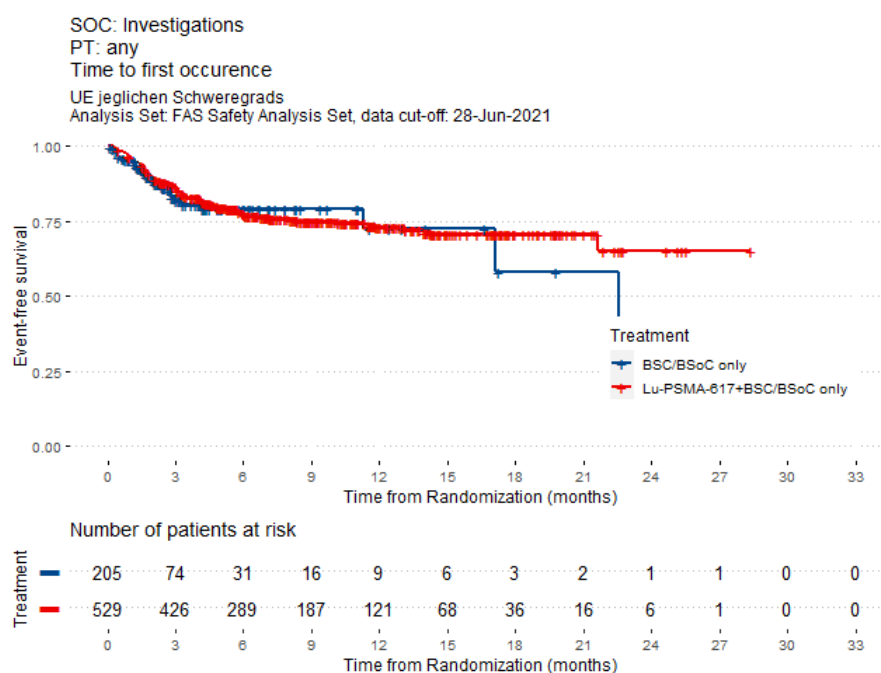


Abbildung 302: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations; PT: any

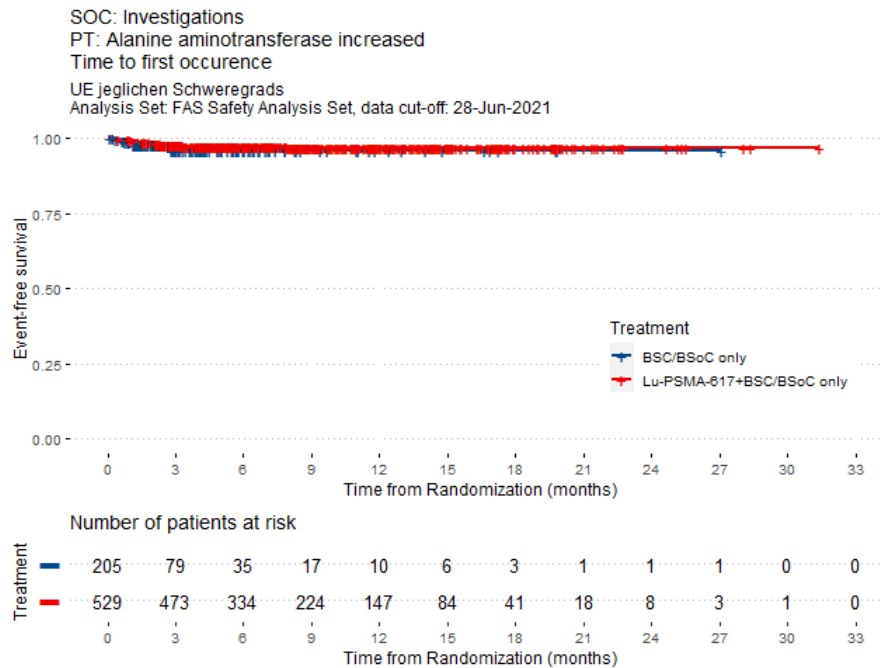


Abbildung 303: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations;
PT: Alanine aminotransferase increased

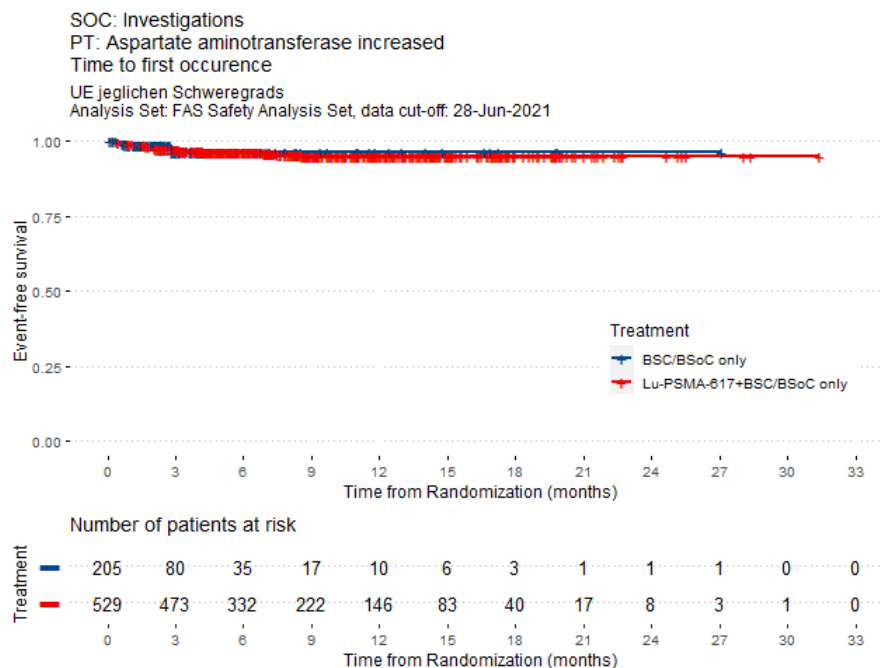


Abbildung 304: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations;
PT: Aspartate aminotransferase increased

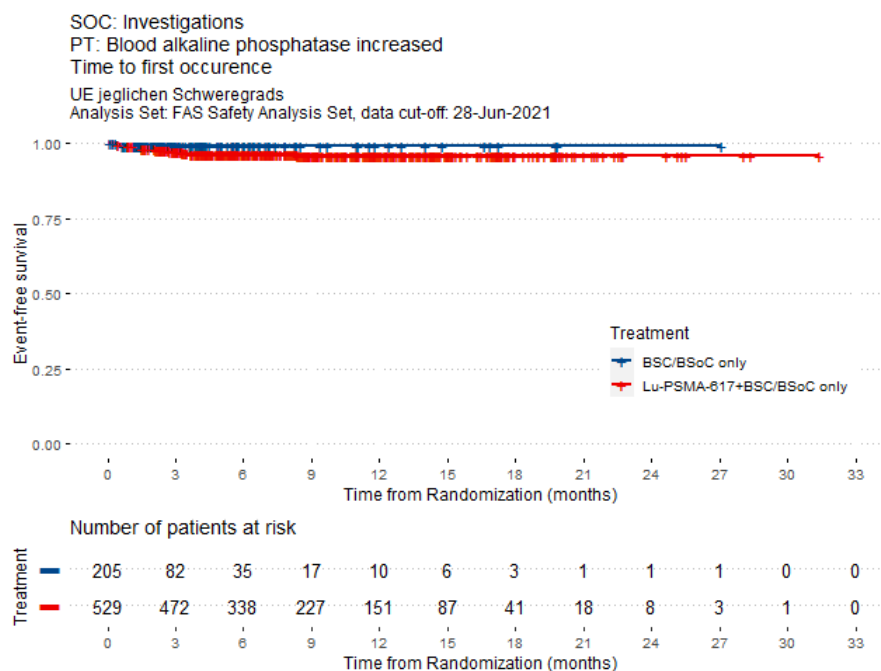


Abbildung 305: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations;
PT: Blood alkaline phosphatase increased

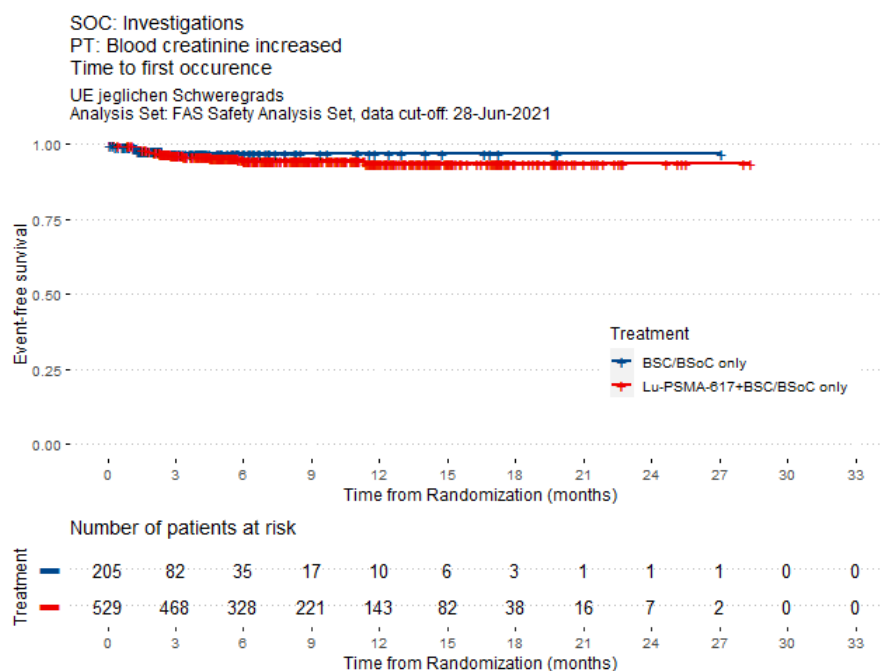


Abbildung 306: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations;
PT: Blood creatinine increased

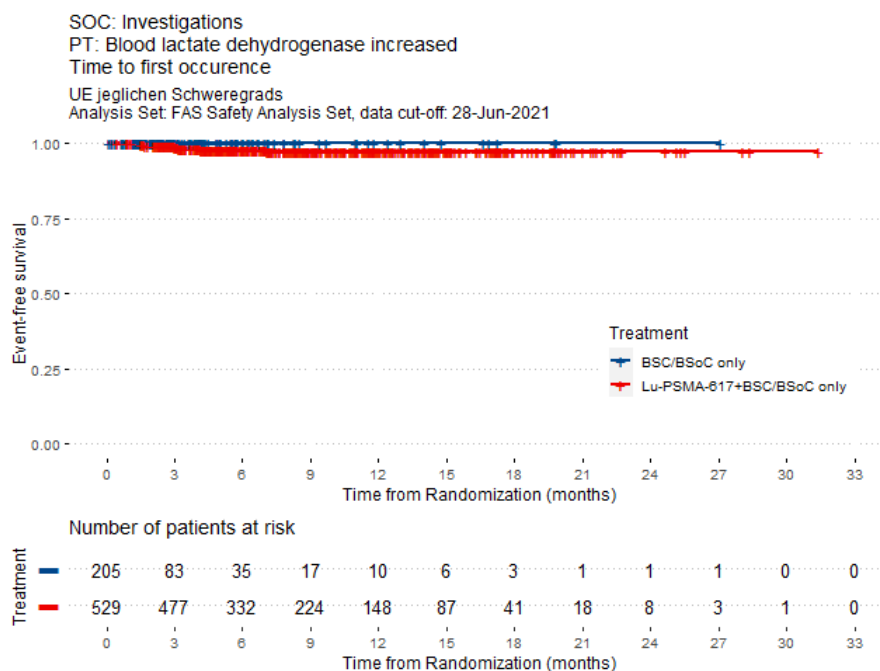


Abbildung 307: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations;
PT: Blood lactate dehydrogenase increased

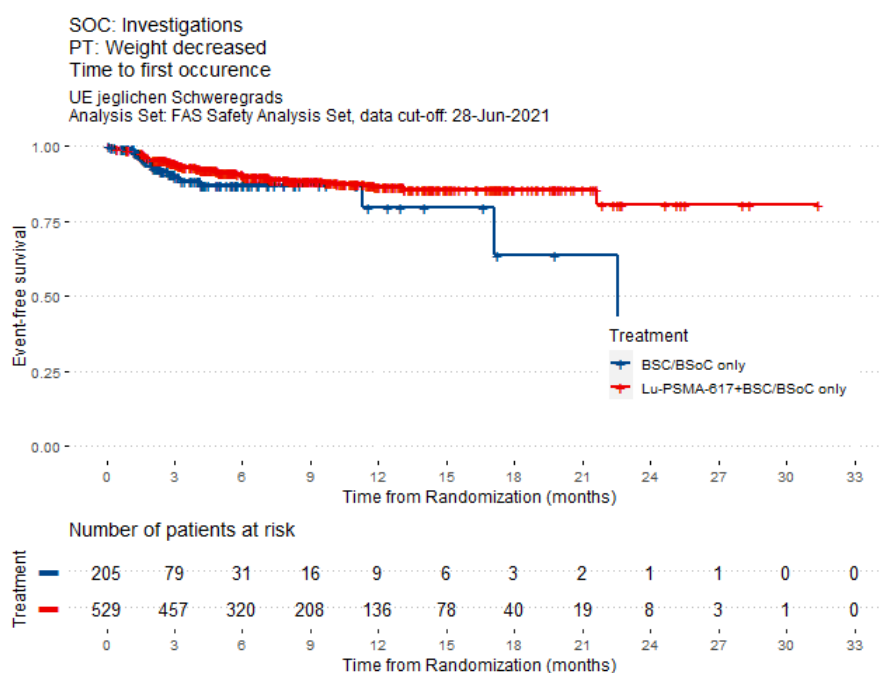


Abbildung 308: UE jeglichen Schweregrads: Time to first occurrence of SOC: Investigations;
PT: Weight decreased

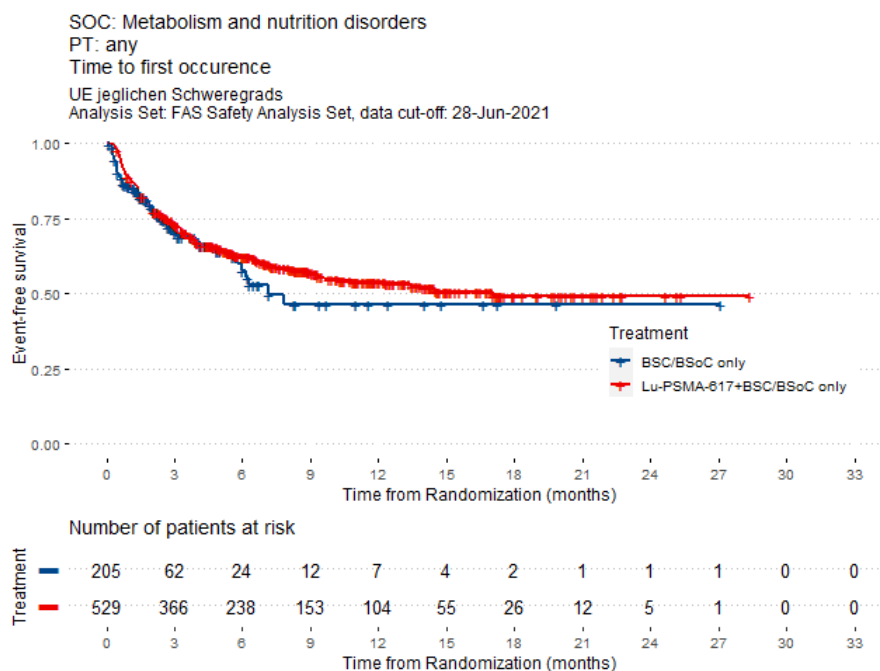


Abbildung 309: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: any

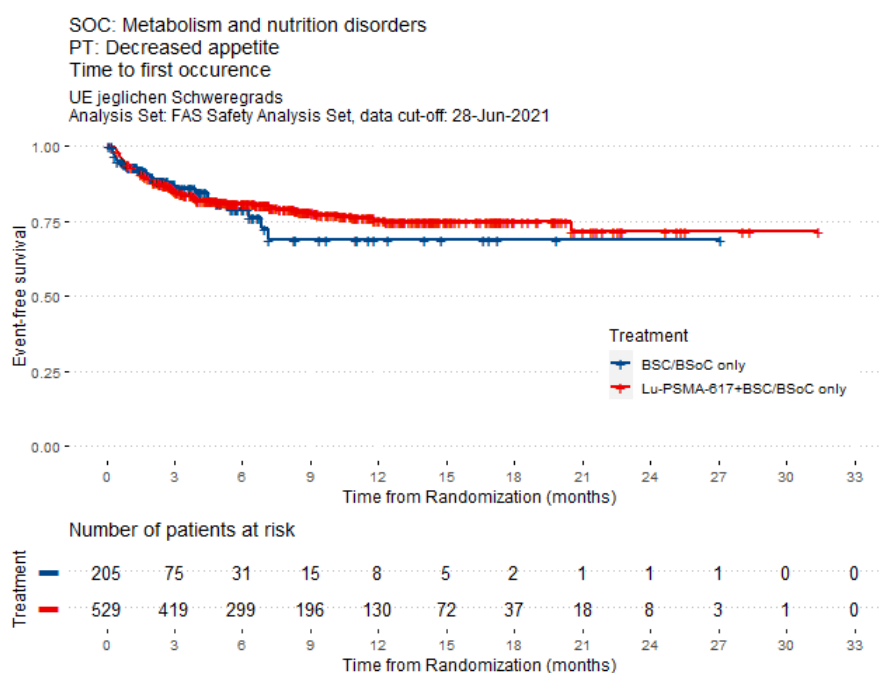


Abbildung 310: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Decreased appetite

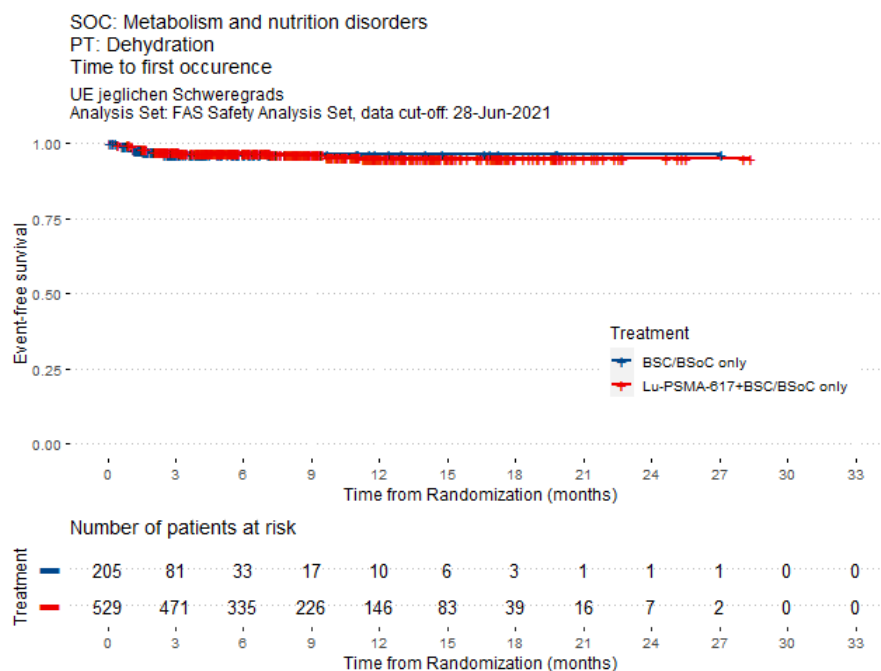


Abbildung 311: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Dehydration

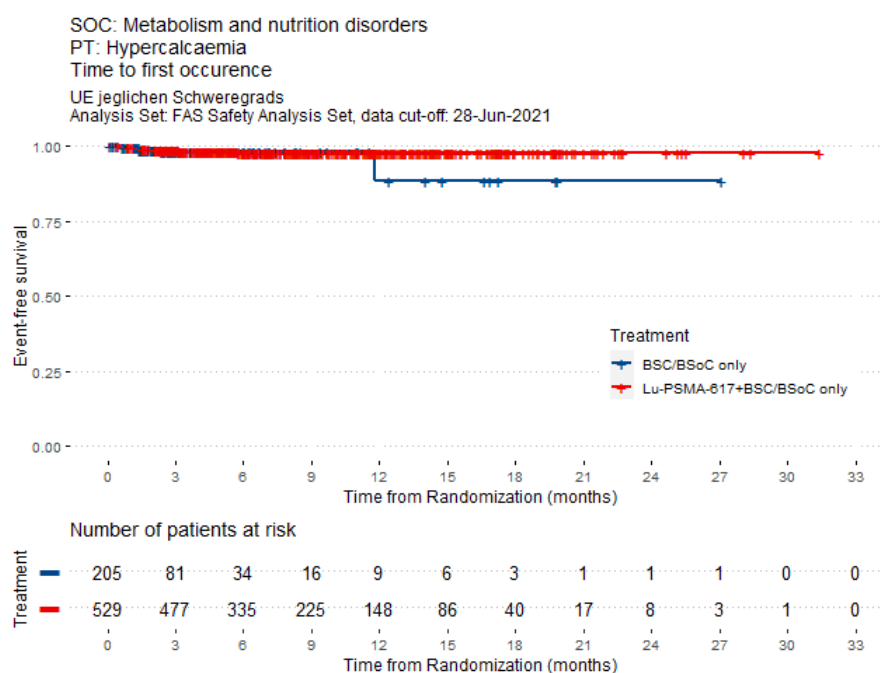


Abbildung 312: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypercalcaemia

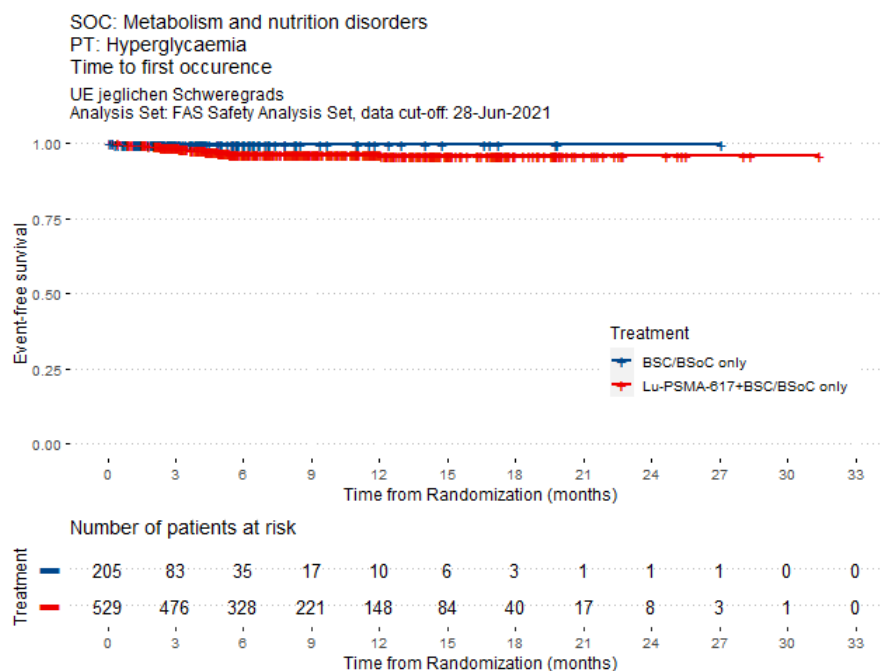


Abbildung 313: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hyperglycaemia

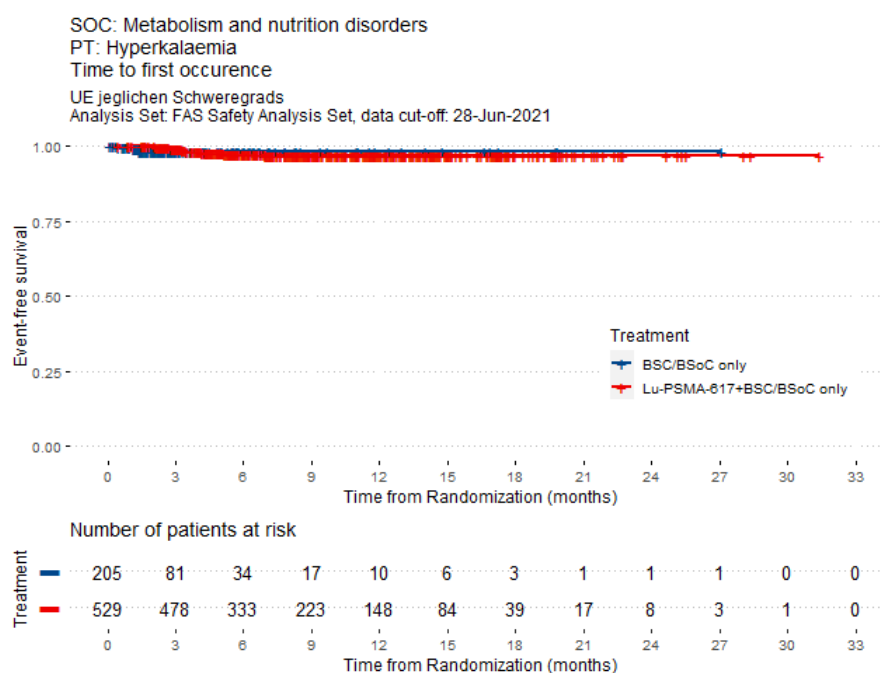


Abbildung 314: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hyperkalaemia

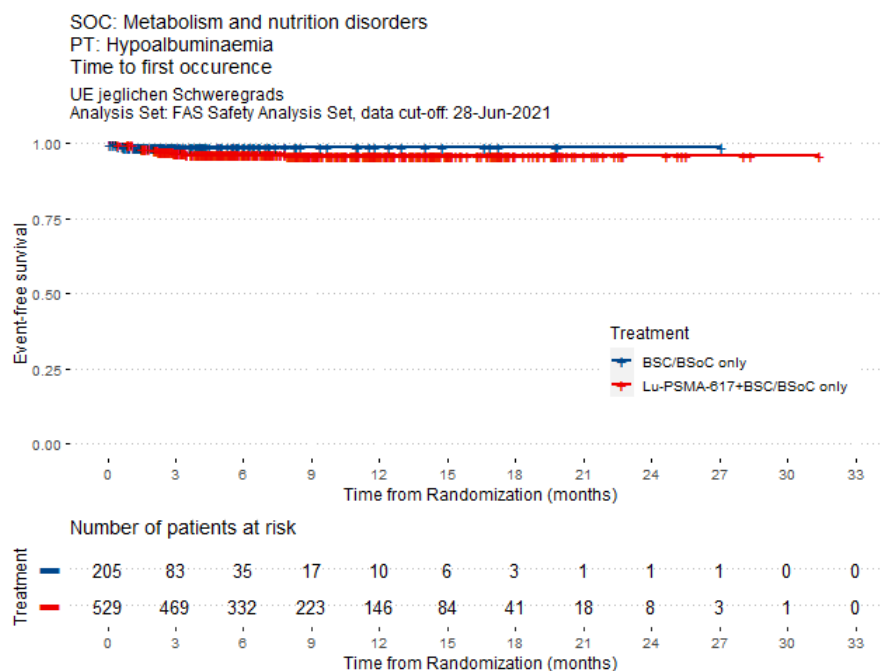


Abbildung 315: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypoalbuminaemia

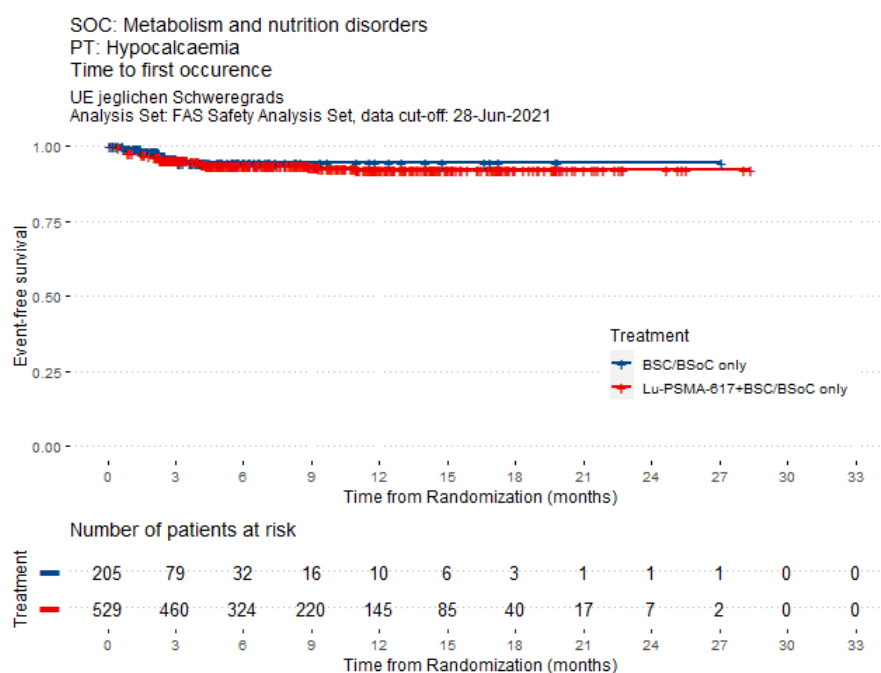


Abbildung 316: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypocalcaemia

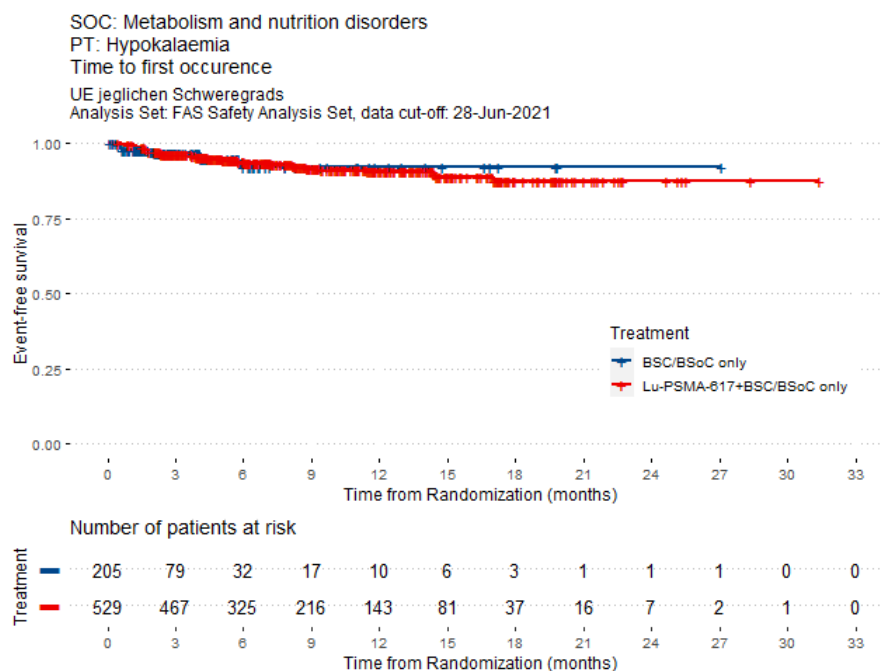


Abbildung 317: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypokalaemia

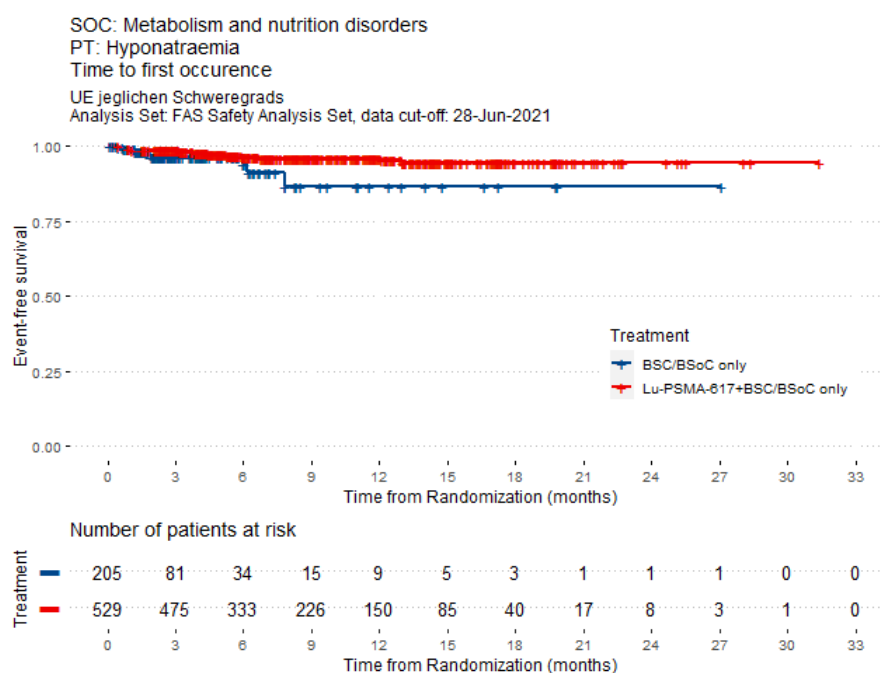


Abbildung 318: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hyponatraemia

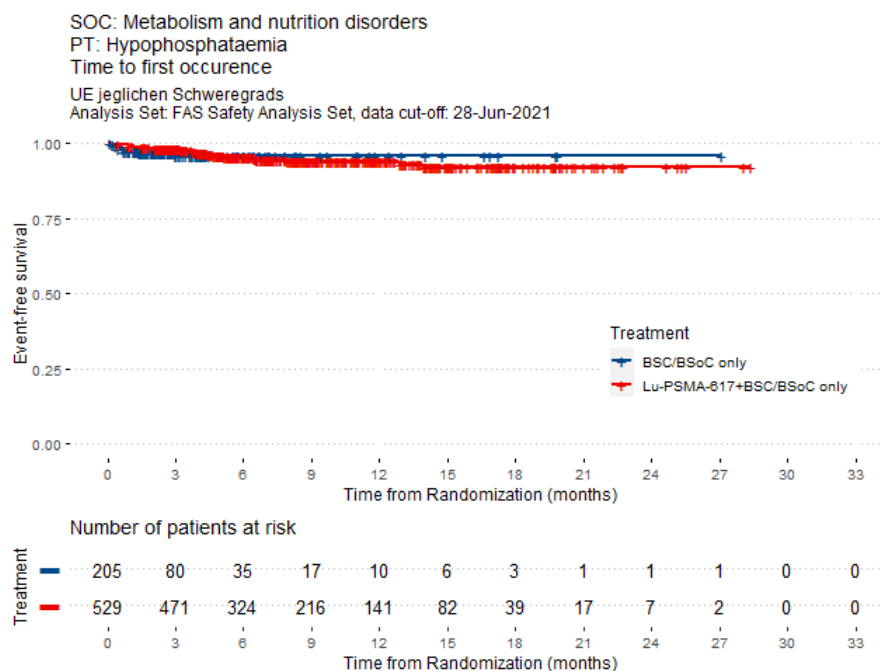


Abbildung 319: UE jeglichen Schweregrads: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Hypophosphataemia

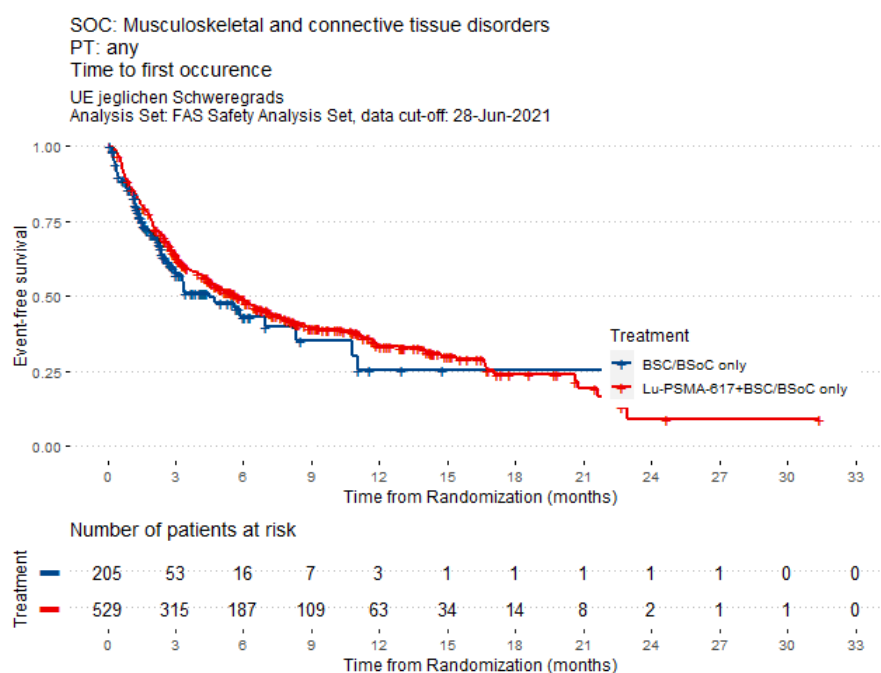


Abbildung 320: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: any

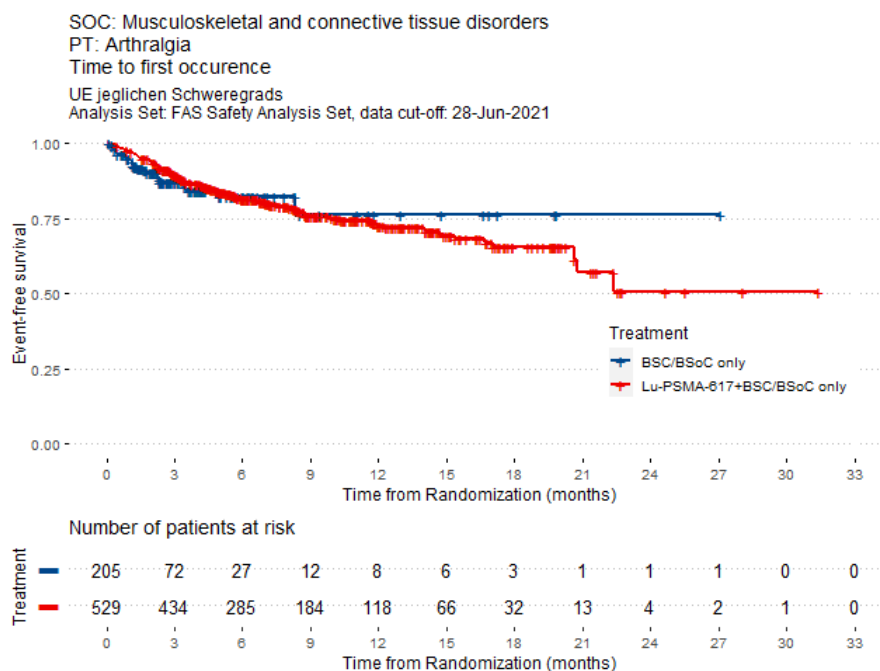


Abbildung 321: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Arthralgia

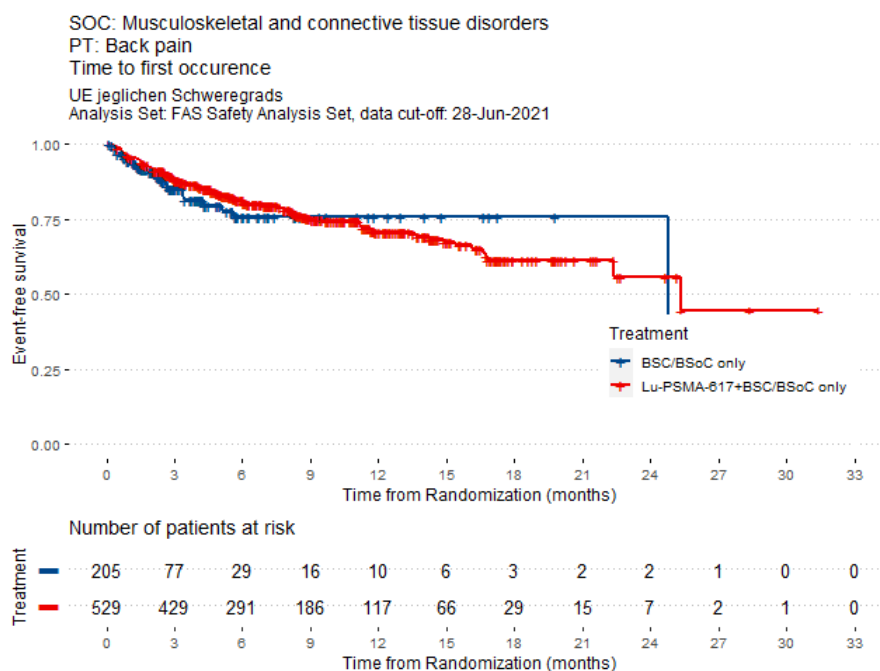


Abbildung 322: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Back pain

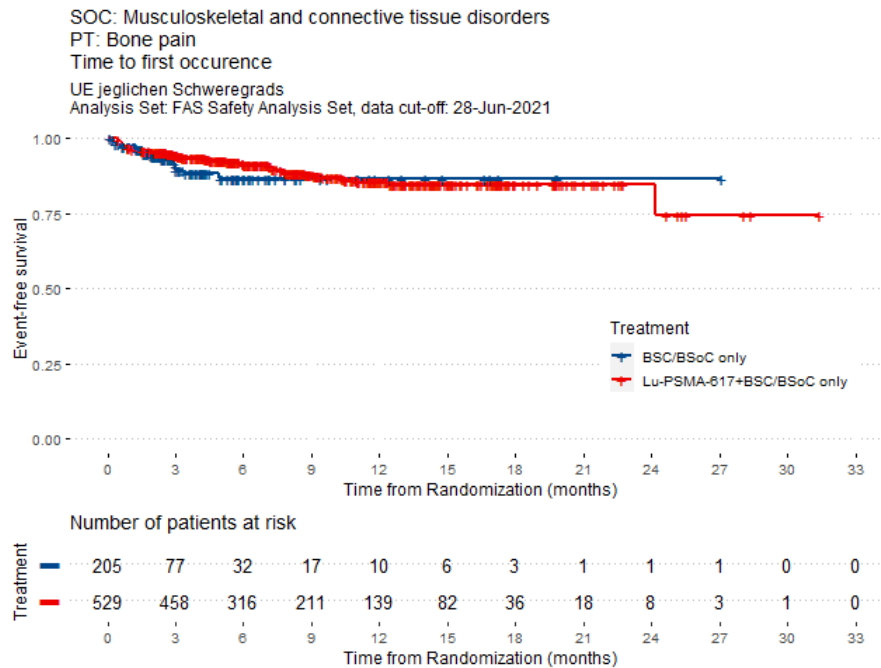


Abbildung 323: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Bone pain

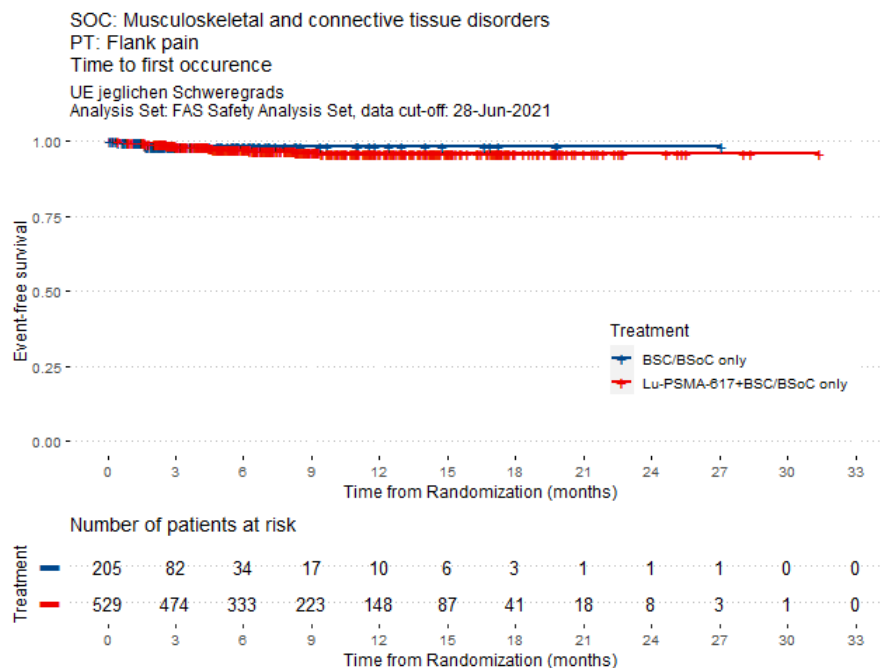


Abbildung 324: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Flank pain

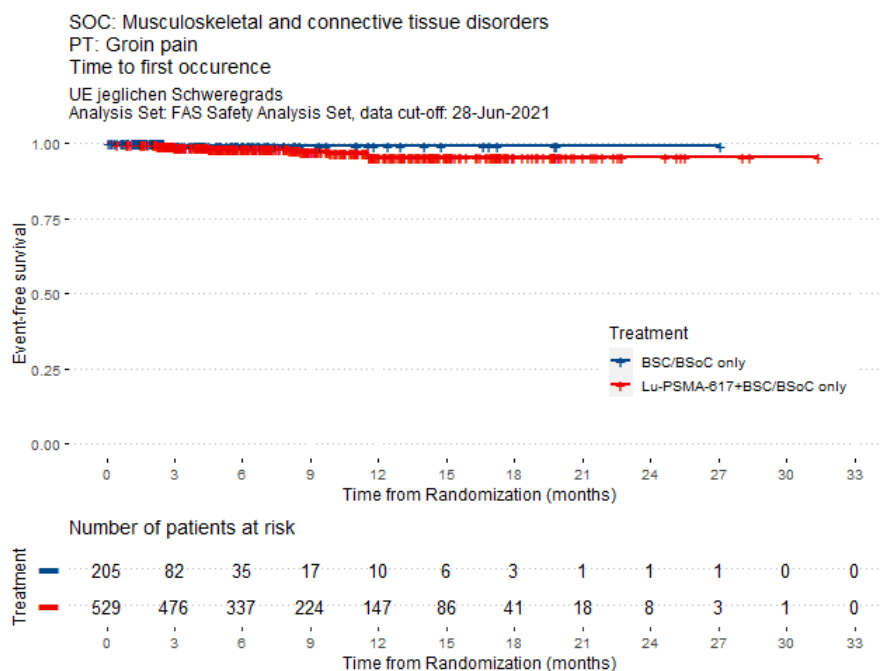


Abbildung 325: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Groin pain

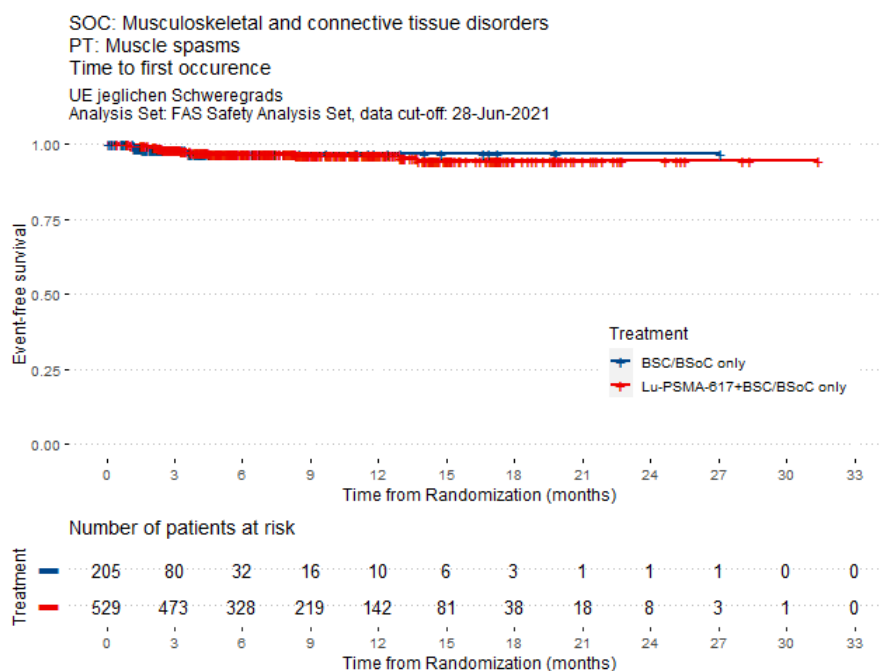


Abbildung 326: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Muscle spasms

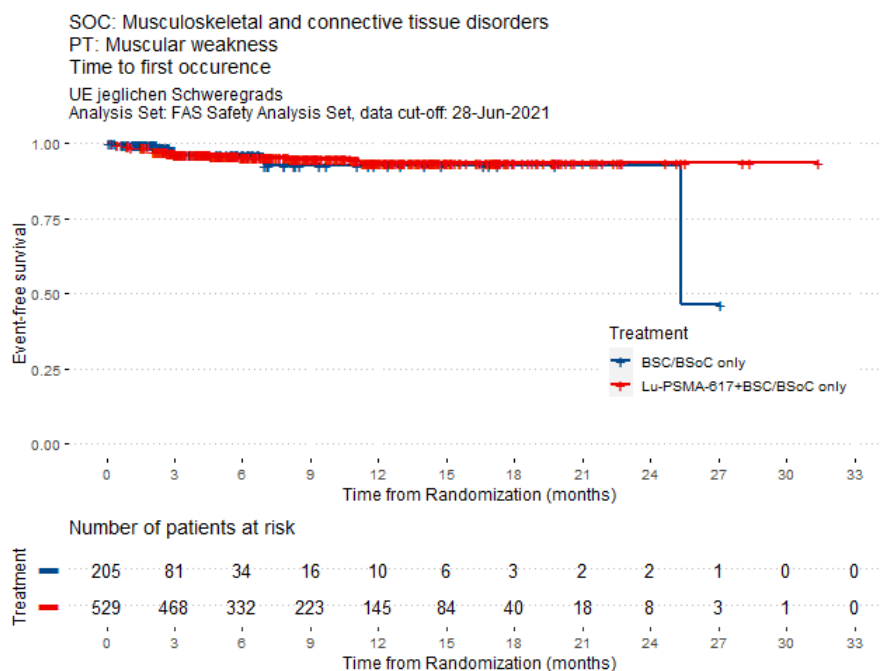


Abbildung 327: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Muscular weakness

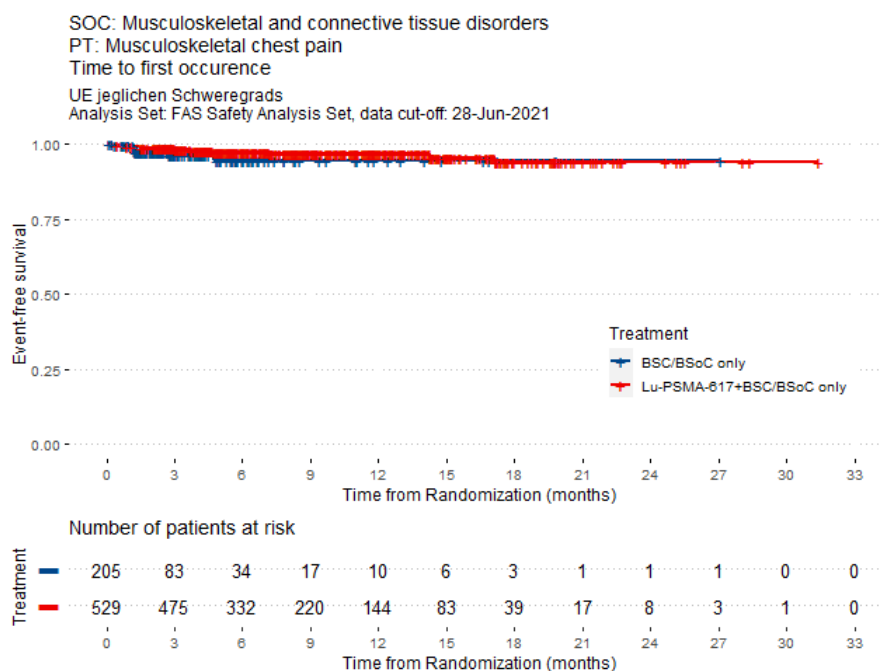


Abbildung 328: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Musculoskeletal chest pain

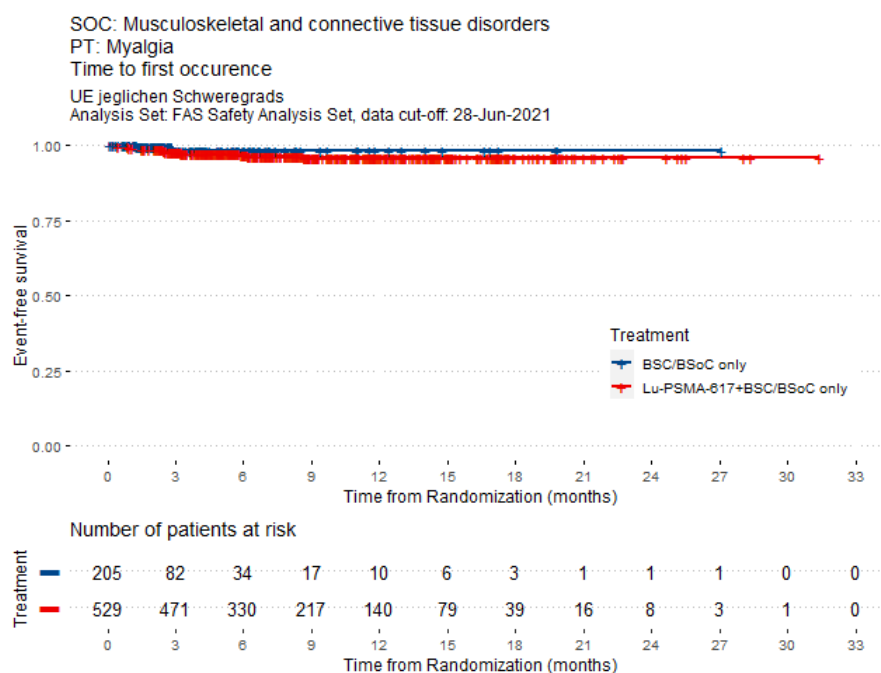


Abbildung 329: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Myalgia

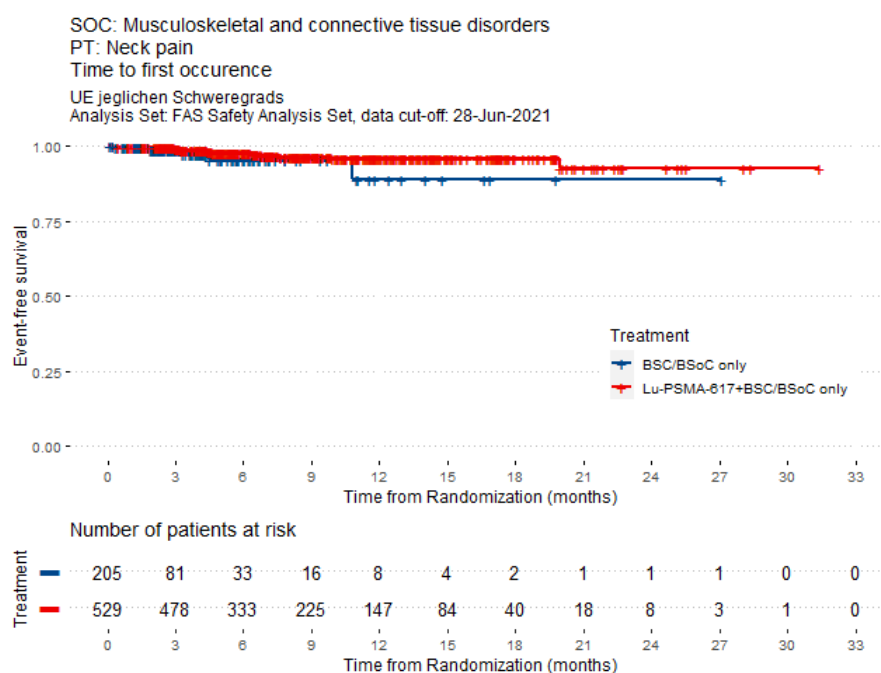


Abbildung 330: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Neck pain

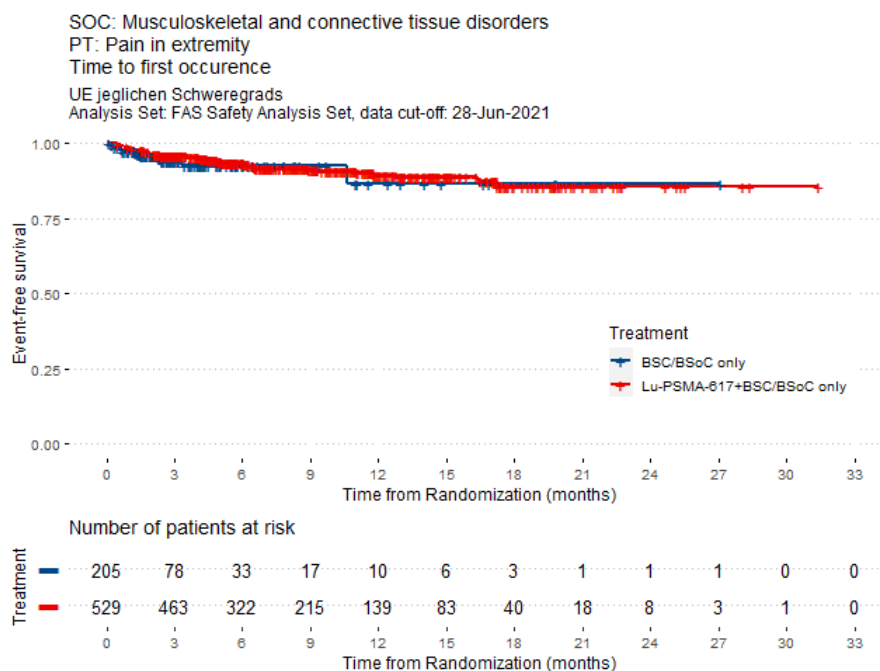


Abbildung 331: UE jeglichen Schweregrads: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Pain in extremity

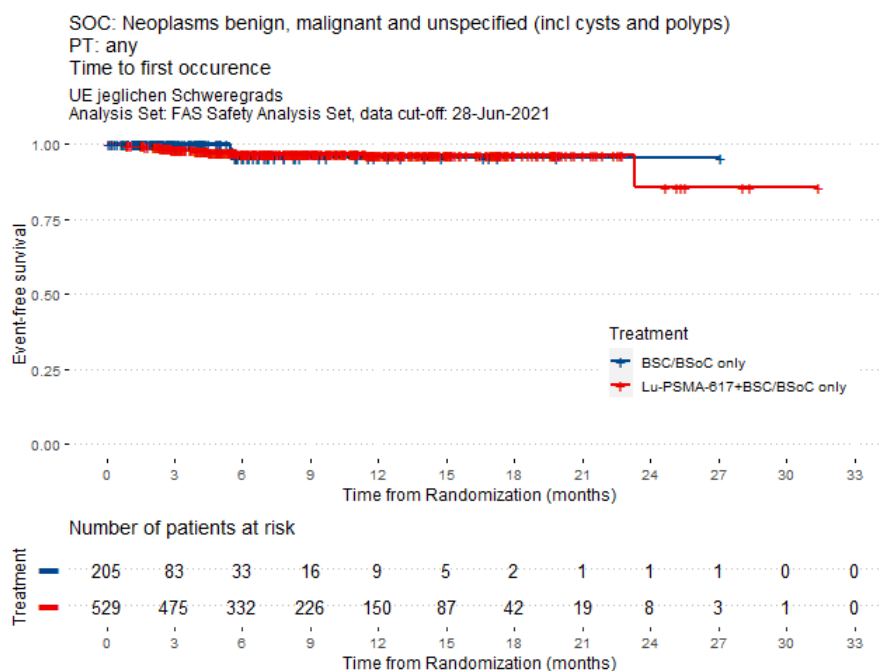


Abbildung 332: UE jeglichen Schweregrads: Time to first occurrence of SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps); PT: any

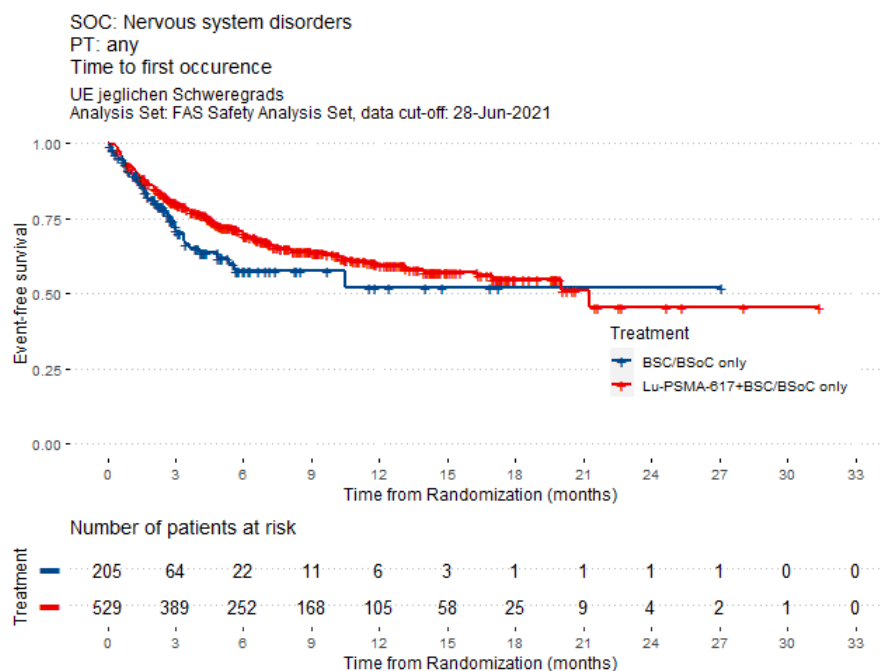


Abbildung 333: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: any

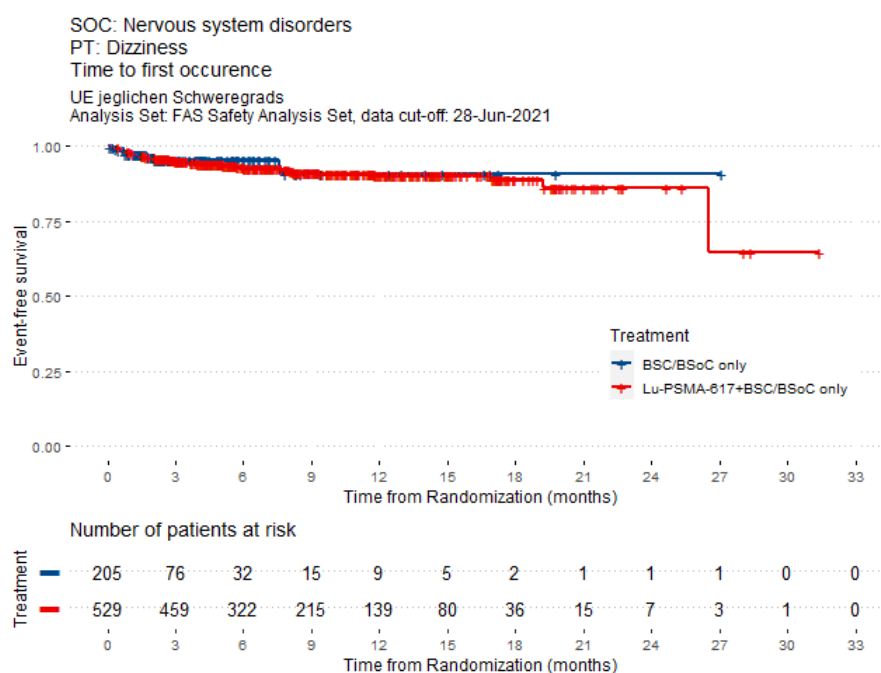


Abbildung 334: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Dizziness

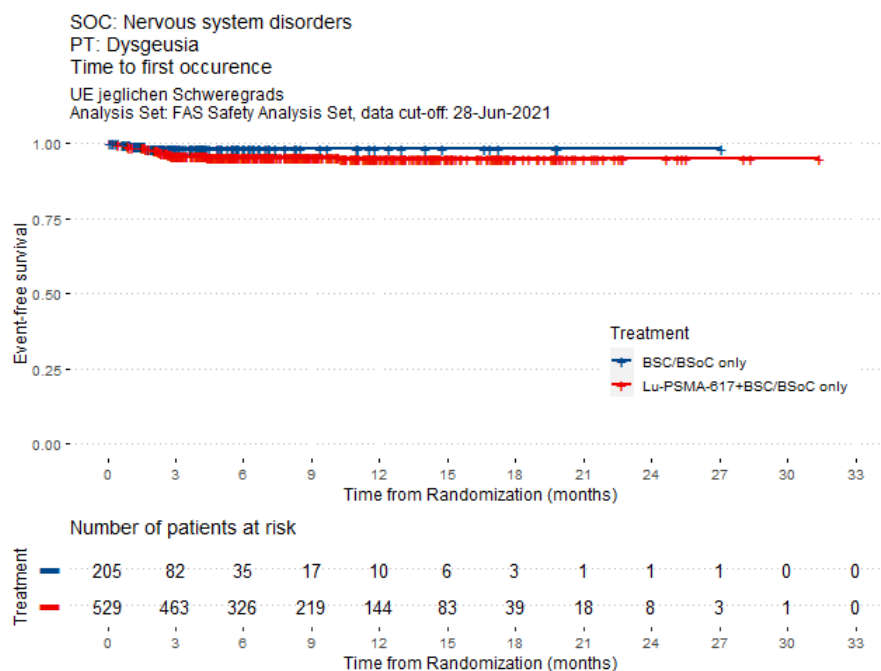


Abbildung 335: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Dysgeusia

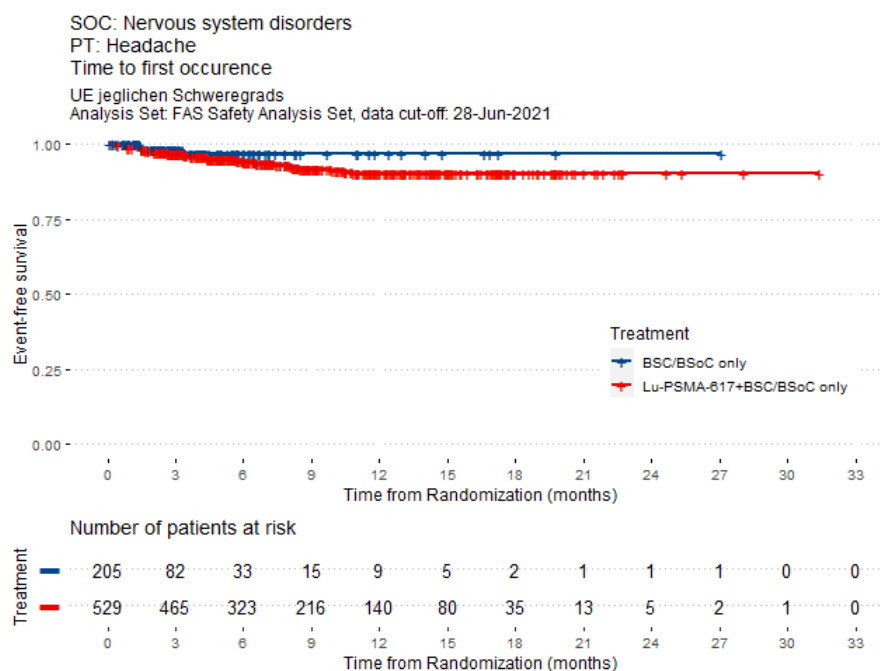


Abbildung 336: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Headache

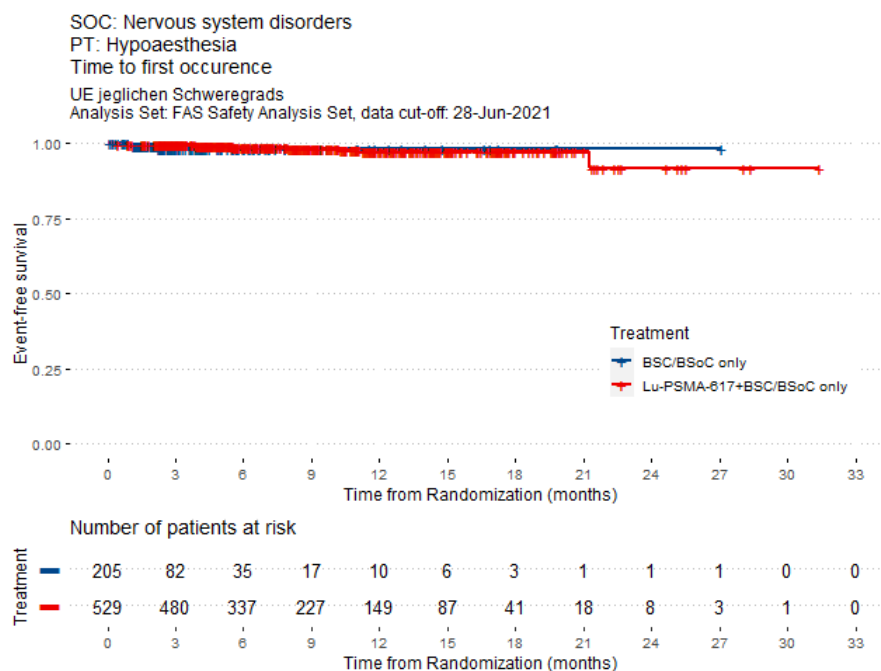


Abbildung 337: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Hypoaesthesia

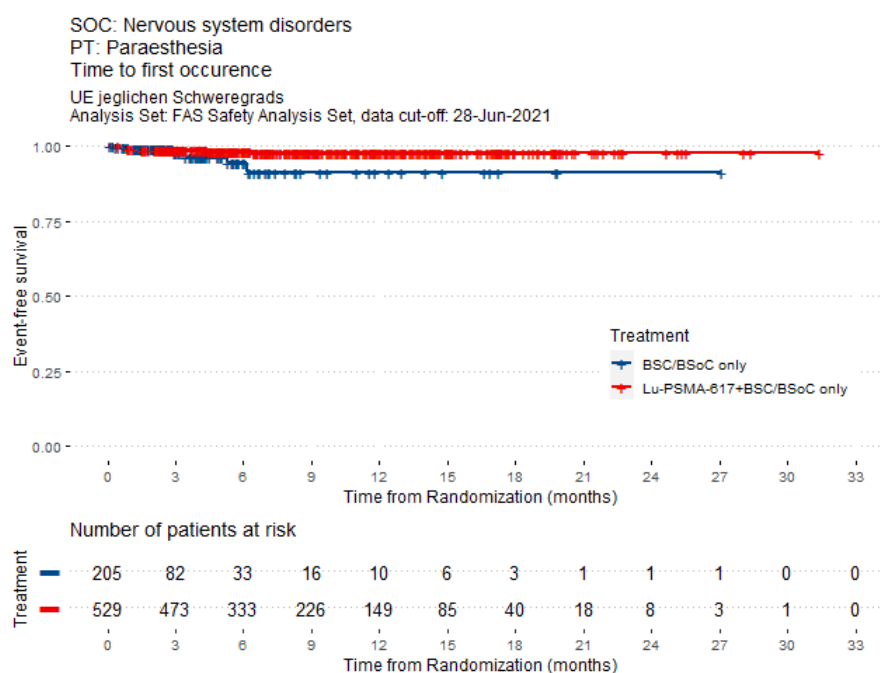


Abbildung 338: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Paraesthesia

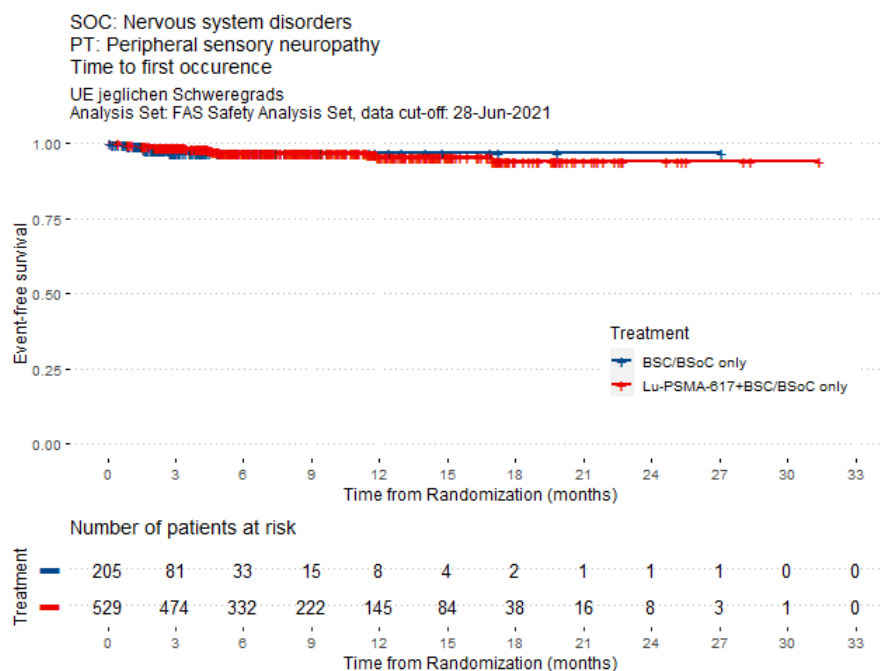


Abbildung 339: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Peripheral sensory neuropathy

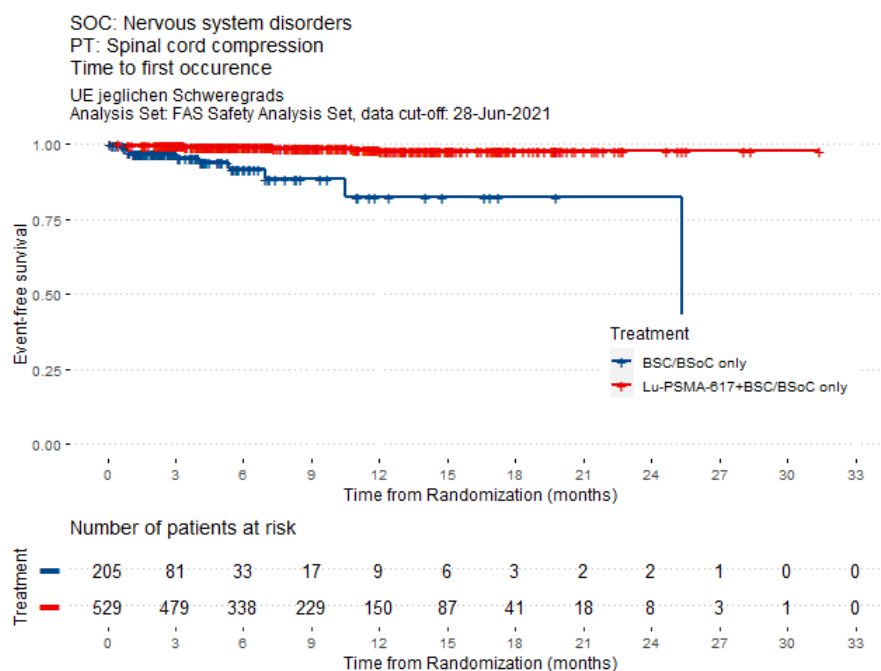


Abbildung 340: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Spinal cord compression

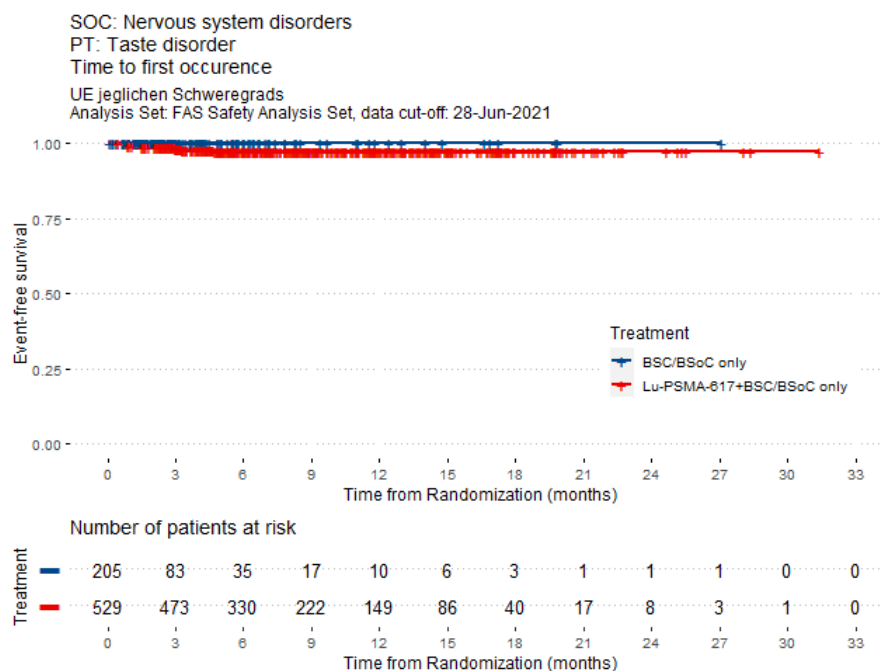


Abbildung 341: UE jeglichen Schweregrads: Time to first occurrence of SOC: Nervous system disorders; PT: Taste disorder

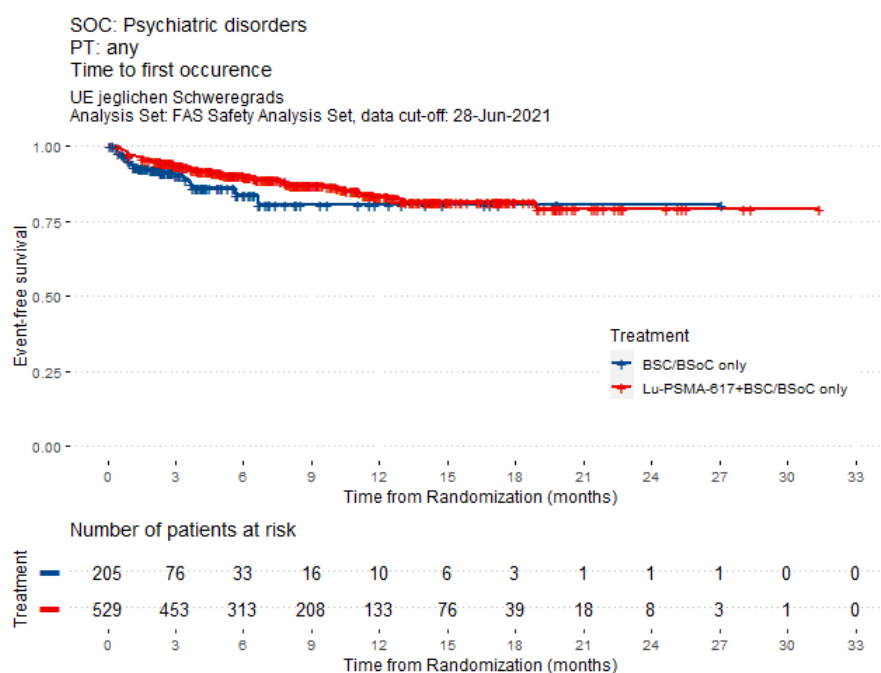


Abbildung 342: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: any

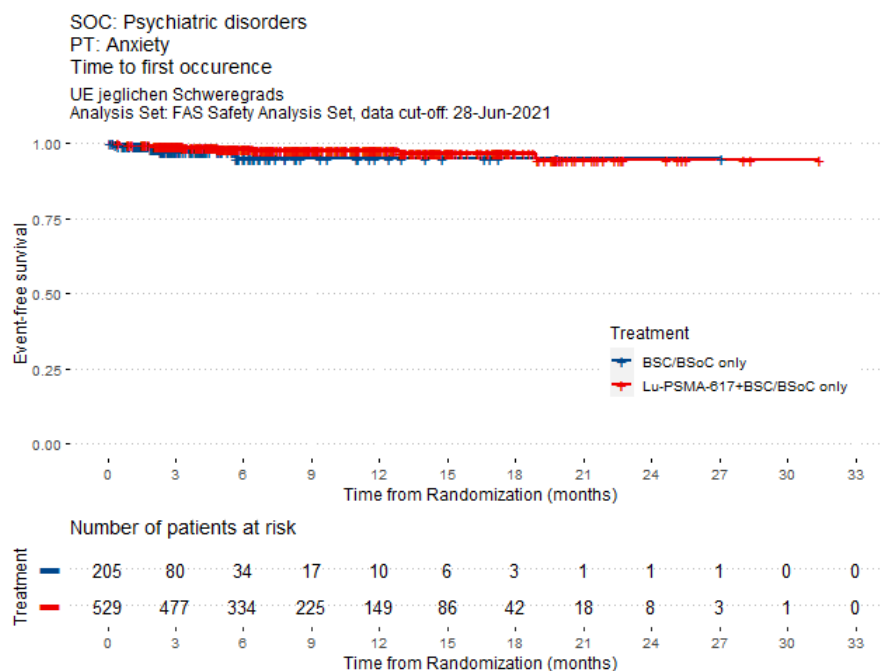


Abbildung 343: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Anxiety

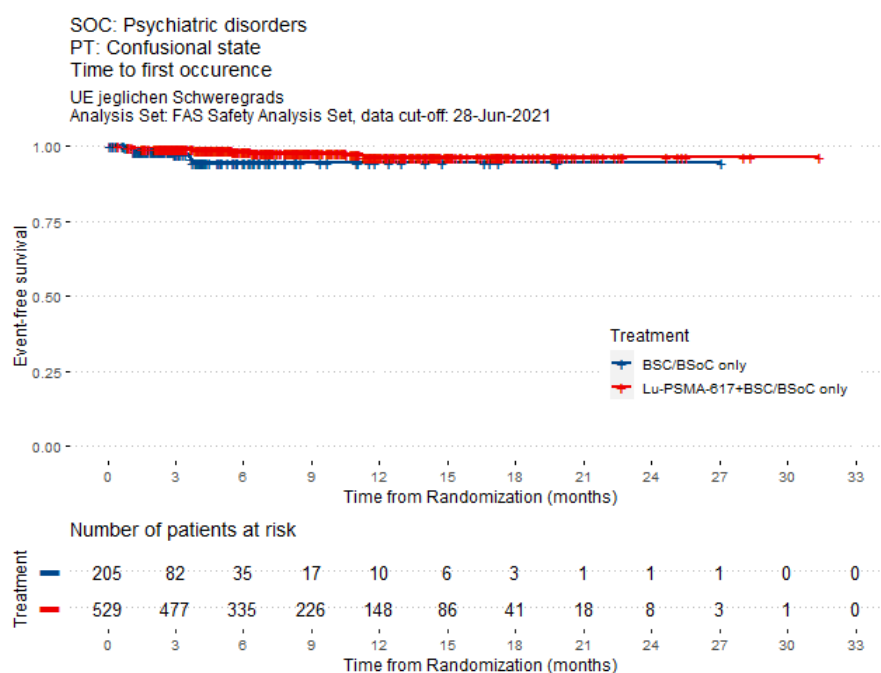


Abbildung 344: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Confusional state

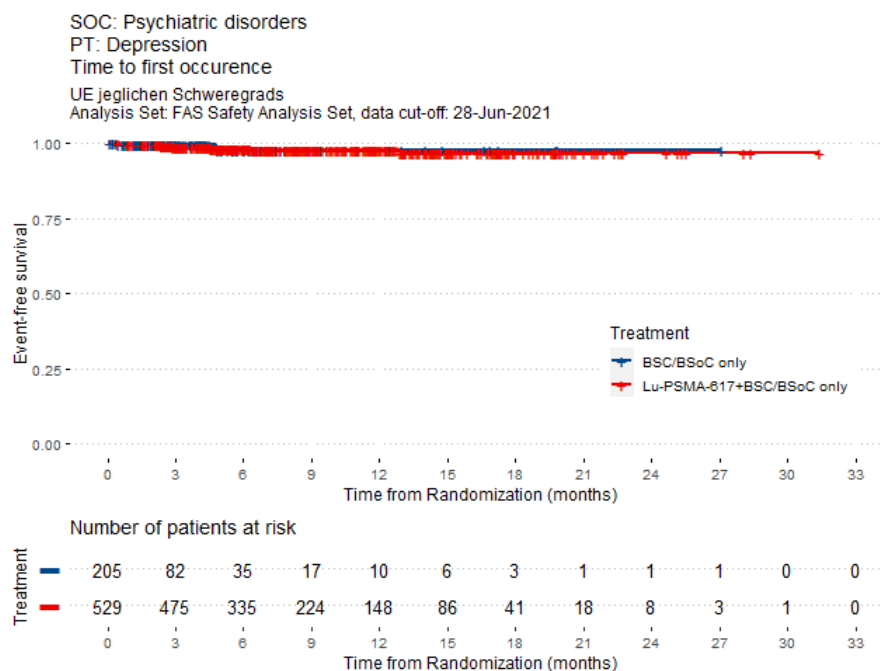


Abbildung 345: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Depression

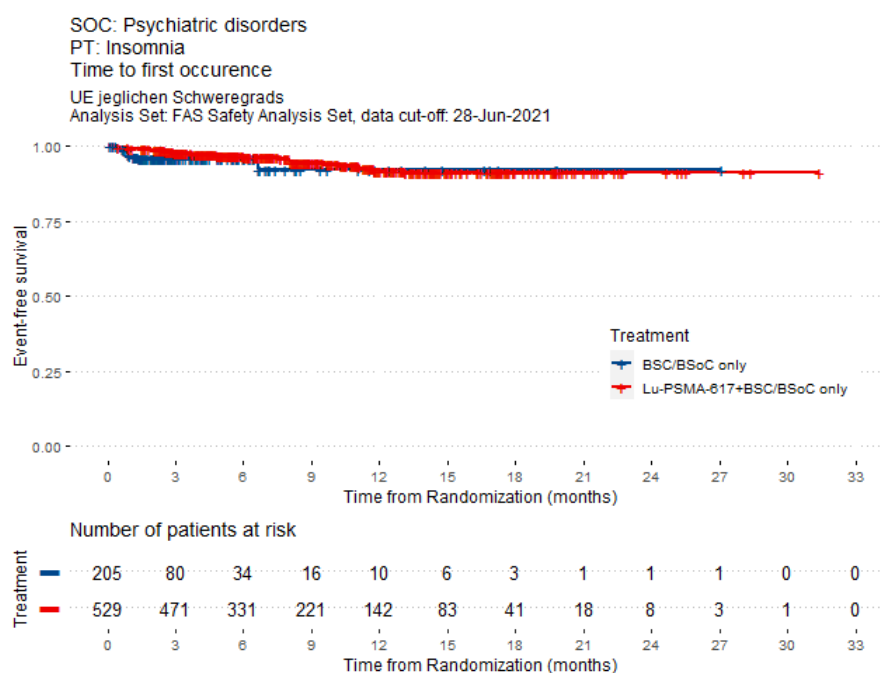


Abbildung 346: UE jeglichen Schweregrads: Time to first occurrence of SOC: Psychiatric disorders; PT: Insomnia

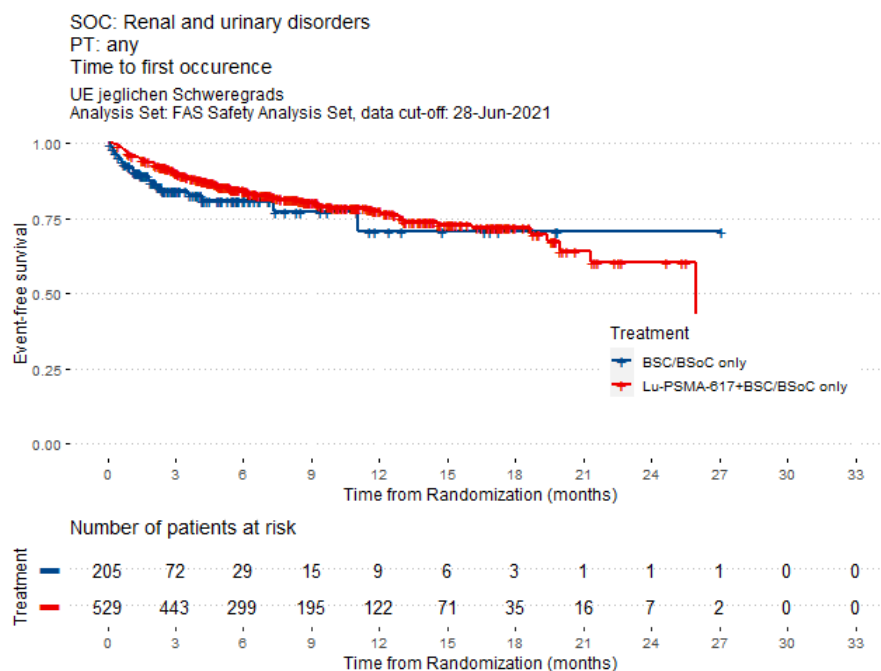


Abbildung 347: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: any

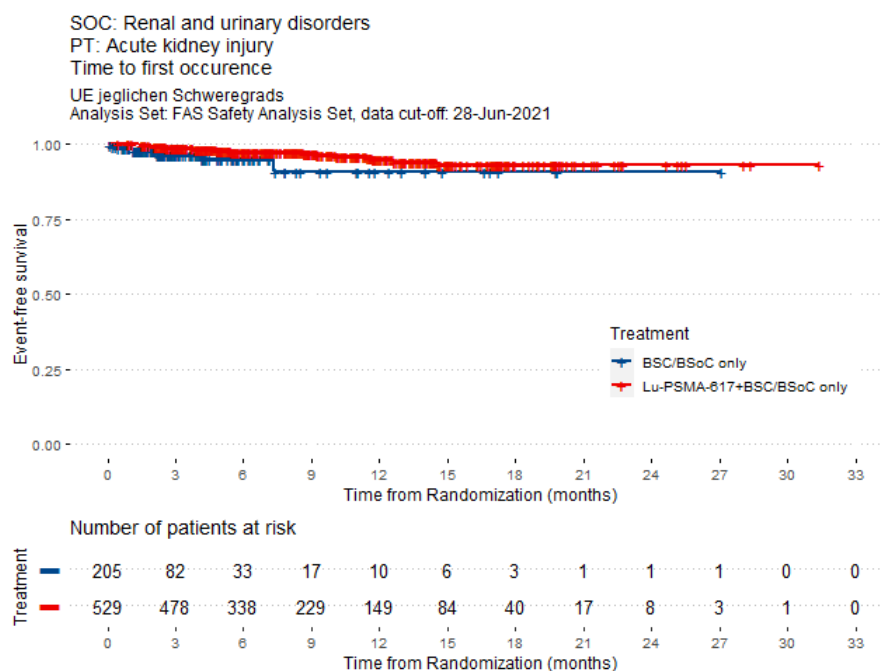


Abbildung 348: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Acute kidney injury

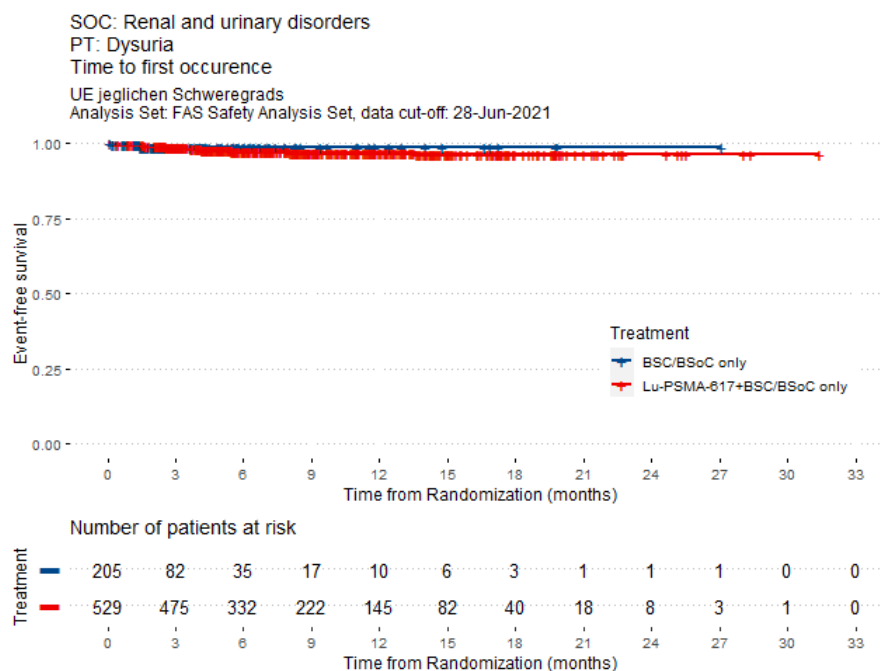


Abbildung 349: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Dysuria

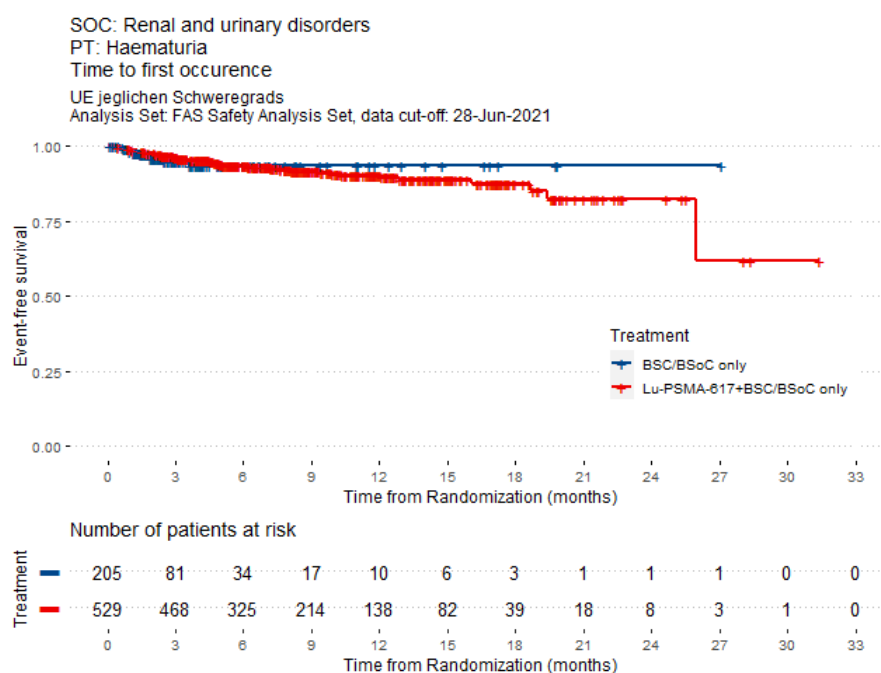


Abbildung 350: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Haematuria

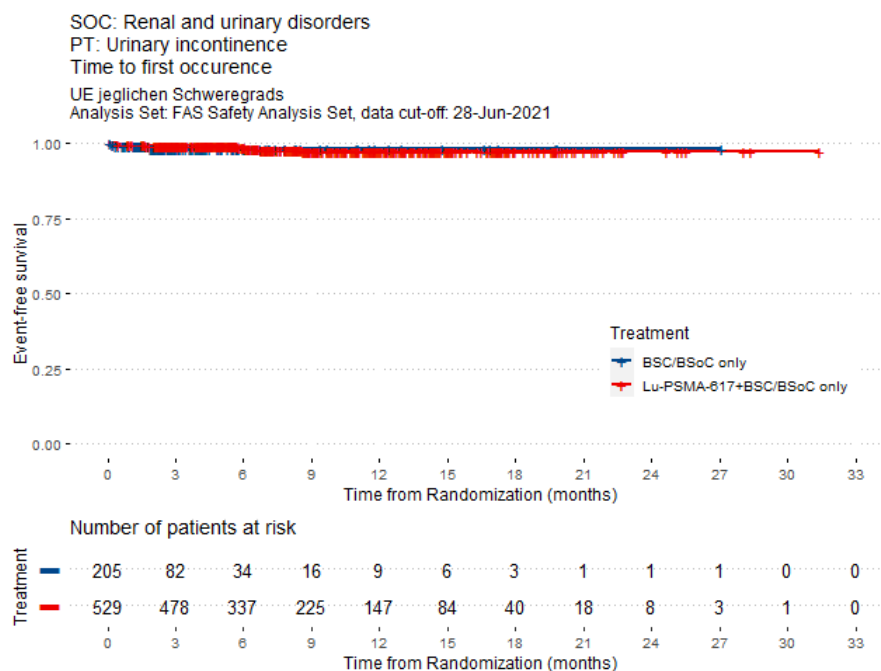


Abbildung 351: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Urinary incontinence

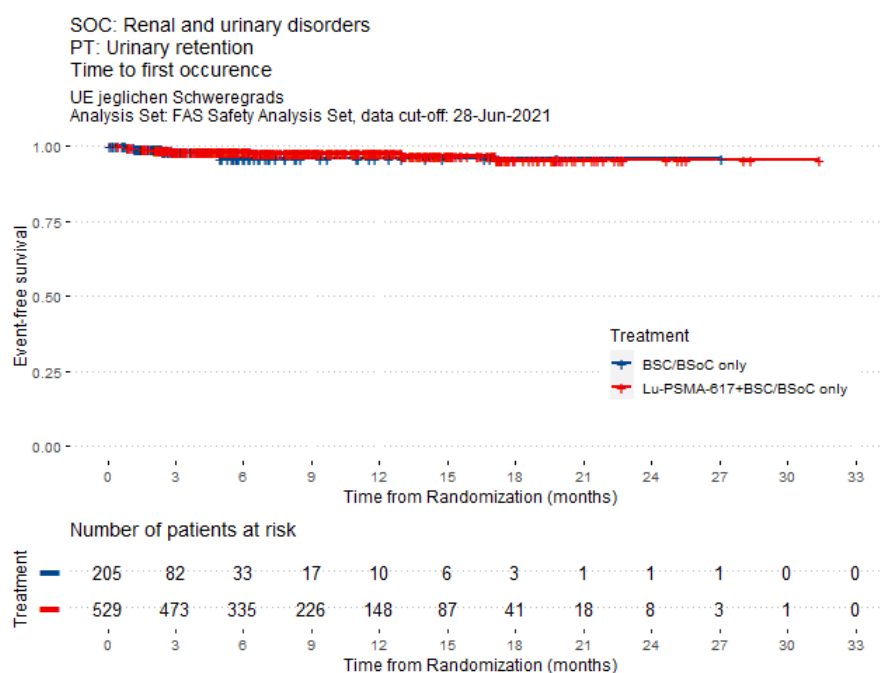


Abbildung 352: UE jeglichen Schweregrads: Time to first occurrence of SOC: Renal and urinary disorders; PT: Urinary retention

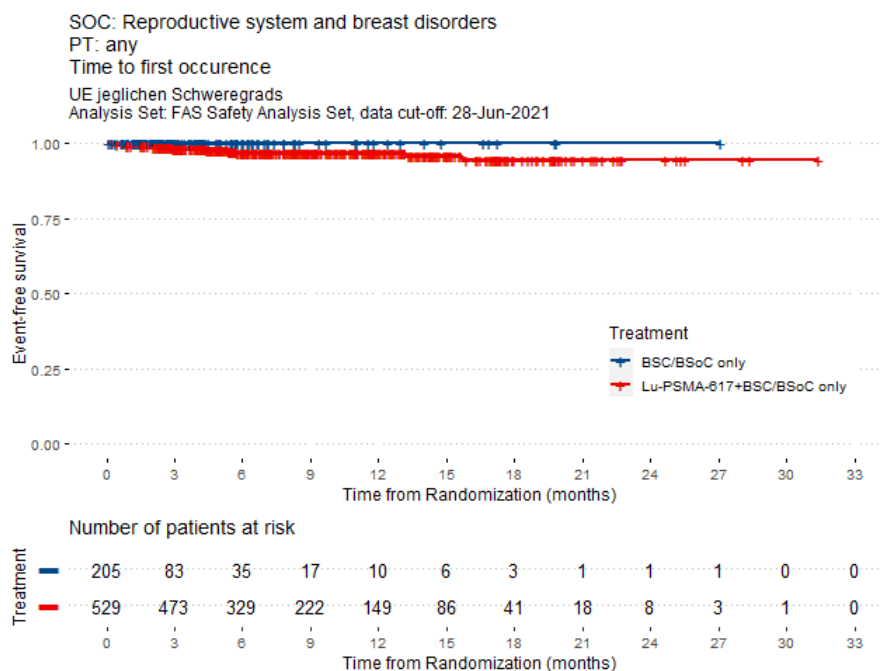


Abbildung 353: UE jeglichen Schweregrads: Time to first occurrence of SOC: Reproductive system and breast disorders; PT: any

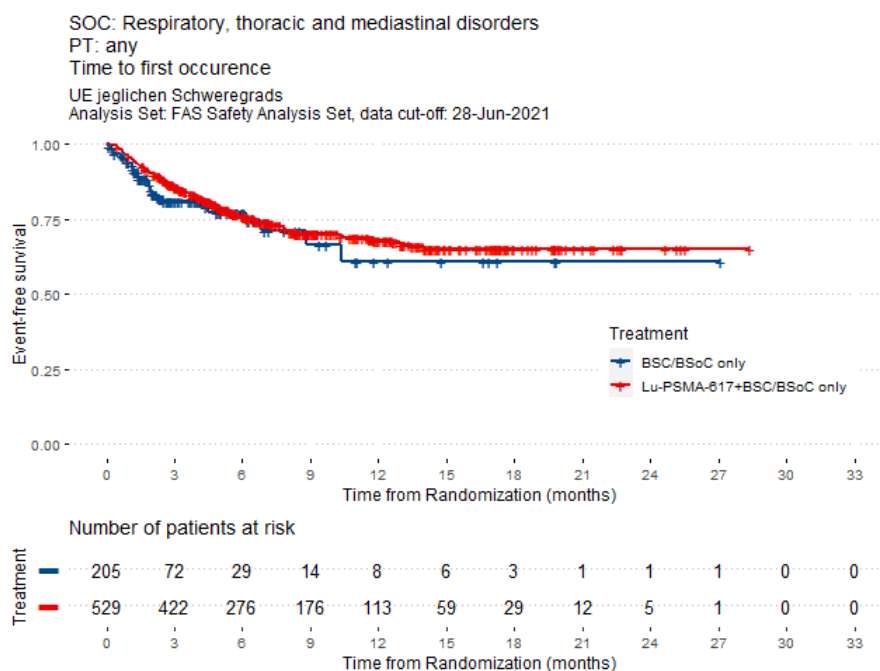


Abbildung 354: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: any

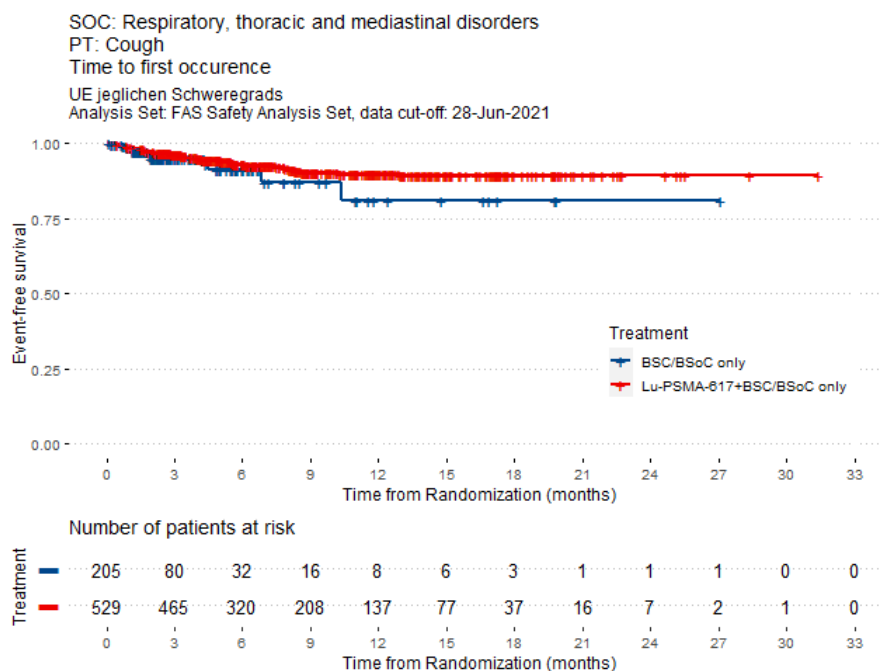


Abbildung 355: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: Cough

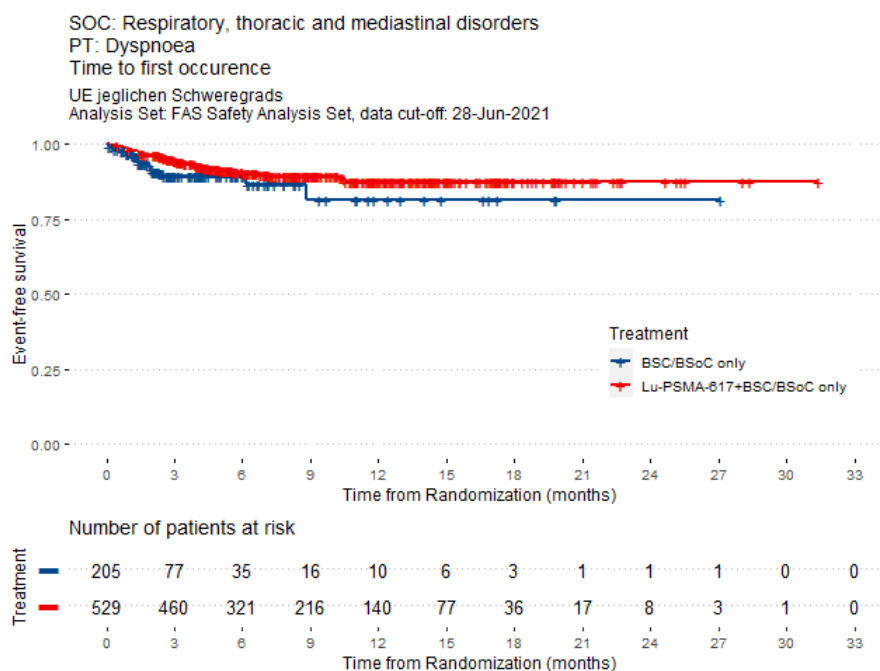


Abbildung 356: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea

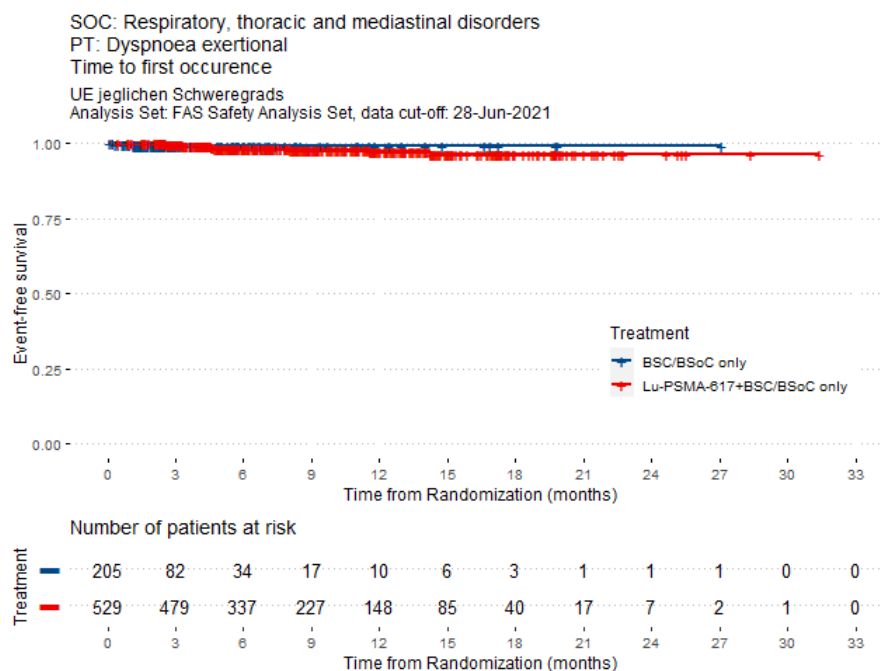


Abbildung 357: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: Dyspnoea exertional

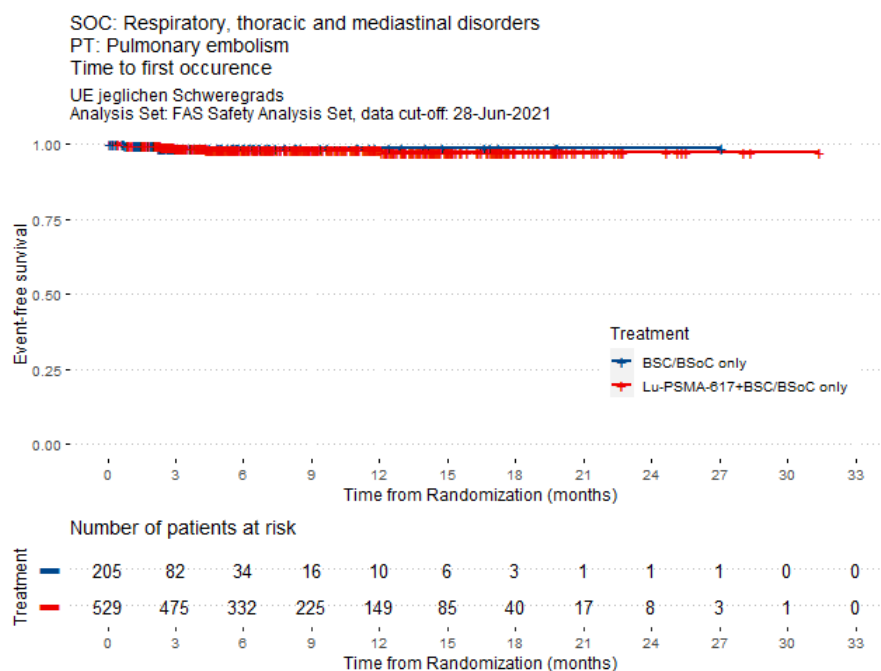


Abbildung 358: UE jeglichen Schweregrads: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: Pulmonary embolism

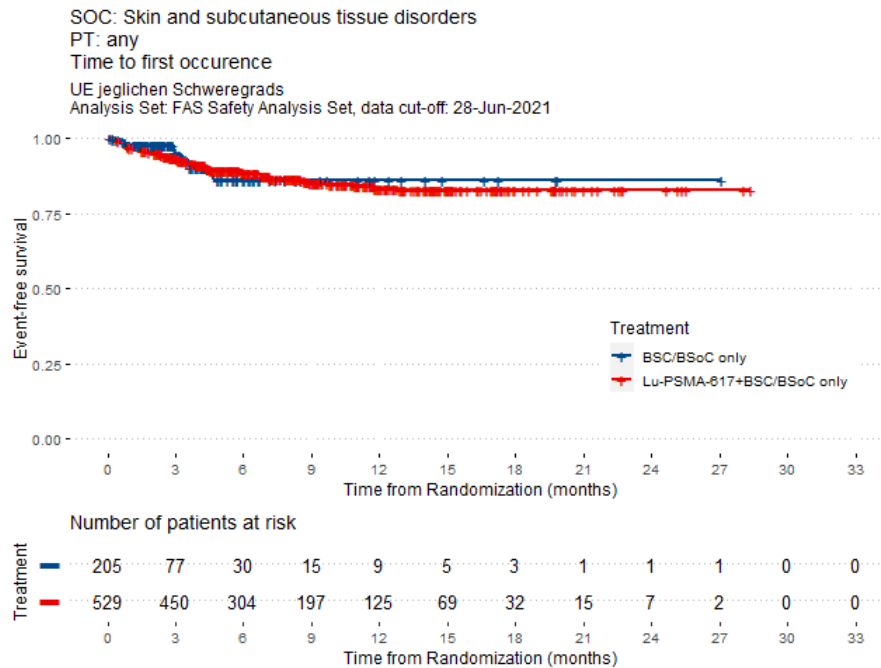


Abbildung 359: UE jeglichen Schweregrads: Time to first occurrence of SOC: Skin and subcutaneous tissue disorders; PT: any

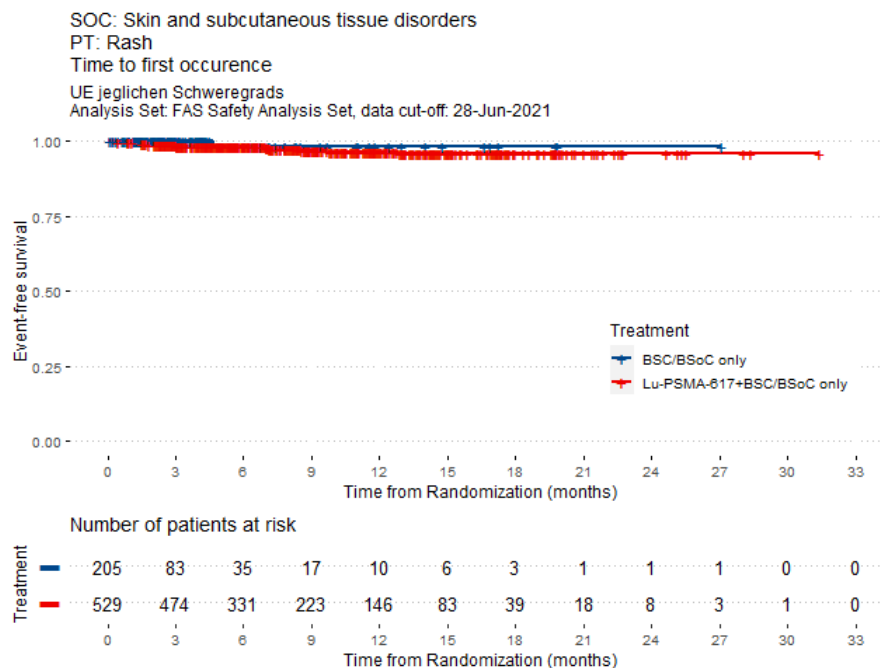


Abbildung 360: UE jeglichen Schweregrads: Time to first occurrence of SOC: Skin and subcutaneous tissue disorders; PT: Rash

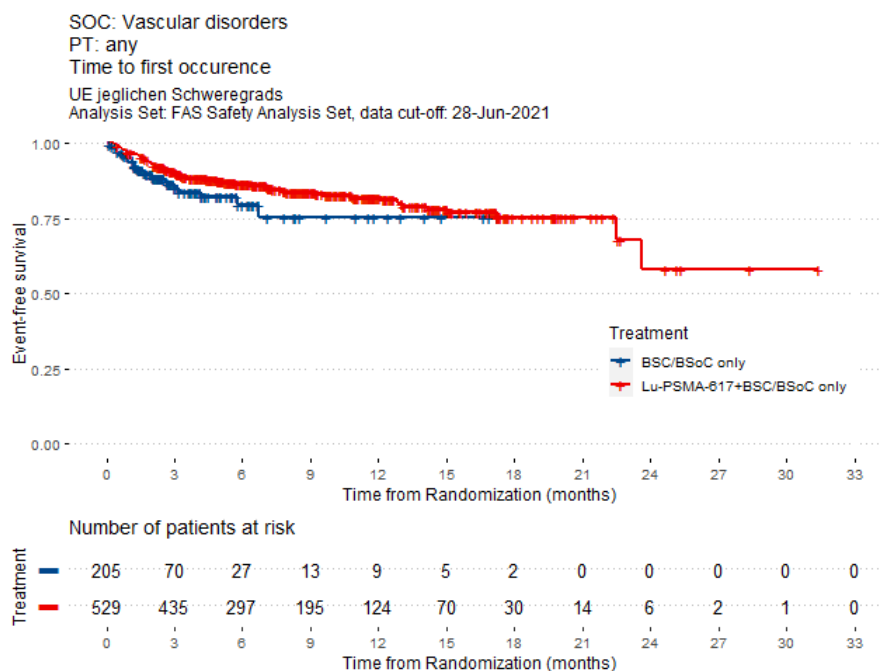


Abbildung 361: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: any

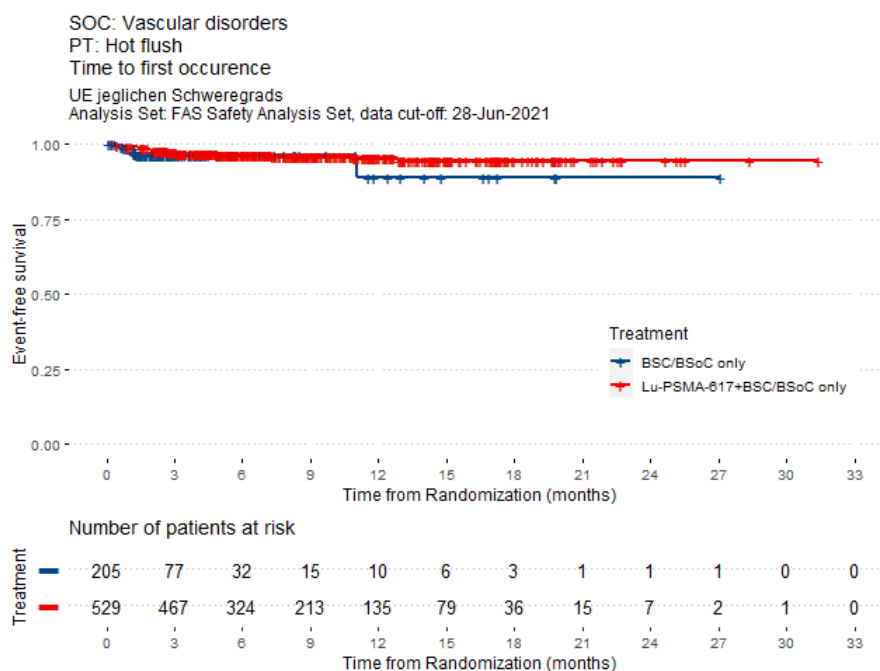


Abbildung 362: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: Hot flush

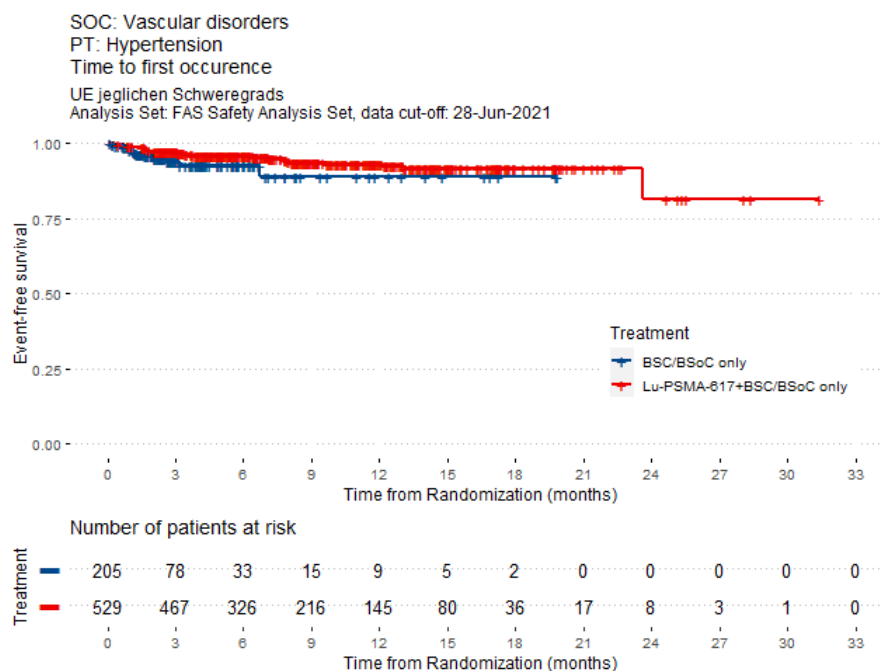


Abbildung 363: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: Hypertension

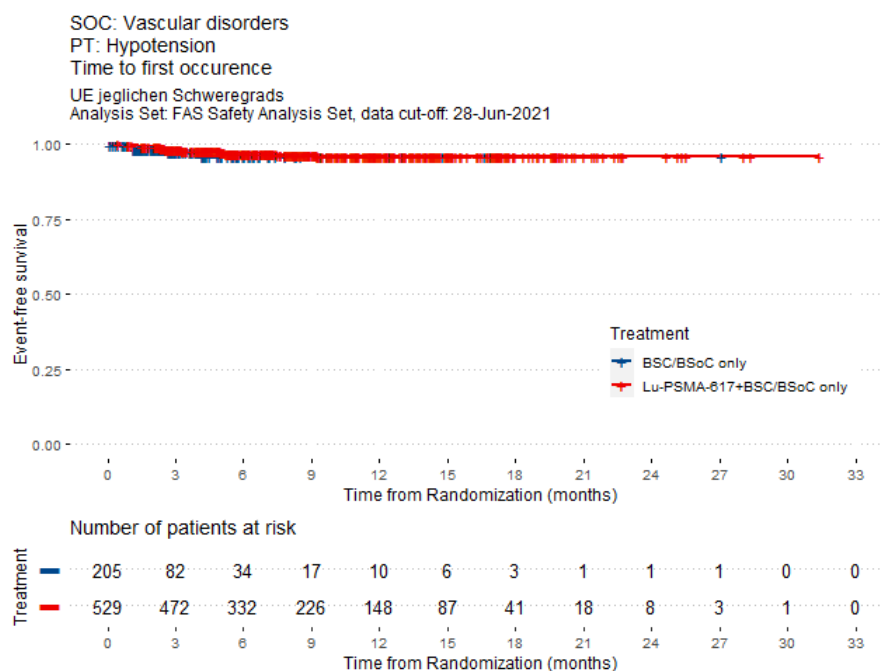
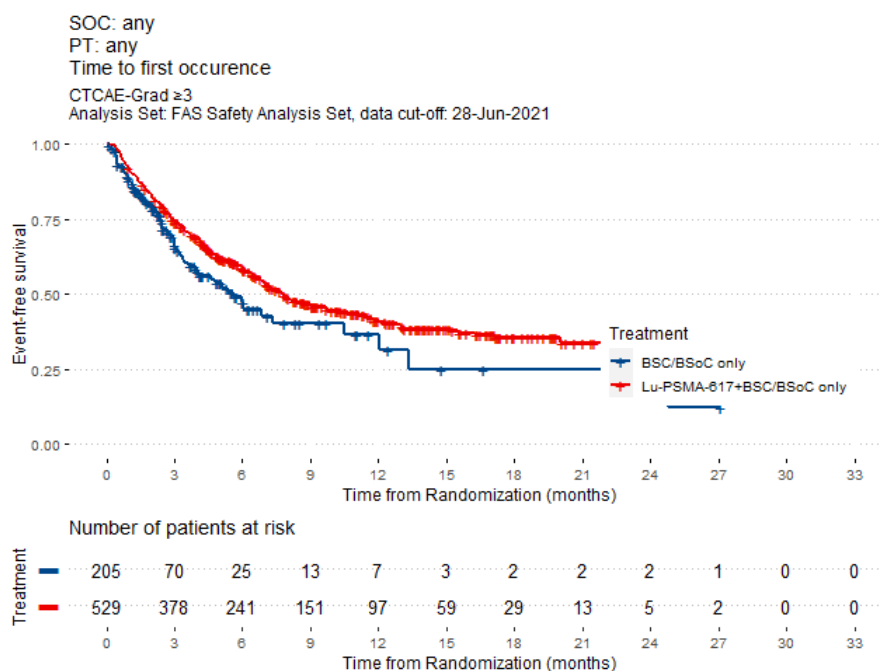
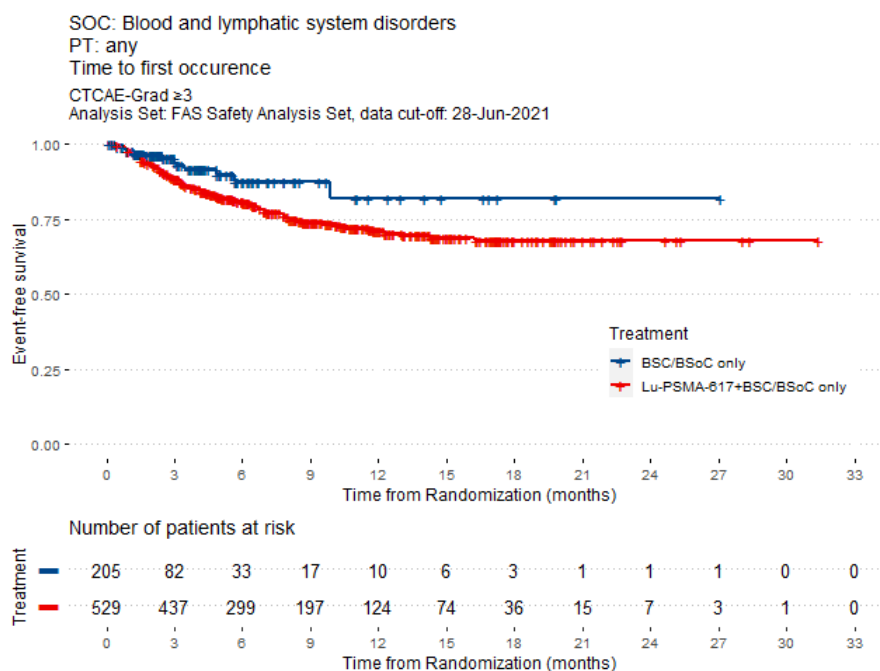


Abbildung 364: UE jeglichen Schweregrads: Time to first occurrence of SOC: Vascular disorders; PT: Hypotension

Anhang 4-H.3.4.2: Schwere UE (CTCAE-Grad ≥ 3)Abbildung 365: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: any; PT: anyAbbildung 366: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: any

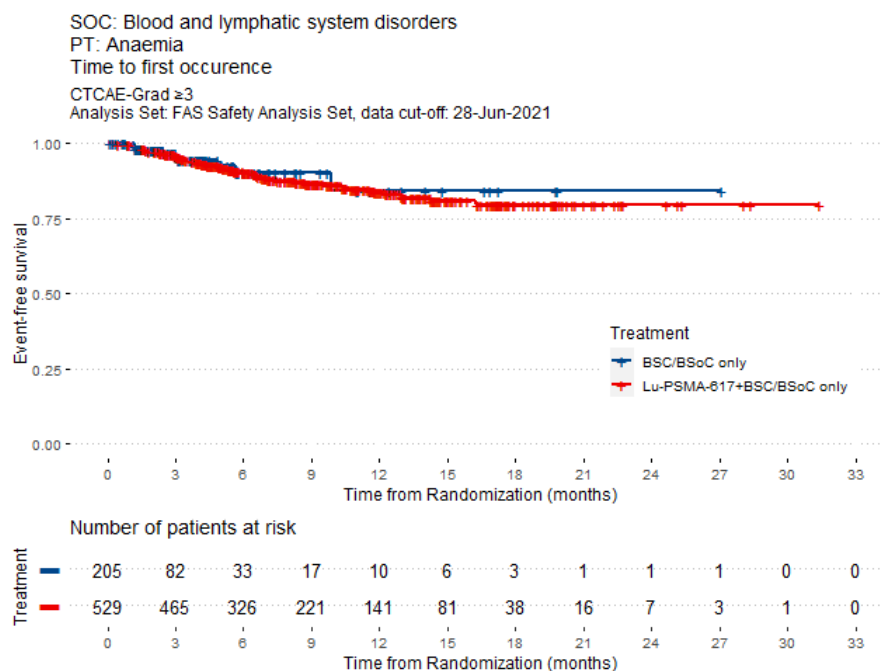


Abbildung 367: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Anaemia

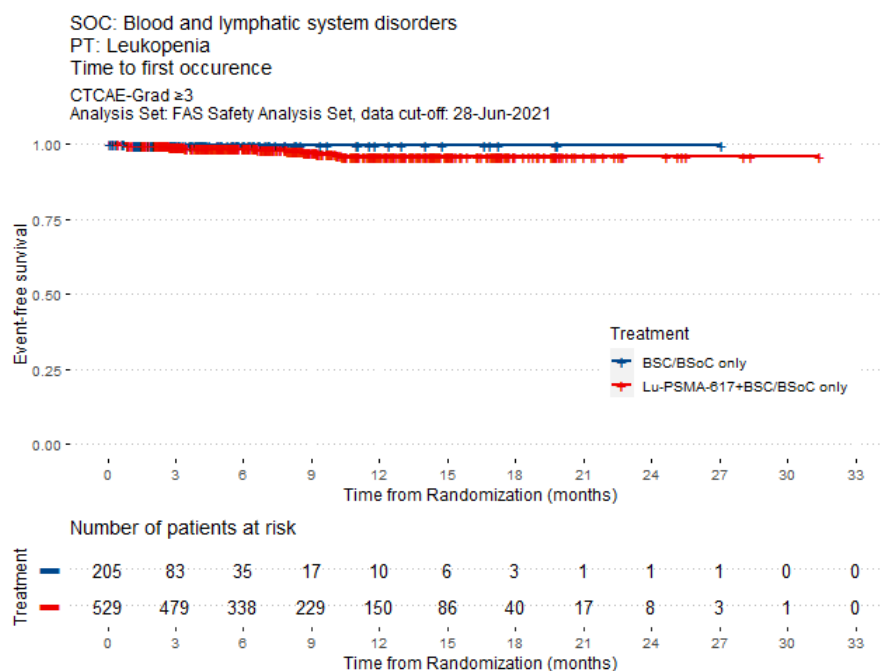


Abbildung 368: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Leukopenia

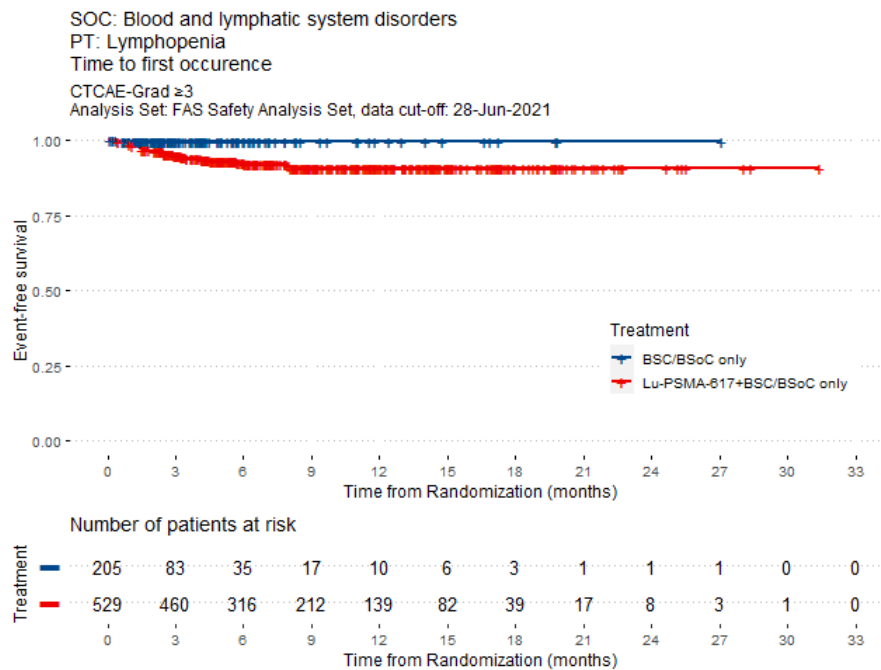


Abbildung 369: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Lymphopenia

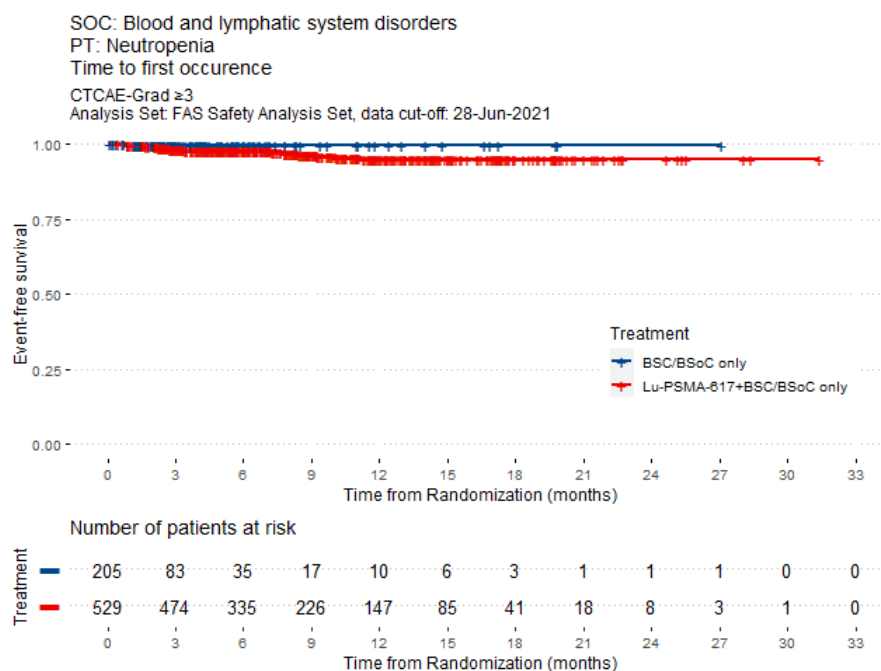


Abbildung 370: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Neutropenia

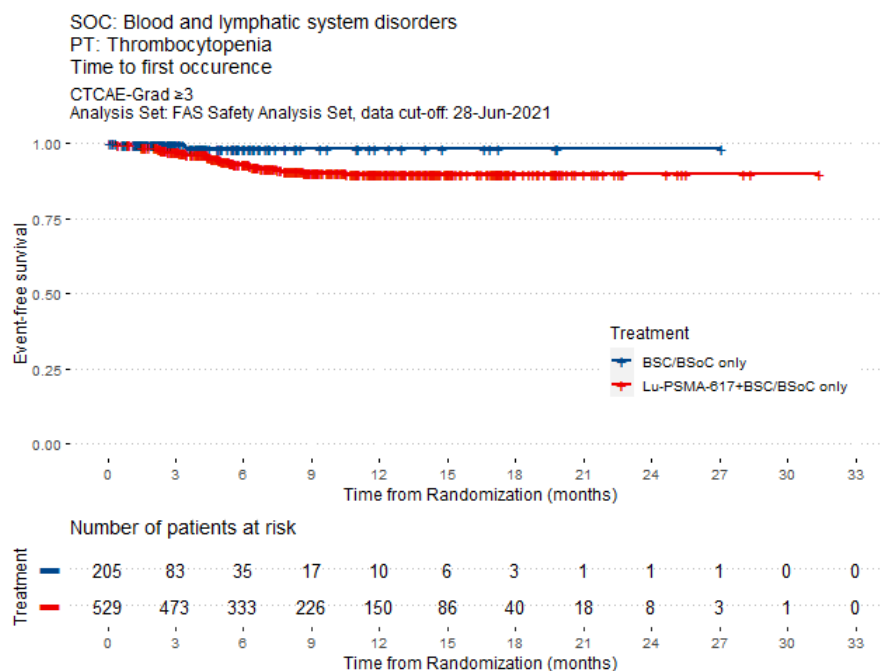


Abbildung 371: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Thrombocytopenia

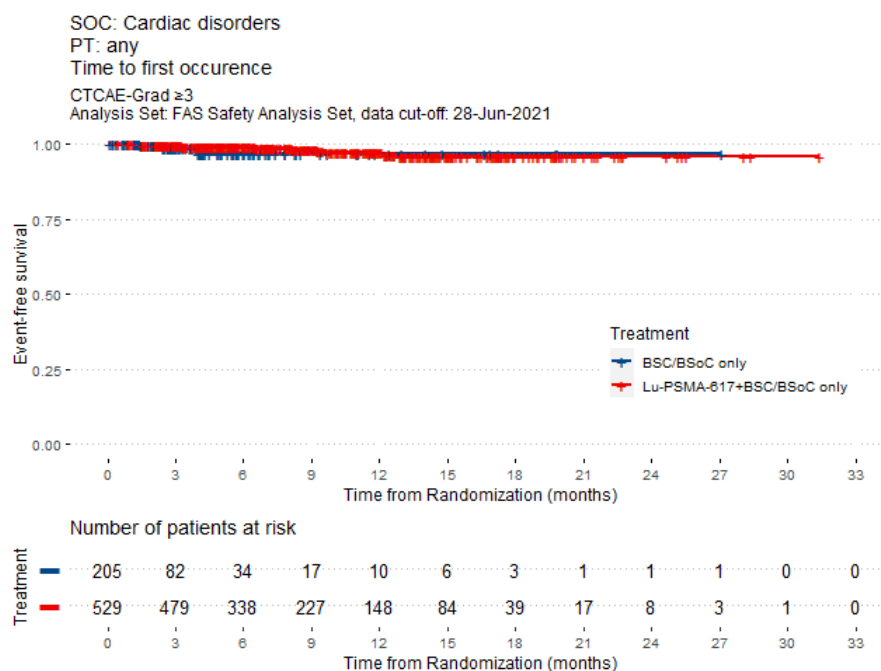


Abbildung 372: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Cardiac disorders; PT: any

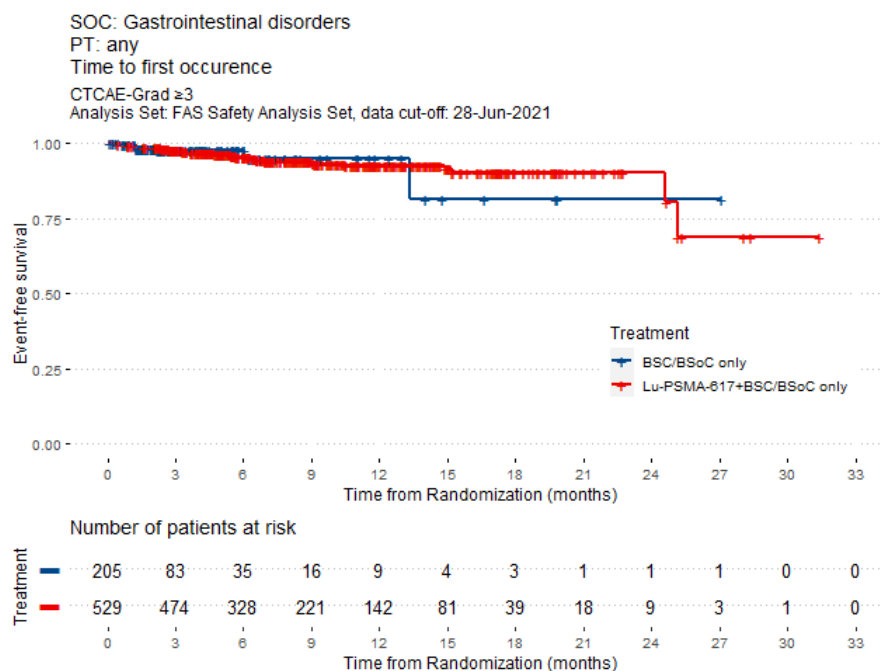


Abbildung 373: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Gastrointestinal disorders; PT: any

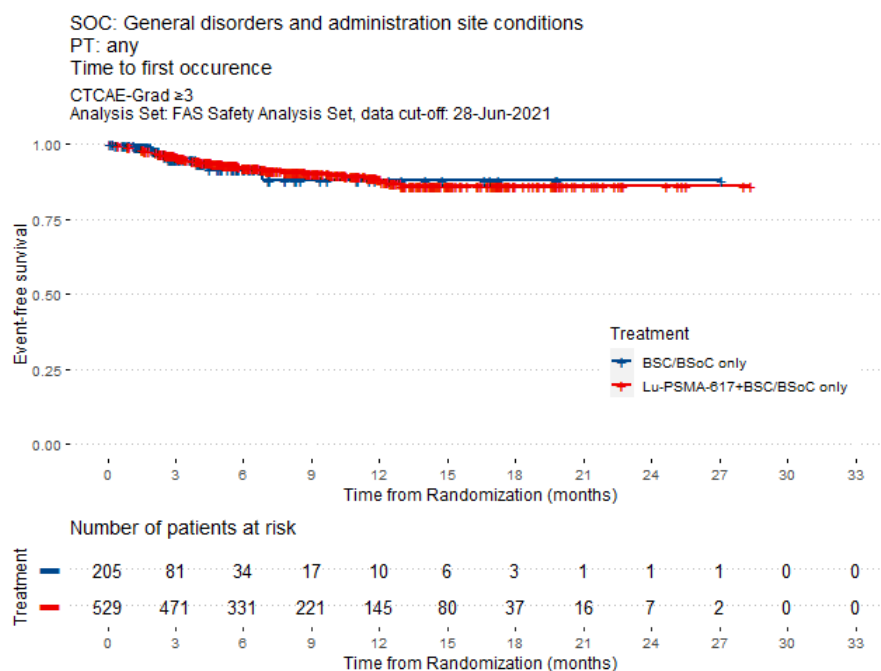


Abbildung 374: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: General disorders and administration site conditions; PT: any

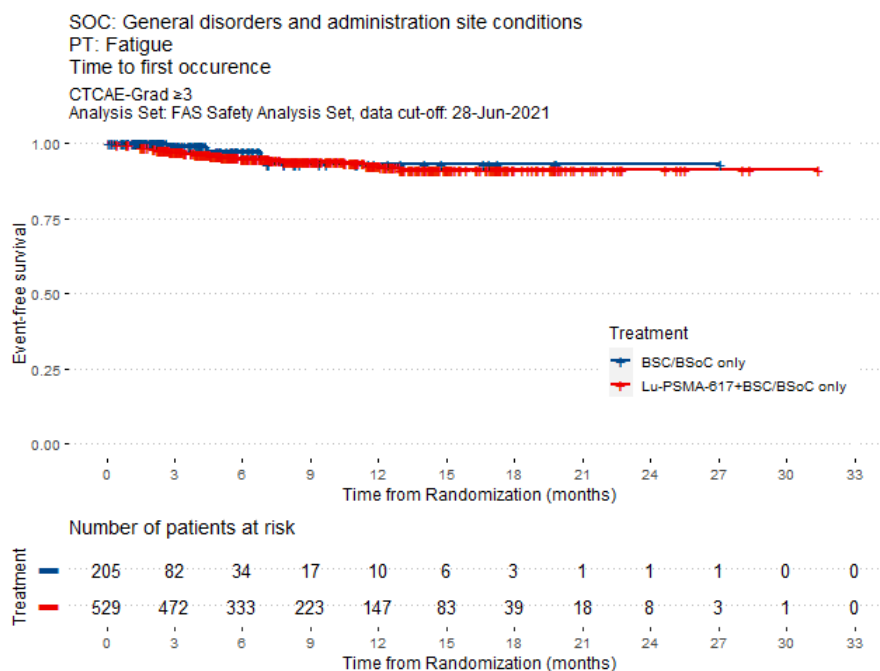


Abbildung 375: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: General disorders and administration site conditions; PT: Fatigue

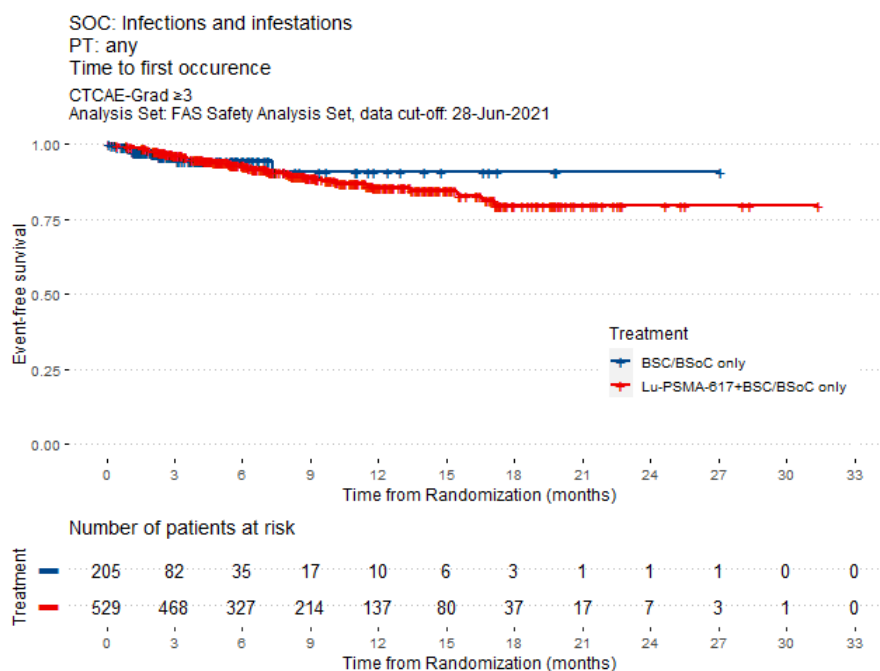


Abbildung 376: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Infections and infestations; PT: any

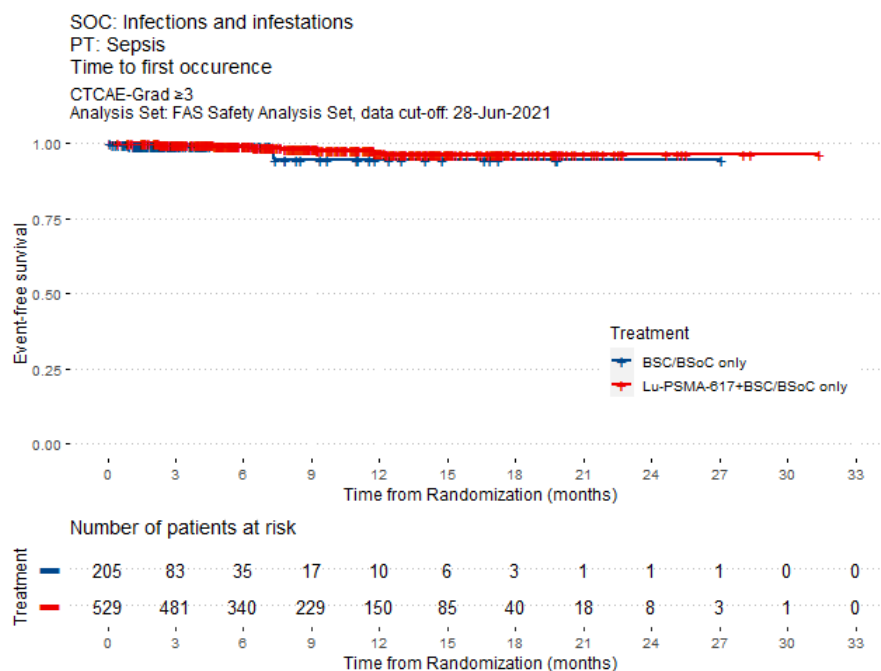


Abbildung 377: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Infections and infestations; PT: Sepsis

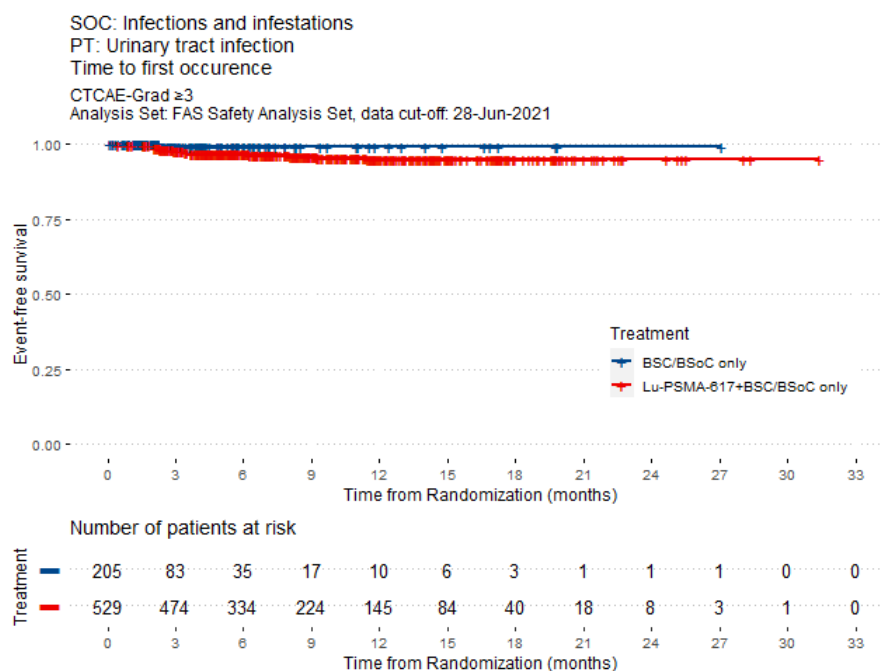


Abbildung 378: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Infections and infestations; PT: Urinary tract infection

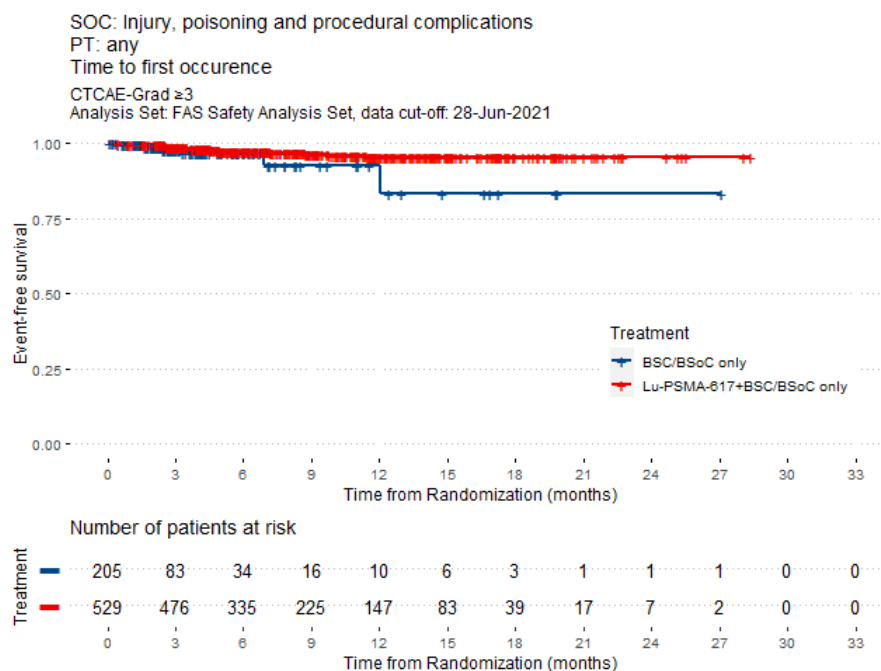


Abbildung 379: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: any

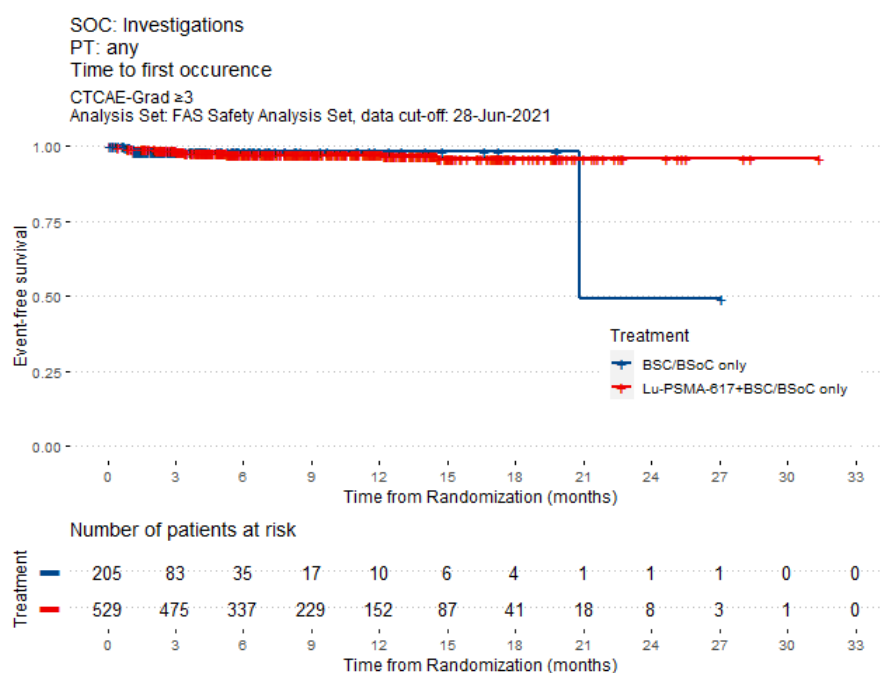


Abbildung 380: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Investigations; PT: any

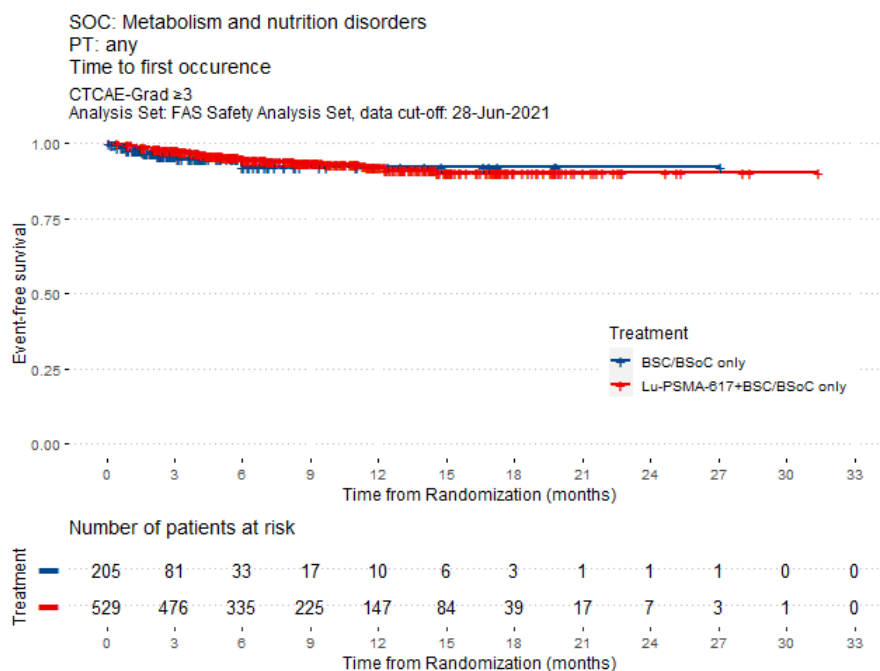


Abbildung 381: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: any

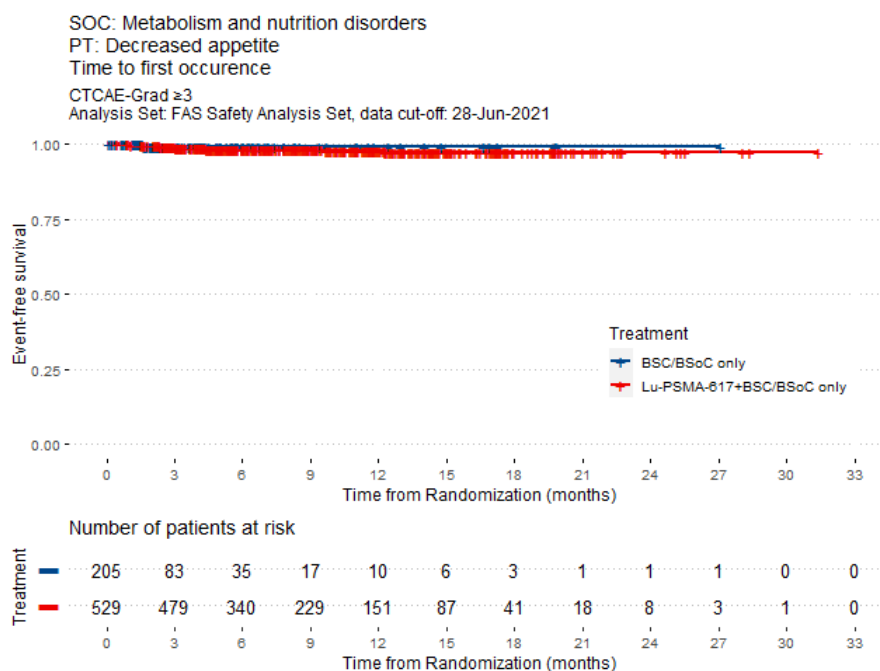


Abbildung 382: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: Decreased appetite

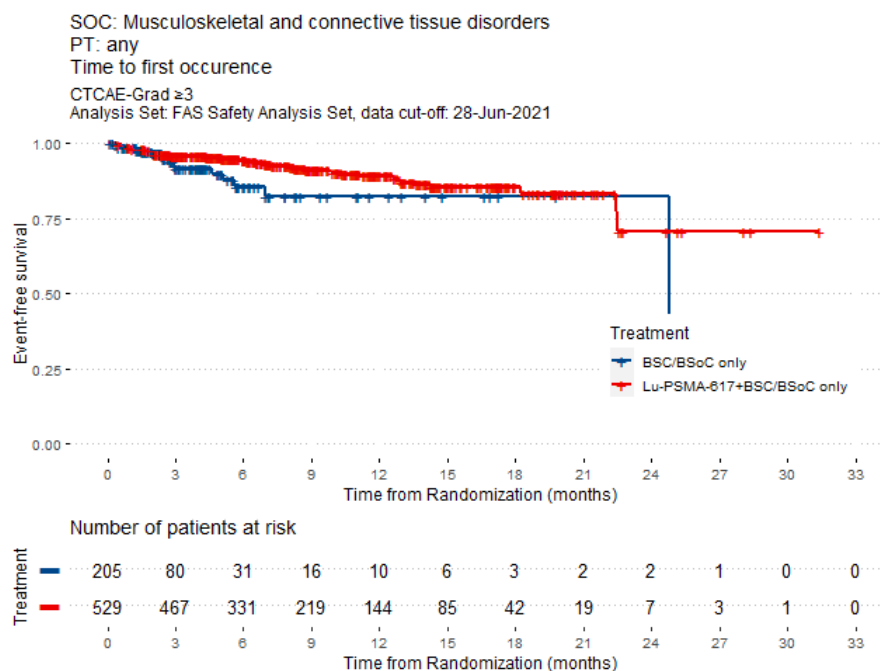


Abbildung 383: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: any

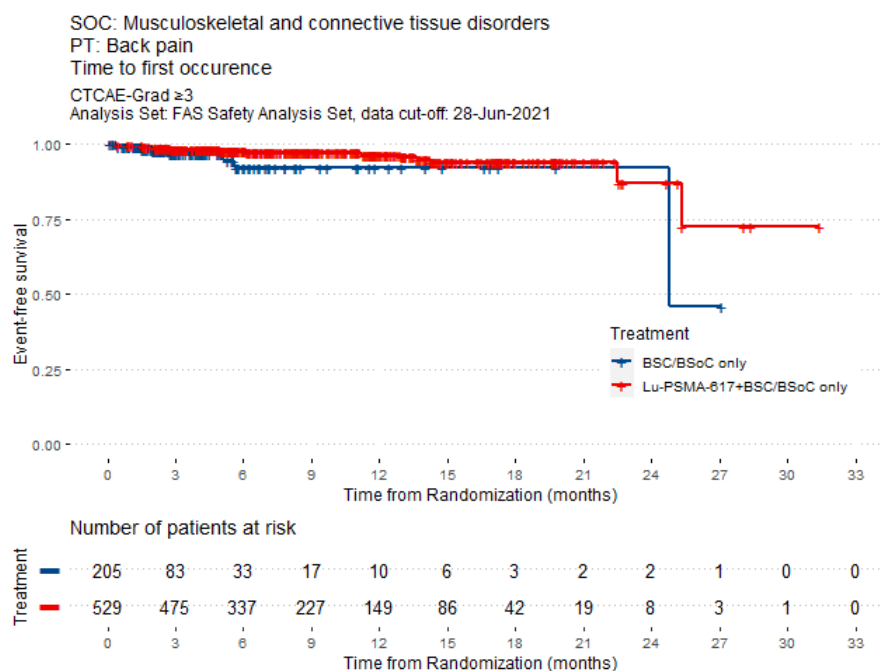


Abbildung 384: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Back pain

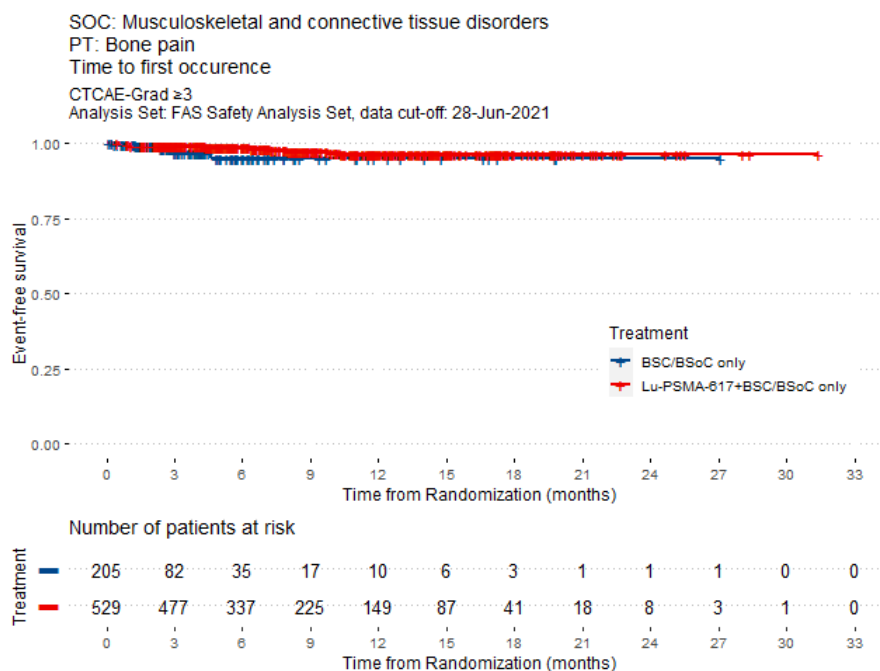


Abbildung 385: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Bone pain

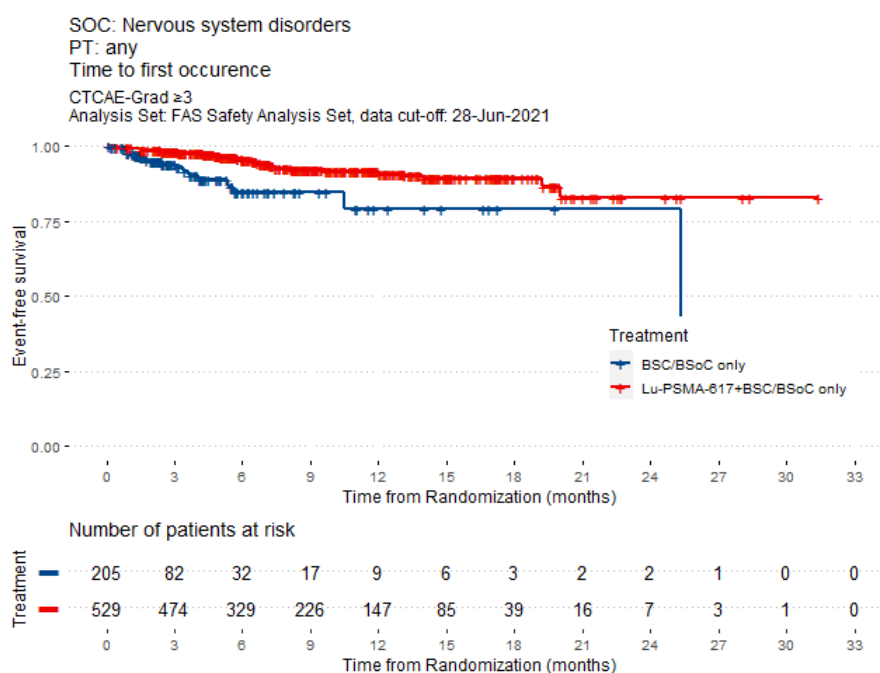


Abbildung 386: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Nervous system disorders; PT: any

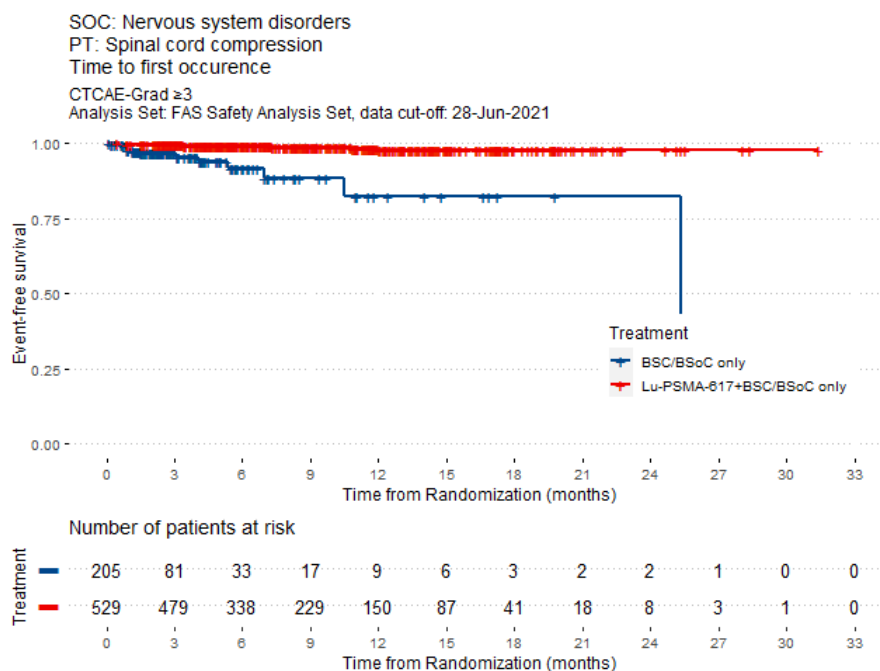


Abbildung 387: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Nervous system disorders; PT: Spinal cord compression

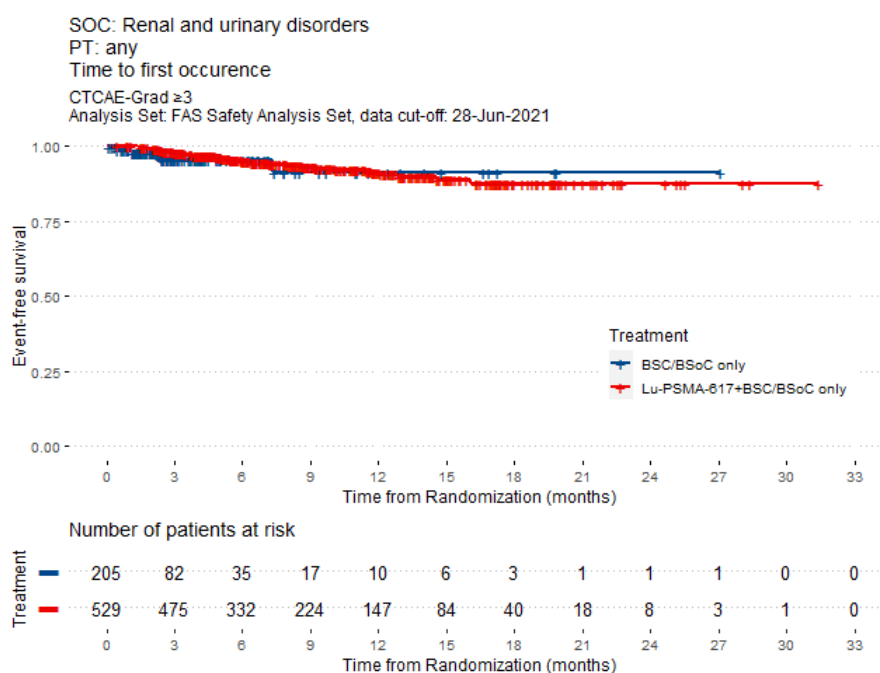


Abbildung 388: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Renal and urinary disorders; PT: any

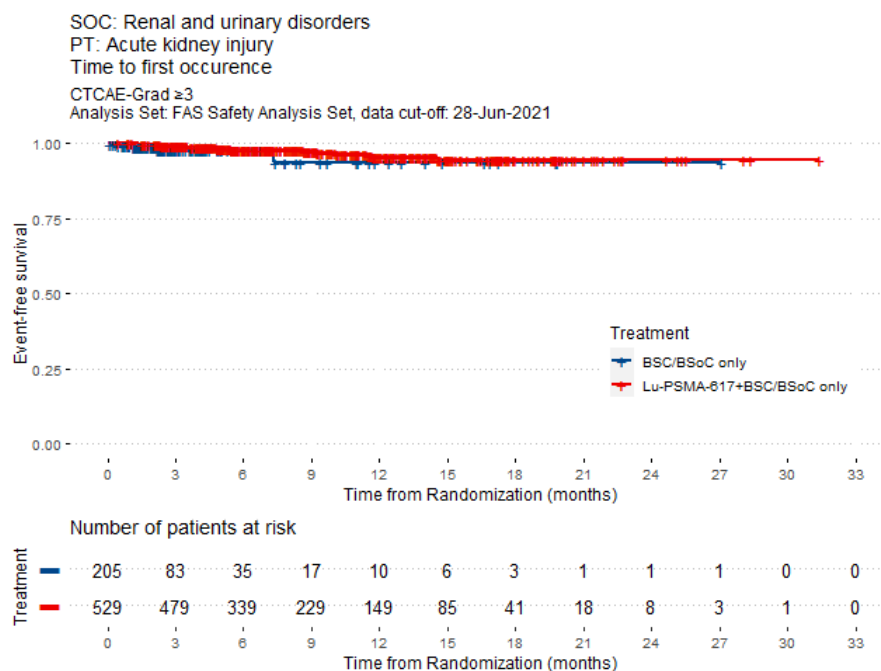


Abbildung 389: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Renal and urinary disorders; PT: Acute kidney injury

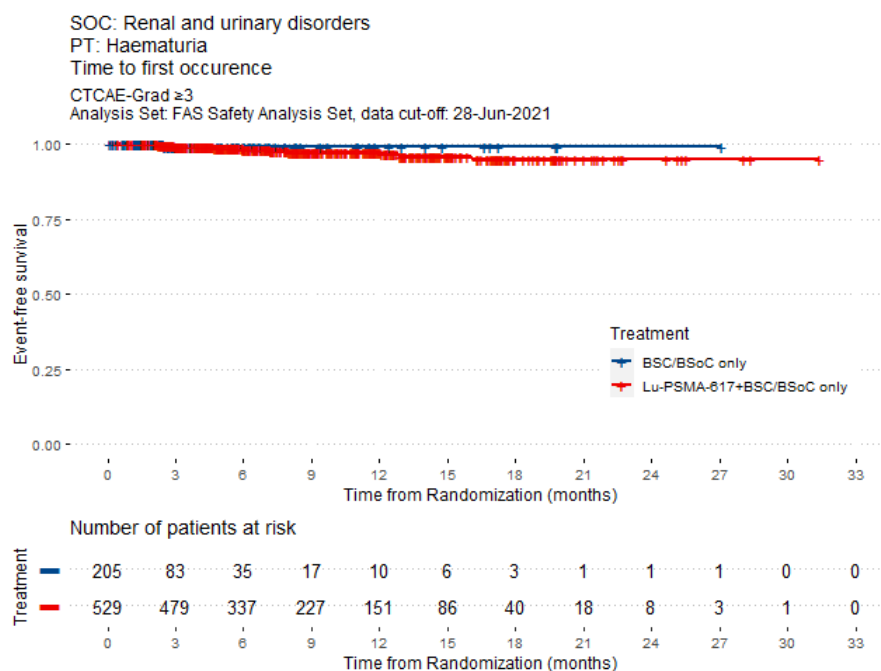


Abbildung 390: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Renal and urinary disorders; PT: Haematuria

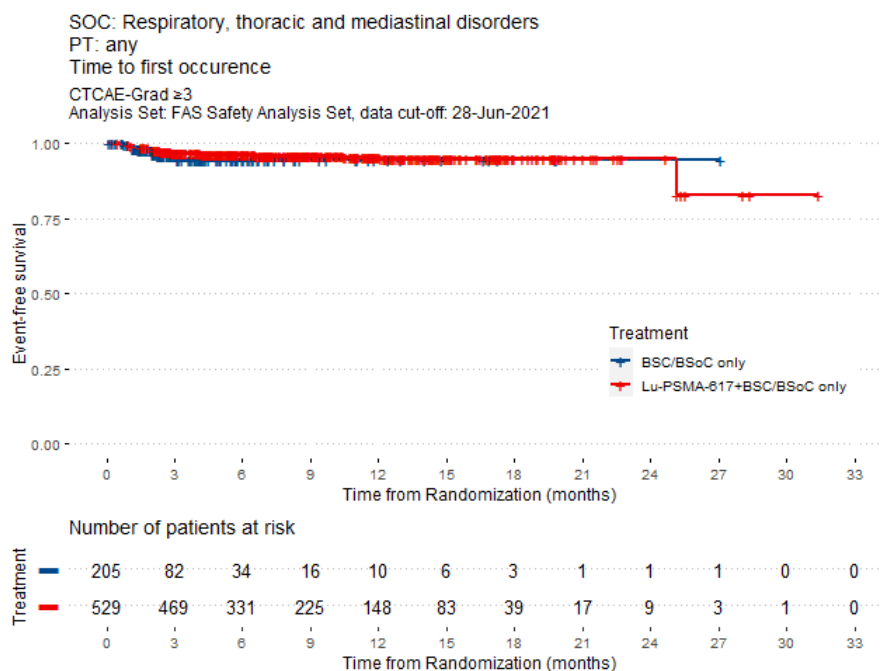


Abbildung 391: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: any

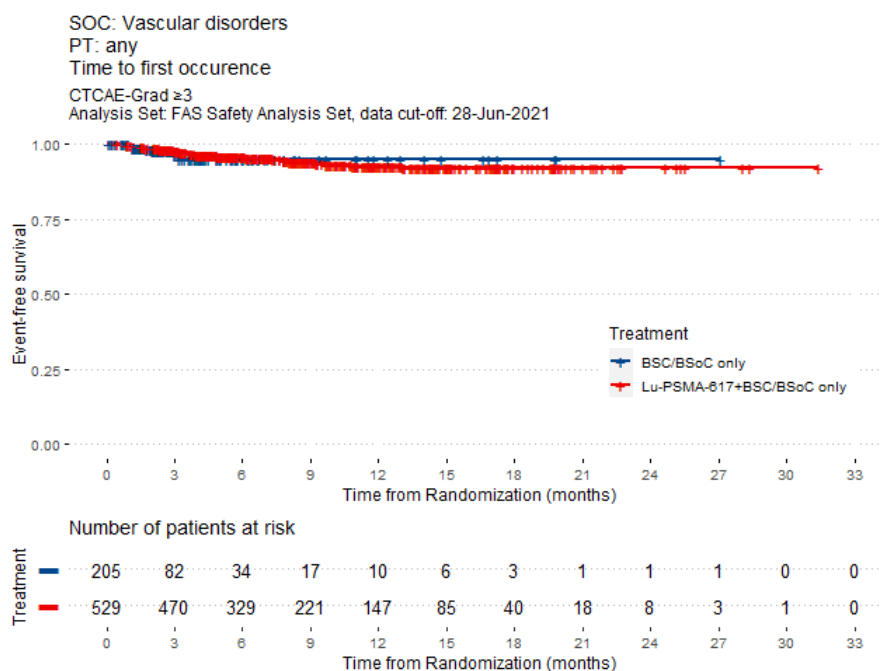


Abbildung 392: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Vascular disorders; PT: any

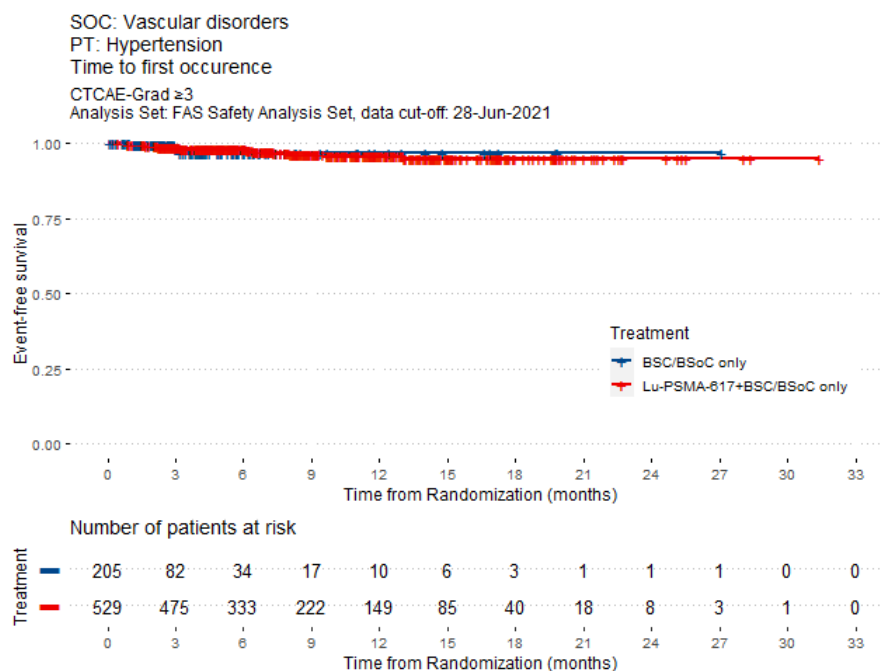


Abbildung 393: CTCAE-Grad ≥ 3 : Time to first occurrence of SOC: Vascular disorders; PT: Hypertension

Anhang 4-H.3.4.3: Schwerwiegende UE

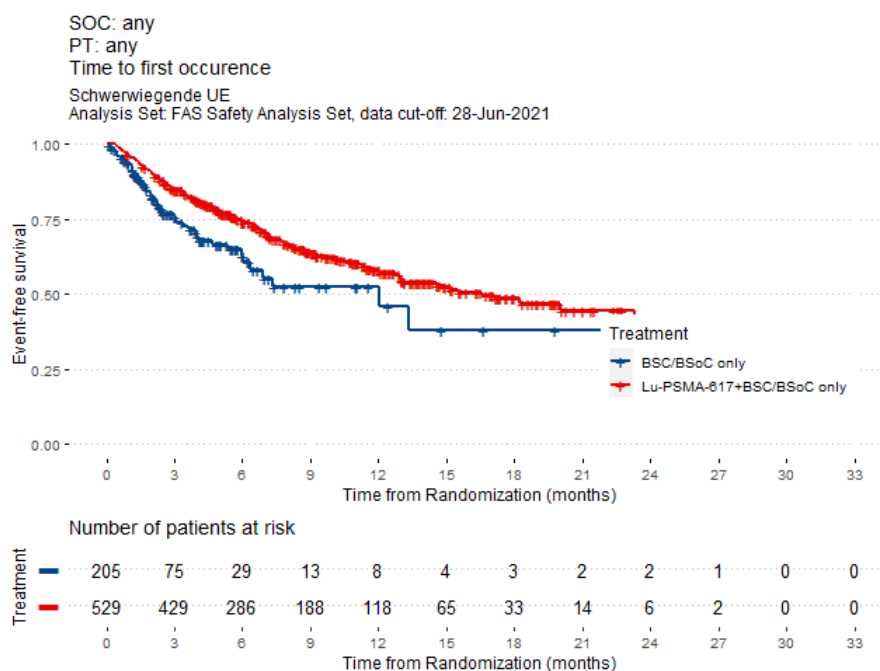


Abbildung 394: Schwerwiegende UE: Time to first occurrence of SOC: any; PT: any

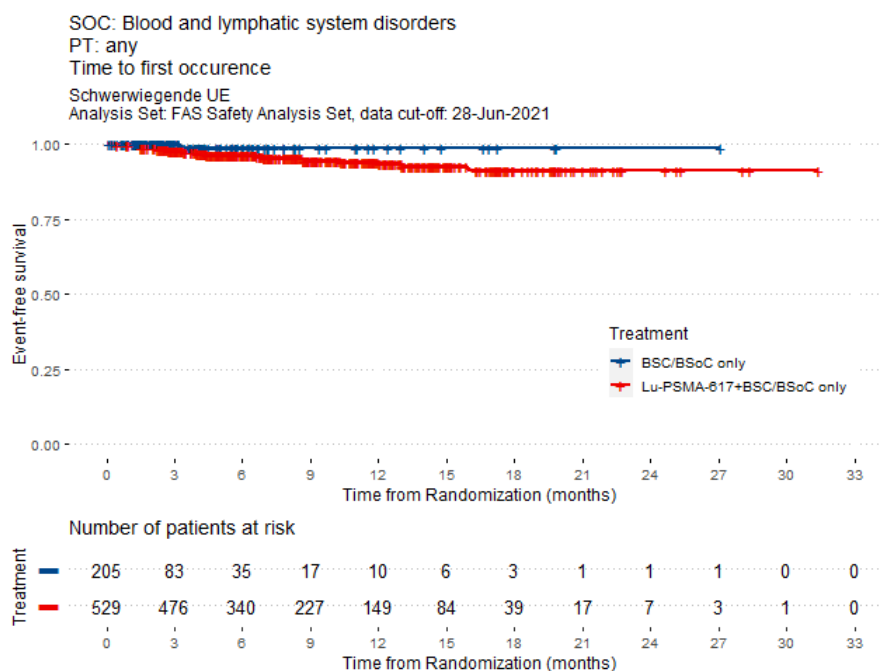


Abbildung 395: Schwerwiegende UE: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: any

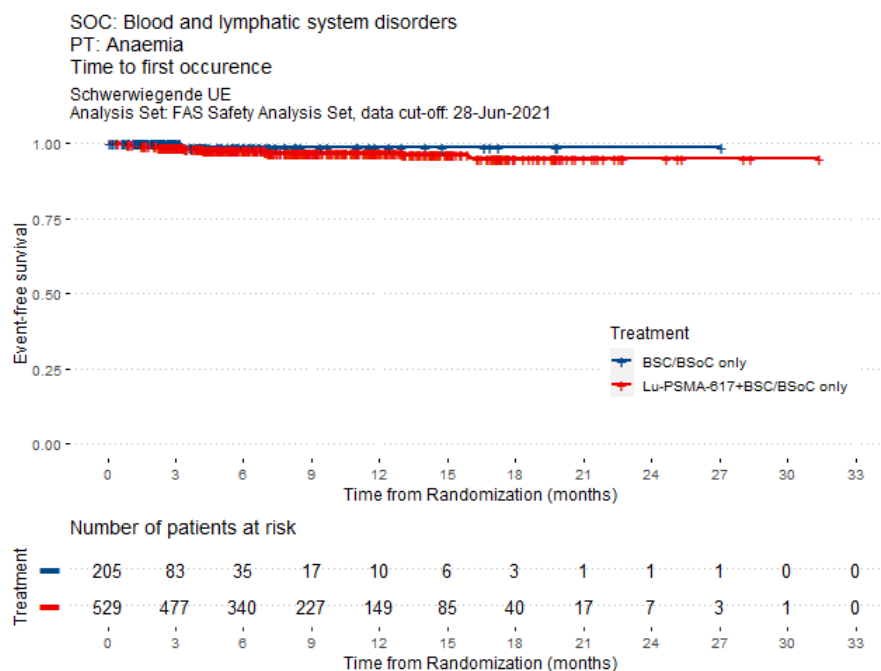


Abbildung 396: Schwerwiegende UE: Time to first occurrence of SOC: Blood and lymphatic system disorders; PT: Anaemia

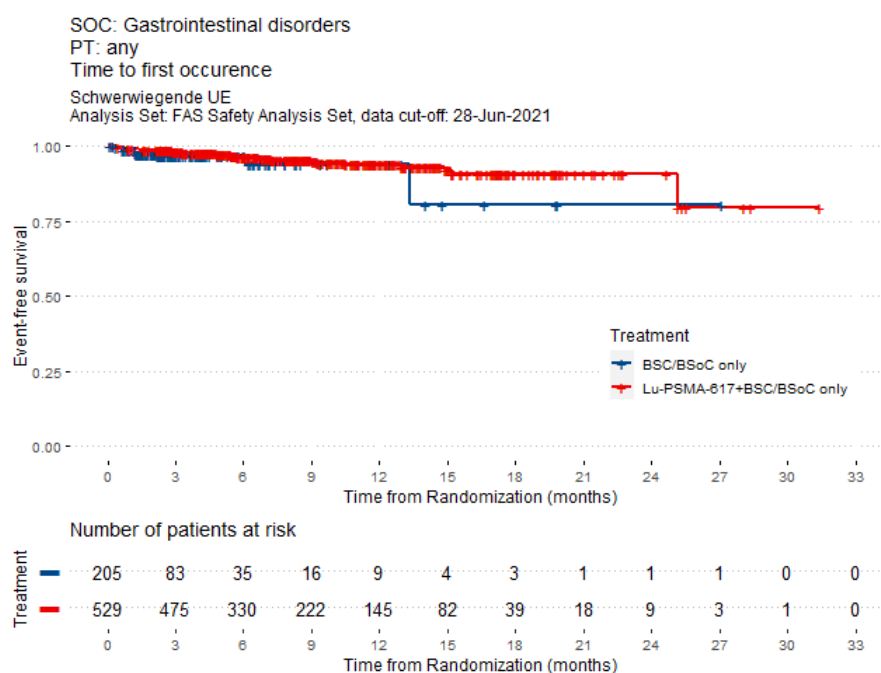


Abbildung 397: Schwerwiegende UE: Time to first occurrence of SOC: Gastrointestinal disorders; PT: any

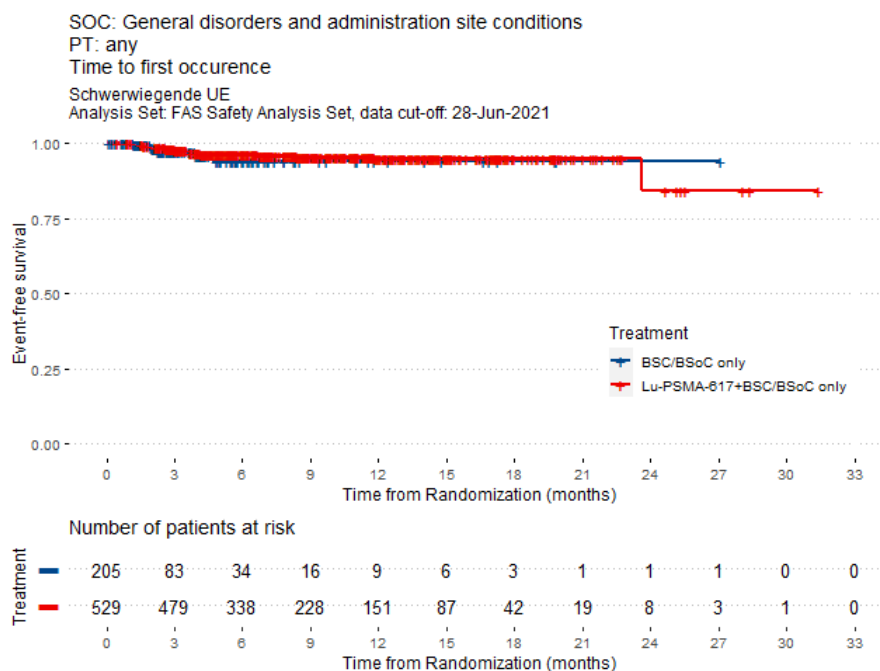


Abbildung 398: Schwerwiegende UE: Time to first occurrence of SOC: General disorders and administration site conditions; PT: any

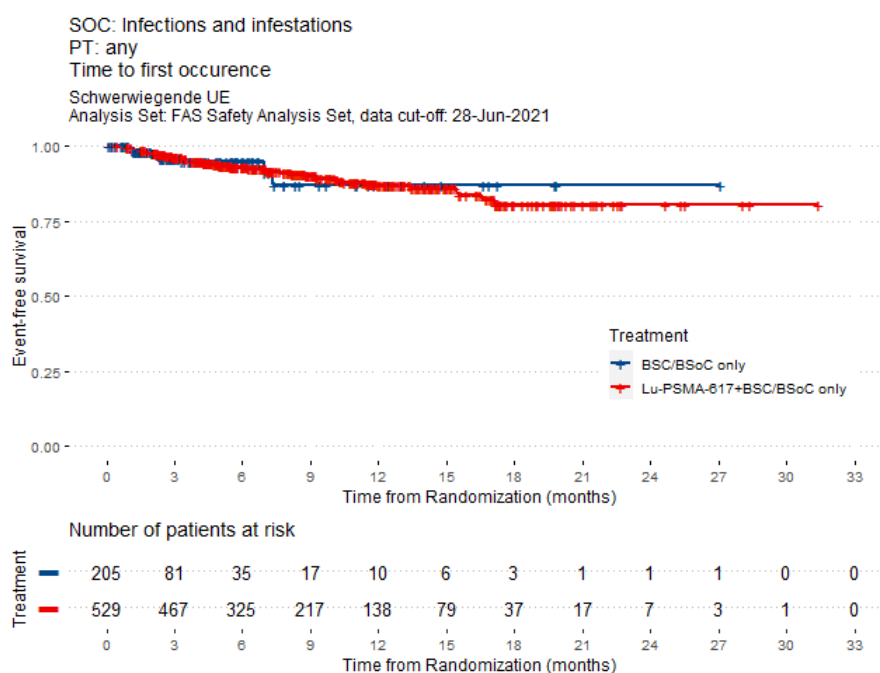


Abbildung 399: Schwerwiegende UE: Time to first occurrence of SOC: Infections and infestations; PT: any

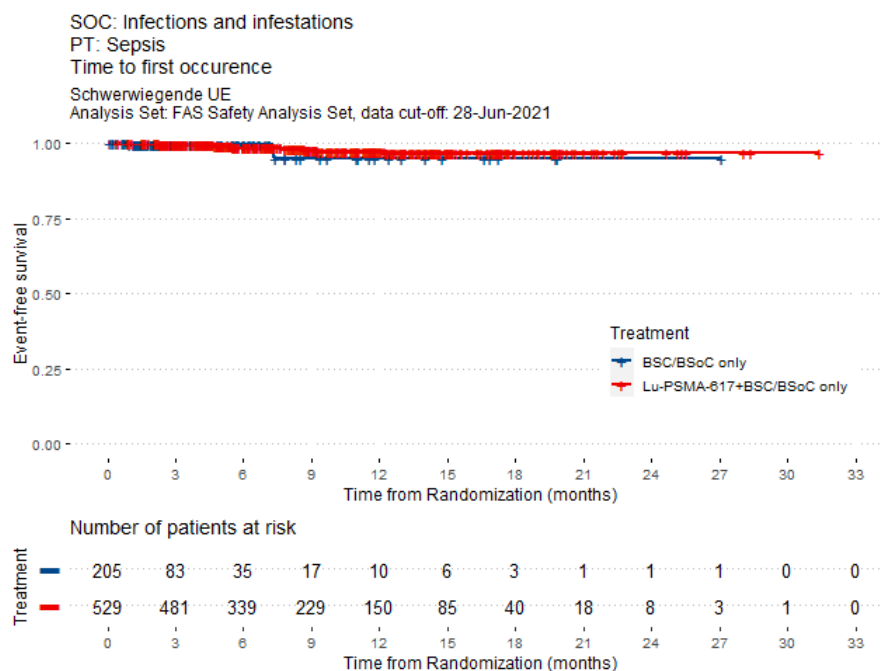


Abbildung 400: Schwerwiegende UE: Time to first occurrence of SOC: Infections and infestations; PT: Sepsis

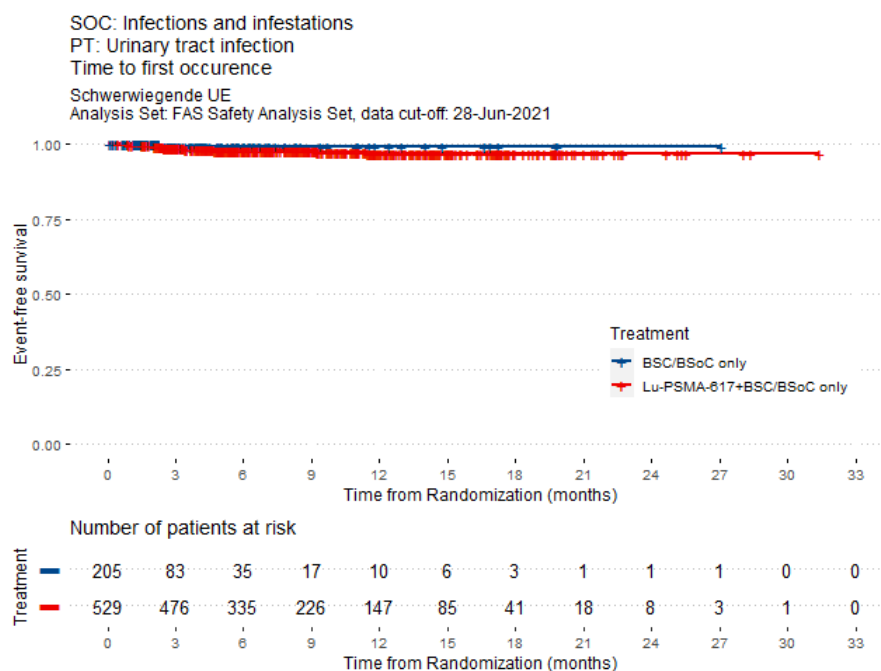


Abbildung 401: Schwerwiegende UE: Time to first occurrence of SOC: Infections and infestations; PT: Urinary tract infection

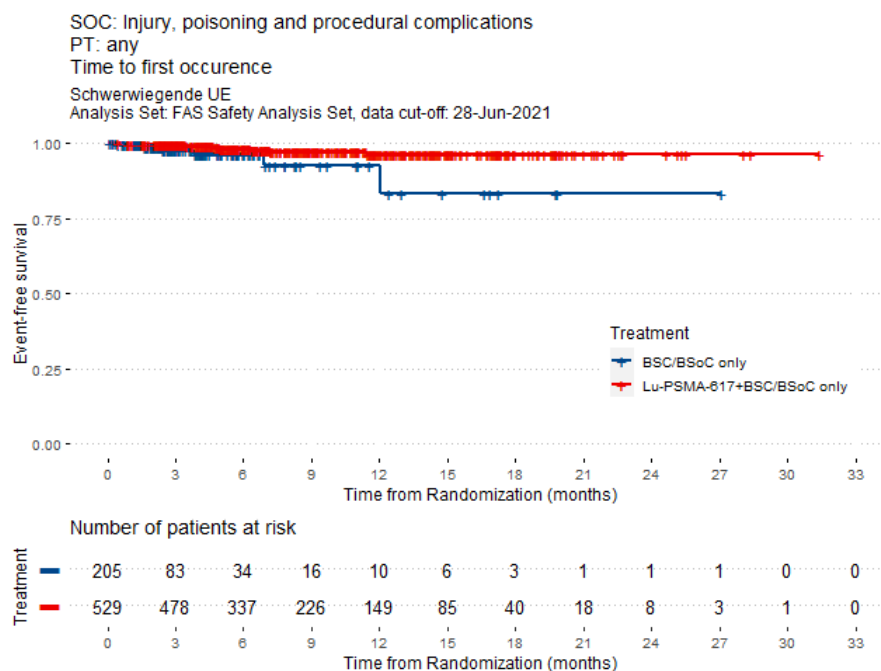


Abbildung 402: Schwerwiegende UE: Time to first occurrence of SOC: Injury, poisoning and procedural complications; PT: any

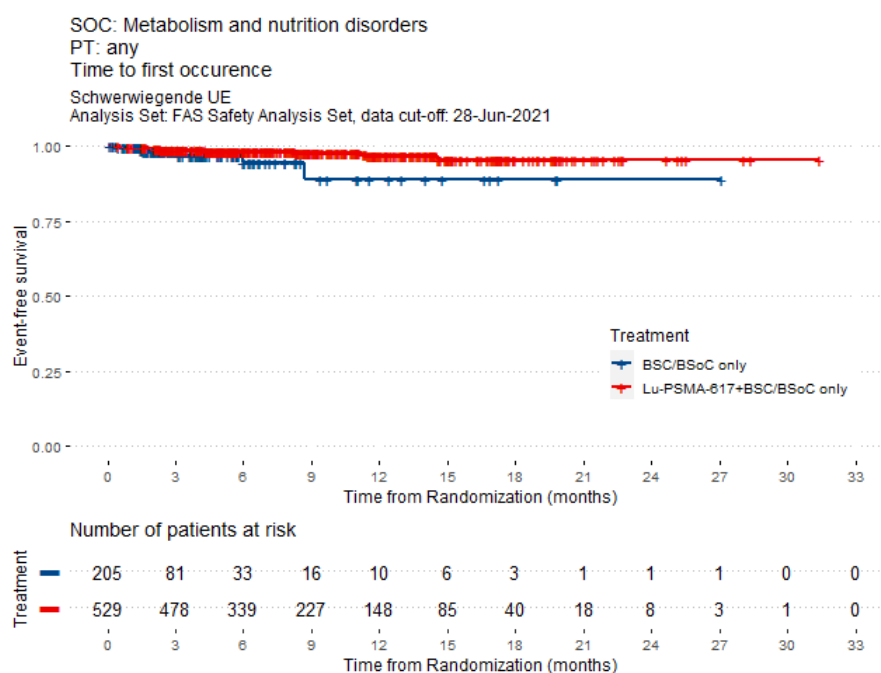


Abbildung 403: Schwerwiegende UE: Time to first occurrence of SOC: Metabolism and nutrition disorders; PT: any

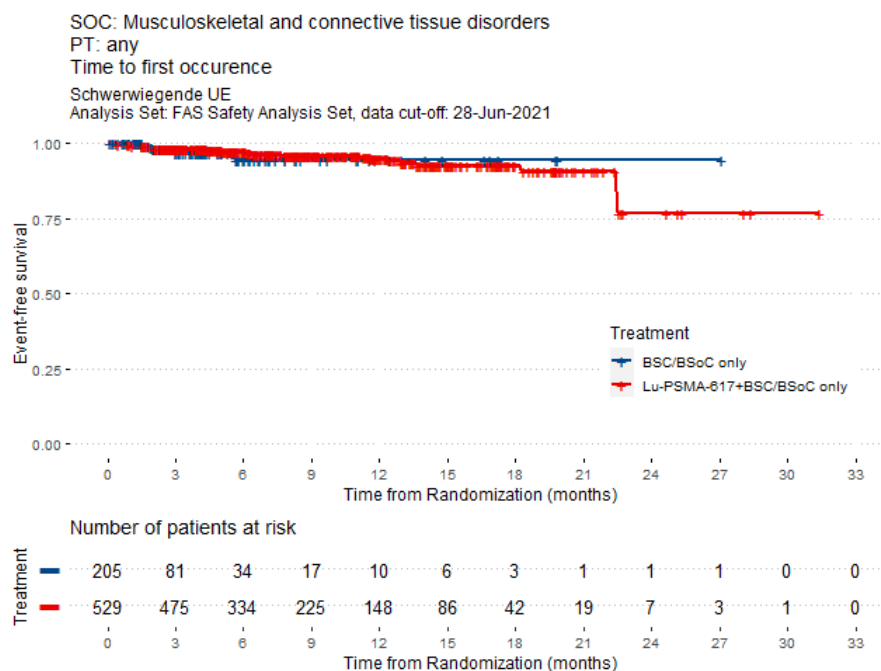


Abbildung 404: Schwerwiegende UE: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: any

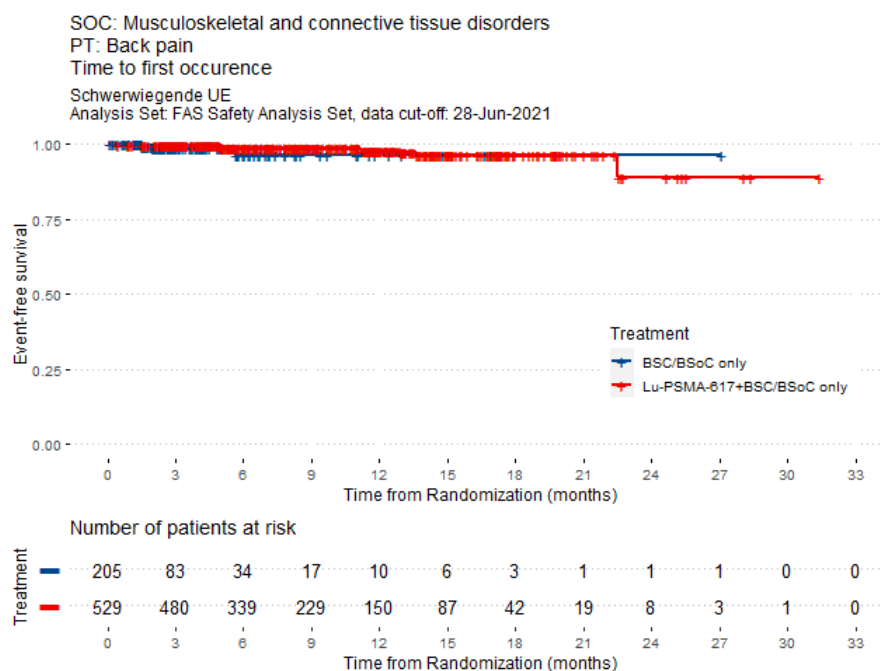


Abbildung 405: Schwerwiegende UE: Time to first occurrence of SOC: Musculoskeletal and connective tissue disorders; PT: Back pain

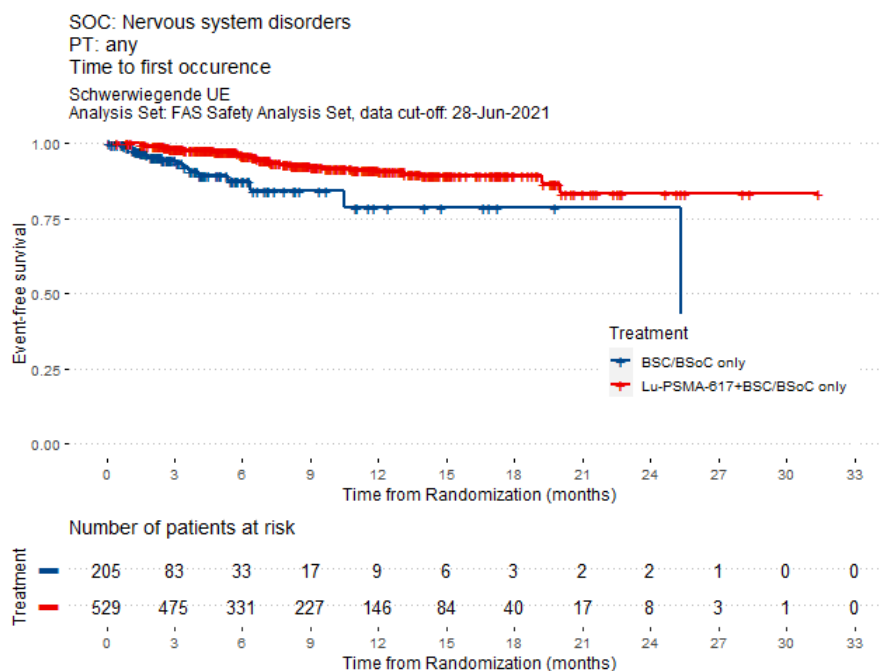


Abbildung 406: Schwerwiegende UE: Time to first occurrence of SOC: Nervous system disorders; PT: any

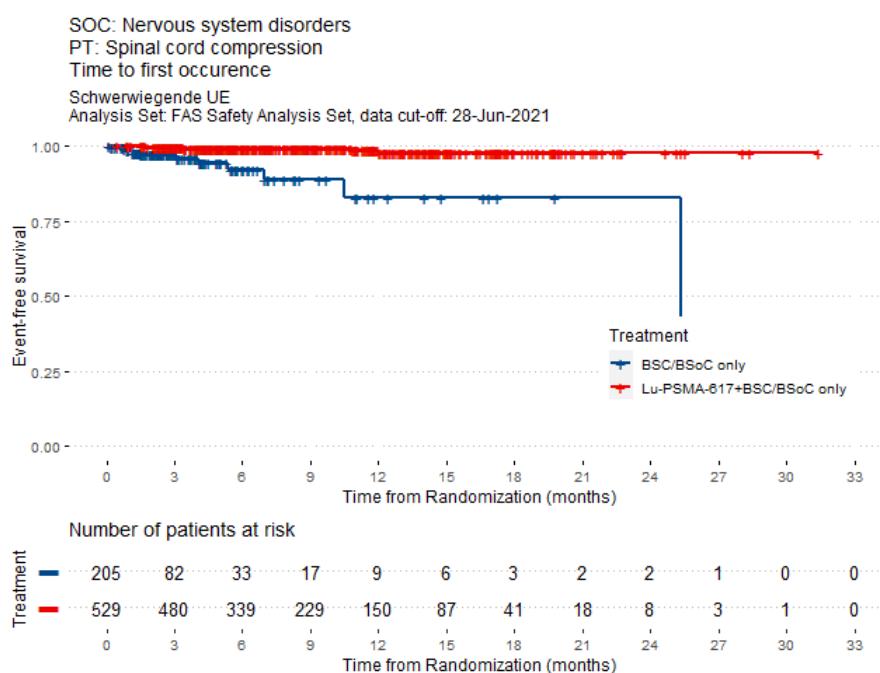


Abbildung 407: Schwerwiegende UE: Time to first occurrence of SOC: Nervous system disorders; PT: Spinal cord compression

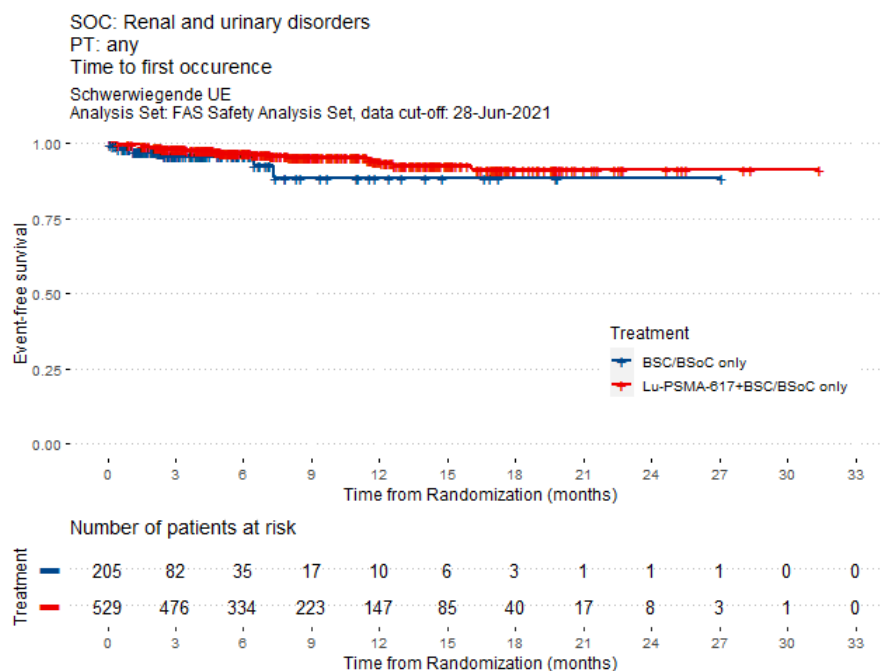


Abbildung 408: Schwerwiegende UE: Time to first occurrence of SOC: Renal and urinary disorders; PT: any

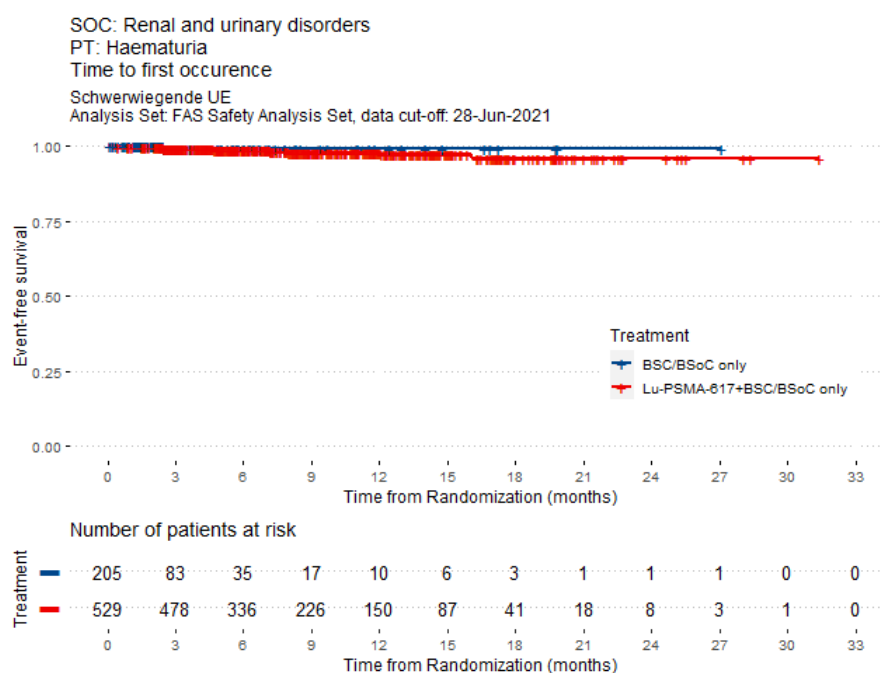


Abbildung 409: Schwerwiegende UE: Time to first occurrence of SOC: Renal and urinary disorders; PT: Haematuria

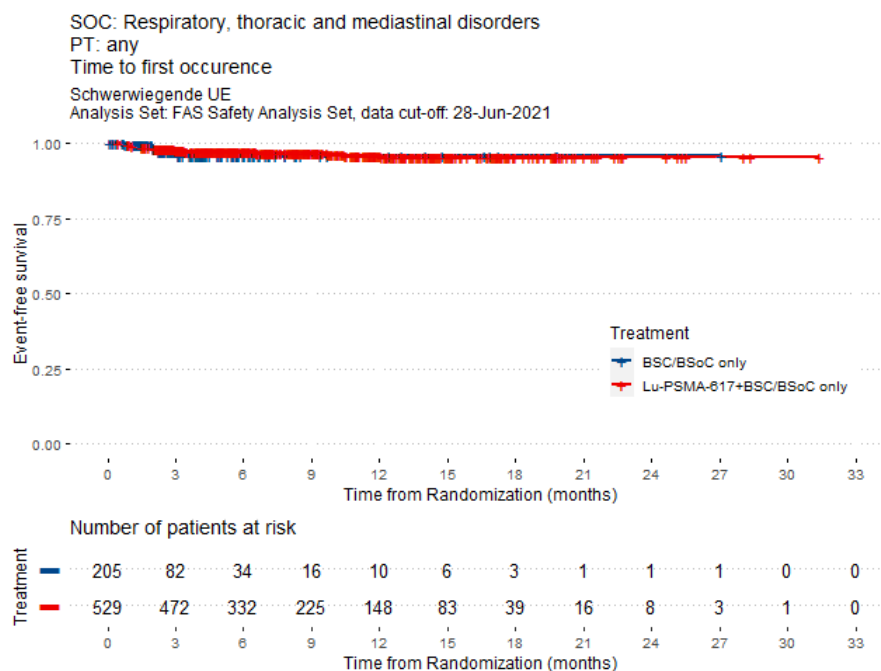


Abbildung 410: Schwerwiegende UE: Time to first occurrence of SOC: Respiratory, thoracic and mediastinal disorders; PT: any

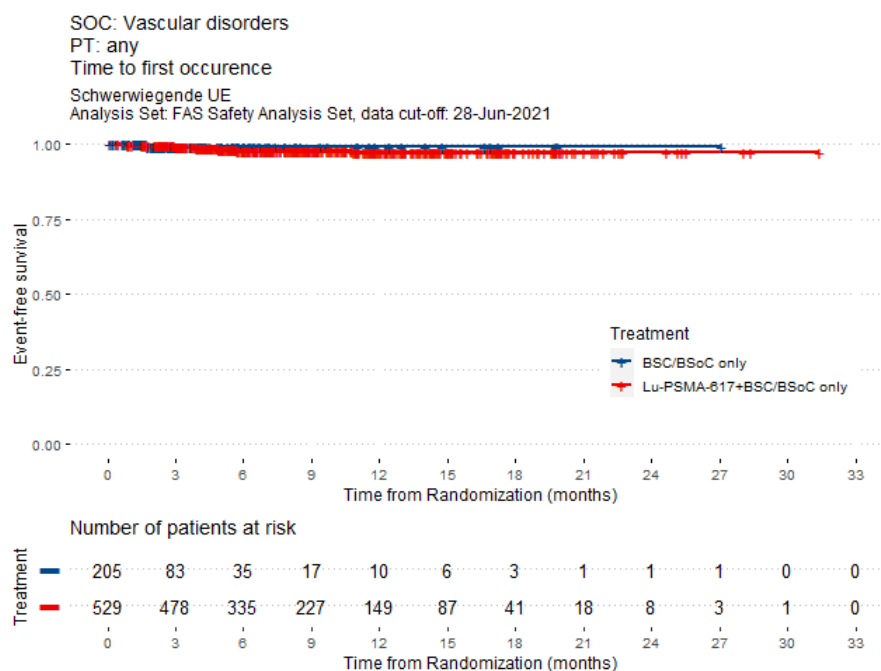


Abbildung 411: Schwerwiegende UE: Time to first occurrence of SOC: Vascular disorders; PT: any