

### **Anhang 4G – Ergänzende Tabellen**

In den folgenden Tabellen sind die Medical History der Patienten getrennt nach Altersgruppen (< 75 Jahre, ≥ 75 Jahre) sowie die im Rahmen des Studieneinschlusses dokumentierten Komorbiditäten der Patienten < 75 Jahre dargestellt.

**ASTX727-02 AML CSR****Population: Safety Analysis Set**

**Table 14.2.2.2**  
**Medical History by SOC and Preferred Term by Age**

<b>MedDRA System Organ Class</b>	<b>Age&lt;75 Years</b>	<b>Age≥75 Years</b>
<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
Subjects with Any Medical History	31 (100.0)	56 (100.0)
<b>BLOOD AND LYMPHATIC SYSTEM DISORDERS</b>	<b>28 (90.3)</b>	<b>37 (66.1)</b>
Anaemia	23 (74.2)	30 (53.6)
Thrombocytopenia	20 (64.5)	25 (44.6)
Neutropenia	17 (54.8)	20 (35.7)
Leukopenia	5 (16.1)	10 (17.9)
Leukocytosis	2 (6.5)	3 (5.4)
Pancytopenia	2 (6.5)	1 (1.8)
Anaemia macrocytic	0	1 (1.8)
Hypofibrinogenaemia	1 (3.2)	0
Iron deficiency anaemia	1 (3.2)	0
Leukostasis syndrome	1 (3.2)	0
Spleen disorder	1 (3.2)	0
<b>CARDIAC DISORDERS</b>	<b>10 (32.3)</b>	<b>19 (33.9)</b>
Atrial fibrillation	4 (12.9)	5 (8.9)
Myocardial ischaemia	2 (6.5)	5 (8.9)
Atrial flutter	1 (3.2)	3 (5.4)
Acute myocardial infarction	1 (3.2)	2 (3.6)
Myocardial infarction	2 (6.5)	1 (1.8)

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<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
Bundle branch block right	0	2 (3.6)
Coronary artery disease	1 (3.2)	1 (1.8)
Tachycardia	1 (3.2)	1 (1.8)
Aortic valve sclerosis	1 (3.2)	0
Arteriosclerosis coronary artery	0	1 (1.8)
Atrial thrombosis	1 (3.2)	0
Atrioventricular block first degree	0	1 (1.8)
Bifascicular block	1 (3.2)	0
Bundle branch block left	0	1 (1.8)
Cardiac disorder	1 (3.2)	0
Coronary artery stenosis	0	1 (1.8)
Hypertensive heart disease	0	1 (1.8)
Left atrial dilatation	1 (3.2)	0
Pericardial effusion	1 (3.2)	0
Torsade de pointes	0	1 (1.8)
Ventricular hypokinesia	0	1 (1.8)
Ventricular tachycardia	0	1 (1.8)
<b>CONGENITAL, FAMILIAL AND GENETIC DISORDERS</b>	<b>1 (3.2)</b>	<b>4 (7.1)</b>
Blindness congenital	0	1 (1.8)
Cardiac septal defect	0	1 (1.8)

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<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
Gilbert's syndrome	0	1 (1.8)
Renal aplasia	0	1 (1.8)
Thalassaemia minor	1 (3.2)	0
<b>EAR AND LABYRINTH DISORDERS</b>	<b>3 (9.7)</b>	<b>5 (8.9)</b>
Hypoacusis	2 (6.5)	1 (1.8)
Deafness	0	2 (3.6)
Vertigo	1 (3.2)	1 (1.8)
Vertigo positional	0	1 (1.8)
<b>ENDOCRINE DISORDERS</b>	<b>4 (12.9)</b>	<b>7 (12.5)</b>
Hypothyroidism	3 (9.7)	5 (8.9)
Hyperparathyroidism	1 (3.2)	1 (1.8)
Toxic nodular goitre	0	1 (1.8)
<b>EYE DISORDERS</b>	<b>3 (9.7)</b>	<b>7 (12.5)</b>
Macular degeneration	1 (3.2)	2 (3.6)
Cataract	0	2 (3.6)
Glaucoma	1 (3.2)	1 (1.8)
Blindness unilateral	0	1 (1.8)
Neovascular age-related macular degeneration	0	1 (1.8)

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<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
Retinal detachment	1 (3.2)	0
Subretinal hyperreflective exudation	0	1 (1.8)
<b>GASTROINTESTINAL DISORDERS</b>	<b>13 (41.9)</b>	<b>13 (23.2)</b>
Nausea	2 (6.5)	3 (5.4)
Constipation	3 (9.7)	1 (1.8)
Gastritis	2 (6.5)	1 (1.8)
Gastrooesophageal reflux disease	2 (6.5)	1 (1.8)
Haemorrhoids	3 (9.7)	0
Abdominal pain	1 (3.2)	1 (1.8)
Chronic gastritis	0	2 (3.6)
Hiatus hernia	1 (3.2)	1 (1.8)
Inguinal hernia	0	2 (3.6)
Large intestine polyp	2 (6.5)	0
Anal fistula	1 (3.2)	0
Diverticulum	0	1 (1.8)
Dyspepsia	1 (3.2)	0
Gastritis erosive	1 (3.2)	0
Haemorrhoidal haemorrhage	1 (3.2)	0
Intestinal ischaemia	0	1 (1.8)
Lip haemorrhage	0	1 (1.8)

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<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
Oesophagitis	1 (3.2)	0
Pancreatitis	0	1 (1.8)
Vomiting	0	1 (1.8)
<b>GENERAL DISORDERS AND ADMINISTRATION SITE</b>	<b>9 (29.0)</b>	<b>10 (17.9)</b>
<b>CONDITIONS</b>		
Asthenia	2 (6.5)	5 (8.9)
Oedema peripheral	3 (9.7)	3 (5.4)
Peripheral swelling	2 (6.5)	2 (3.6)
Fatigue	3 (9.7)	0
Catheter site haematoma	0	2 (3.6)
Chest pain	1 (3.2)	0
Pain	1 (3.2)	0
Pyrexia	0	1 (1.8)
<b>HEPATOBIILIARY DISORDERS</b>	<b>6 (19.4)</b>	<b>6 (10.7)</b>
Hepatic steatosis	2 (6.5)	3 (5.4)
Cholelithiasis	1 (3.2)	3 (5.4)
Hepatic cyst	1 (3.2)	0
Hepatitis	1 (3.2)	0
Liver disorder	1 (3.2)	0

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<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
IMMUNE SYSTEM DISORDERS	1 (3.2)	2 (3.6)
Drug hypersensitivity	0	1 (1.8)
Hypersensitivity	1 (3.2)	0
Seasonal allergy	0	1 (1.8)
INFECTIONS AND INFESTATIONS	10 (32.3)	10 (17.9)
Corona virus infection	2 (6.5)	1 (1.8)
Herpes zoster	0	3 (5.4)
Appendicitis	1 (3.2)	1 (1.8)
Rhinitis	0	2 (3.6)
Urinary tract infection	2 (6.5)	0
Cellulitis	0	1 (1.8)
Cystitis	0	1 (1.8)
Diverticulitis	0	1 (1.8)
Eczema herpeticum	1 (3.2)	0
Erysipelas	1 (3.2)	0
Fungal infection	0	1 (1.8)
Haematoma infection	1 (3.2)	0
Helicobacter infection	0	1 (1.8)
Hepatitis C	1 (3.2)	0
Infection	0	1 (1.8)

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<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
Oral fungal infection	1 (3.2)	0
Peritonsillar abscess	0	1 (1.8)
Pneumonia	1 (3.2)	0
Pseudomonas infection	1 (3.2)	0
Sepsis	1 (3.2)	0
Urosepsis	1 (3.2)	0
<b>INJURY, POISONING AND PROCEDURAL COMPLICATIONS</b>	<b>6 (19.4)</b>	<b>4 (7.1)</b>
Ankle fracture	1 (3.2)	0
Contusion	0	1 (1.8)
Femur fracture	0	1 (1.8)
Lower limb fracture	1 (3.2)	0
Lumbar vertebral fracture	0	1 (1.8)
Pelvic fracture	1 (3.2)	0
Rib fracture	1 (3.2)	0
Spinal column injury	0	1 (1.8)
Splenic injury	1 (3.2)	0
Thermal burn	1 (3.2)	0

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<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
<b>INVESTIGATIONS</b>	5 (16.1)	7 (12.5)
Blood creatinine increased	3 (9.7)	1 (1.8)
Alanine aminotransferase increased	1 (3.2)	2 (3.6)
Gamma-glutamyltransferase increased	2 (6.5)	1 (1.8)
Aspartate aminotransferase increased	0	2 (3.6)
Blood bilirubin increased	0	2 (3.6)
Blood uric acid increased	1 (3.2)	1 (1.8)
C-reactive protein increased	1 (3.2)	1 (1.8)
Bilirubin conjugated increased	0	1 (1.8)
Blood lactate dehydrogenase increased	0	1 (1.8)
Blood urea increased	1 (3.2)	0
Mycobacterium tuberculosis complex test positive	0	1 (1.8)
Neutrophil count decreased	0	1 (1.8)
Serum ferritin increased	1 (3.2)	0
Ureteroscopy	1 (3.2)	0
White blood cell count increased	0	1 (1.8)
<b>METABOLISM AND NUTRITION DISORDERS</b>	17 (54.8)	32 (57.1)
Type 2 diabetes mellitus	4 (12.9)	11 (19.6)
Hyperlipidaemia	3 (9.7)	8 (14.3)
Dyslipidaemia	4 (12.9)	5 (8.9)

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<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
Hyperuricaemia	4 (12.9)	5 (8.9)
Hypercholesterolaemia	3 (9.7)	4 (7.1)
Diabetes mellitus	2 (6.5)	2 (3.6)
Decreased appetite	1 (3.2)	2 (3.6)
Hypoalbuminaemia	1 (3.2)	2 (3.6)
Hypocalcaemia	2 (6.5)	1 (1.8)
Hyperferritinaemia	1 (3.2)	1 (1.8)
Hyperglycaemia	0	2 (3.6)
Hypokalaemia	1 (3.2)	1 (1.8)
Obesity	1 (3.2)	1 (1.8)
Folate deficiency	1 (3.2)	0
Glucose tolerance impaired	0	1 (1.8)
Gout	0	1 (1.8)
Hypertriglyceridaemia	1 (3.2)	0
Hyponatraemia	0	1 (1.8)
Iron deficiency	0	1 (1.8)
Tetany	1 (3.2)	0
<b>MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS</b>	<b>7 (22.6)</b>	<b>17 (30.4)</b>
Osteoarthritis	2 (6.5)	5 (8.9)
Osteoporosis	1 (3.2)	3 (5.4)

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<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
Arthralgia	1 (3.2)	1 (1.8)
Arthritis	0	2 (3.6)
Back pain	0	2 (3.6)
Osteoporosis postmenopausal	1 (3.2)	1 (1.8)
Spinal osteoarthritis	1 (3.2)	1 (1.8)
Bone pain	1 (3.2)	0
Facet joint syndrome	0	1 (1.8)
Fibromyalgia	1 (3.2)	0
Foot deformity	0	1 (1.8)
Gouty arthritis	0	1 (1.8)
Inguinal mass	1 (3.2)	0
Intervertebral disc disorder	0	1 (1.8)
Osteopenia	0	1 (1.8)
Osteoporotic fracture	0	1 (1.8)
Pain in extremity	0	1 (1.8)
Polyarthritis	0	1 (1.8)
Spinal pain	0	1 (1.8)
Spinal stenosis	1 (3.2)	0
Synovial cyst	0	1 (1.8)

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<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	14 (45.2)	13 (23.2)
Prostate cancer	1 (3.2)	3 (5.4)
Breast cancer	2 (6.5)	1 (1.8)
Myelofibrosis	1 (3.2)	2 (3.6)
Uterine leiomyoma	2 (6.5)	1 (1.8)
Essential thrombocythaemia	1 (3.2)	1 (1.8)
Myelodysplastic syndrome	2 (6.5)	0
Polycythaemia vera	1 (3.2)	1 (1.8)
Anal cancer	1 (3.2)	0
B-cell lymphoma	0	1 (1.8)
Benign neoplasm of thyroid gland	1 (3.2)	0
Bladder cancer	1 (3.2)	0
Breast fibroma	0	1 (1.8)
Chronic myelomonocytic leukaemia	0	1 (1.8)
Colorectal adenocarcinoma	0	1 (1.8)
Hairy cell leukaemia	0	1 (1.8)
Leiomyoma	1 (3.2)	0
Malignant melanoma	0	1 (1.8)
Myeloproliferative neoplasm	1 (3.2)	0
Nasal cavity cancer	0	1 (1.8)

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<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
Rectal cancer	0	1 (1.8)
Renal cancer	0	1 (1.8)
<b>NERVOUS SYSTEM DISORDERS</b>	<b>6 (19.4)</b>	<b>13 (23.2)</b>
Carotid arteriosclerosis	0	2 (3.6)
Carotid artery stenosis	1 (3.2)	1 (1.8)
Carpal tunnel syndrome	0	2 (3.6)
Headache	1 (3.2)	1 (1.8)
Transient ischaemic attack	1 (3.2)	1 (1.8)
Cerebrovascular accident	1 (3.2)	0
Cognitive disorder	0	1 (1.8)
Diabetic neuropathy	0	1 (1.8)
Dizziness	0	1 (1.8)
Epilepsy	1 (3.2)	0
Intracranial aneurysm	1 (3.2)	0
Lacunar infarction	0	1 (1.8)
Lumbar radiculopathy	0	1 (1.8)
Neuralgia	1 (3.2)	0
Neuritis	0	1 (1.8)
Neuropathy peripheral	1 (3.2)	0
Post herpetic neuralgia	0	1 (1.8)

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	<b>n (%)</b>	<b>n (%)</b>
Syncope	0	1 (1.8)
Tension headache	1 (3.2)	0
Thalamic infarction	0	1 (1.8)
<b>PREGNANCY, PUERPERIUM AND PERINATAL CONDITIONS</b>	<b>0</b>	<b>1 (1.8)</b>
Ectopic pregnancy	0	1 (1.8)
<b>PSYCHIATRIC DISORDERS</b>	<b>12 (38.7)</b>	<b>5 (8.9)</b>
Insomnia	6 (19.4)	3 (5.4)
Anxiety	4 (12.9)	2 (3.6)
Depression	2 (6.5)	1 (1.8)
Bipolar disorder	1 (3.2)	0
Panic attack	1 (3.2)	0
Tobacco abuse	1 (3.2)	0
<b>RENAL AND URINARY DISORDERS</b>	<b>8 (25.8)</b>	<b>11 (19.6)</b>
Chronic kidney disease	0	4 (7.1)
Nephrolithiasis	1 (3.2)	2 (3.6)
Renal colic	1 (3.2)	1 (1.8)
Renal failure	1 (3.2)	1 (1.8)
Calculus urinary	1 (3.2)	0

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	<b>n (%)</b>	<b>n (%)</b>
Diabetic nephropathy	0	1 (1.8)
Glomerulonephritis	0	1 (1.8)
Haematuria	1 (3.2)	0
Incontinence	1 (3.2)	0
Microalbuminuria	0	1 (1.8)
Micturition urgency	1 (3.2)	0
Pollakiuria	1 (3.2)	0
Renal cyst	1 (3.2)	0
Ureterolithiasis	1 (3.2)	0
Urinary incontinence	0	1 (1.8)
<b>REPRODUCTIVE SYSTEM AND BREAST DISORDERS</b>	<b>5 (16.1)</b>	<b>11 (19.6)</b>
Benign prostatic hyperplasia	3 (9.7)	10 (17.9)
Uterine polyp	2 (6.5)	0
Endometrial atrophy	1 (3.2)	0
Gynaecomastia	1 (3.2)	0
Ovarian cyst	1 (3.2)	0
Vaginal discharge	0	1 (1.8)

Program Location: k:\astx727\02\csr\phase3\_eu\_final\_csr\devel\programs\tf\medhist\_age.sas, Database Extracted: 25MAY2023  
Output: t\_14.2.2.2\_medhist\_age.rtf (Date Generated: 04AUG2023:14:08), Source Data: ADAMDATA.ADSL, ADMH

**ASTX727-02 AML CSR****Population: Safety Analysis Set**

**Table 14.2.2.2**  
**Medical History by SOC and Preferred Term by Age**

<b>MedDRA System Organ Class</b>	<b>Age&lt;75 Years</b>	<b>Age≥75 Years</b>
<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
<b>RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS</b>	12 (38.7)	14 (25.0)
Chronic obstructive pulmonary disease	4 (12.9)	7 (12.5)
Asthma	2 (6.5)	2 (3.6)
Dyspnoea	0	2 (3.6)
Dyspnoea exertional	1 (3.2)	1 (1.8)
Epistaxis	2 (6.5)	0
Sleep apnoea syndrome	2 (6.5)	0
Cough	0	1 (1.8)
Hypersensitivity pneumonitis	0	1 (1.8)
Interstitial lung disease	0	1 (1.8)
Nasal polyps	1 (3.2)	0
Pharyngeal haemorrhage	0	1 (1.8)
Pulmonary embolism	1 (3.2)	0
Pulmonary fibrosis	1 (3.2)	0
Rhinitis allergic	0	1 (1.8)
<b>SKIN AND SUBCUTANEOUS TISSUE DISORDERS</b>	2 (6.5)	4 (7.1)
Actinic keratosis	0	2 (3.6)
Intertrigo	0	1 (1.8)
Night sweats	1 (3.2)	0
Pyoderma gangrenosum	1 (3.2)	0

Program Location: k:\astx727\02\csr\phase3\_eu\_final\_csr\devel\programs\tf\medhist\_age.sas, Database Extracted: 25MAY2023  
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**ASTX727-02 AML CSR****Population: Safety Analysis Set**

**Table 14.2.2.2**  
**Medical History by SOC and Preferred Term by Age**

<b>MedDRA System Organ Class</b>	<b>Age&lt;75 Years</b>	<b>Age≥75 Years</b>
<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
Skin lesion	0	1 (1.8)
Xeroderma	0	1 (1.8)
<b>SOCIAL CIRCUMSTANCES</b>	<b>4 (12.9)</b>	<b>4 (7.1)</b>
Menopause	3 (9.7)	2 (3.6)
Blood product transfusion dependent	1 (3.2)	0
Disease risk factor	0	1 (1.8)
Ex-tobacco user	0	1 (1.8)
<b>SURGICAL AND MEDICAL PROCEDURES</b>	<b>14 (45.2)</b>	<b>17 (30.4)</b>
Appendicectomy	4 (12.9)	4 (7.1)
Cholecystectomy	2 (6.5)	2 (3.6)
Cataract operation	0	3 (5.4)
Knee arthroplasty	2 (6.5)	1 (1.8)
Large intestinal polypectomy	3 (9.7)	0
Skin neoplasm excision	1 (3.2)	2 (3.6)
Tonsillectomy	2 (6.5)	1 (1.8)
Cancer surgery	1 (3.2)	1 (1.8)
Hip arthroplasty	1 (3.2)	1 (1.8)
Hysterectomy	1 (3.2)	1 (1.8)
Anal fistula excision	0	1 (1.8)

Program Location: k:\astx727\02\csr\phase3\_eu\_final\_csr\devel\programs\tfl\t\_medhist\_age.sas, Database Extracted: 25MAY2023  
Output: t\_14.2.2.2\_medhist\_age.rtf (Date Generated: 04AUG2023:14:08), Source Data: ADAMDATA.ADSL, ADMH

**ASTX727-02 AML CSR****Population: Safety Analysis Set**

**Table 14.2.2.2**  
**Medical History by SOC and Preferred Term by Age**

<b>MedDRA System Organ Class</b>	<b>Age&lt;75 Years</b>	<b>Age≥75 Years</b>
<b>MedDRA Preferred Term</b>	<b>(N=31)</b>	<b>(N=56)</b>
	<b>n (%)</b>	<b>n (%)</b>
Arterial therapeutic procedure	1 (3.2)	0
Breast operation	0	1 (1.8)
Caesarean section	0	1 (1.8)
Cardiac pacemaker insertion	1 (3.2)	0
Cervical polypectomy	1 (3.2)	0
Elbow operation	1 (3.2)	0
Female sterilisation	1 (3.2)	0
Gastric banding	1 (3.2)	0
Haemorrhoid operation	1 (3.2)	0
Hernia repair	0	1 (1.8)
Implantable cardiac monitor insertion	0	1 (1.8)
Inguinal hernia repair	0	1 (1.8)
Mastectomy	1 (3.2)	0
Nasal polypectomy	0	1 (1.8)
Nephrectomy	0	1 (1.8)
Prostatectomy	0	1 (1.8)
Sclerotherapy	0	1 (1.8)
Shoulder operation	1 (3.2)	0
Thrombectomy	0	1 (1.8)
Urinary bladder suspension	1 (3.2)	0
Vascular graft	0	1 (1.8)

Program Location: k:\astx727\02\csr\phase3\_eu\_final\_csr\devel\programs\tfl\t\_medhist\_age.sas, Database Extracted: 25MAY2023  
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**ASTX727-02 AML CSR****Population: Safety Analysis Set**

**Table 14.2.2.2**  
**Medical History by SOC and Preferred Term by Age**

<b>MedDRA System Organ Class</b> <b>MedDRA Preferred Term</b>	<b>Age&lt;75 Years</b> <b>(N=31)</b> <b>n (%)</b>	<b>Age≥75 Years</b> <b>(N=56)</b> <b>n (%)</b>
Vitrectomy	1 (3.2)	0
VASCULAR DISORDERS	26 (83.9)	41 (73.2)
Hypertension	25 (80.6)	38 (67.9)
Deep vein thrombosis	0	3 (5.4)
Aortic aneurysm	2 (6.5)	0
Essential hypertension	0	2 (3.6)
Haematoma	2 (6.5)	0
Peripheral arterial occlusive disease	0	2 (3.6)
Peripheral vascular disorder	2 (6.5)	0
Aneurysm	0	1 (1.8)
Arteriosclerosis	1 (3.2)	0
Intermittent claudication	0	1 (1.8)
Penetrating aortic ulcer	1 (3.2)	0
Peripheral ischaemia	0	1 (1.8)
Peripheral venous disease	0	1 (1.8)
Thrombophlebitis	0	1 (1.8)
Thrombophlebitis superficial	0	1 (1.8)
Varicose vein	0	1 (1.8)
Venous thrombosis	0	1 (1.8)

Program Location: k:\astx727\02\csr\phase3\_eu\_final\_csr\devel\programs\tfl\t\_medhist\_age.sas, Database Extracted: 25MAY2023  
Output: t\_14.2.2.2\_medhist\_age.rtf (Date Generated: 04AUG2023:14:08), Source Data: ADAMDATA.ADSL, ADMH

**Comorbidities by SOC and Preferred Term (< 75 years)**

<b>Comorbidity (as documented on the Subject Eligibility Review Form [SERF])</b>	<b>Age&lt;75 Years (N=31) n (%)</b>
LVEF ≤ 50 %, n (%)	2 (6.5)
DL <sub>CO</sub> ≤ 65 %, n (%)	2 (6.5)
FEV1 ≤ 65 %, n (%)	2 (6.5)
Chronic stable angina or congestive heart failure controlled with medication, n (%)	4 (12.9)
Other contraindication(s) to anthracycline therapy, n (%)	1 (3.2)
<b>Other comorbidities by MedDRA SOC / PT</b>	
Psychiatric disorders / Depression	1 (3.2)
Surgical and medical procedures / Cardiac pacemaker insertion	1 (3.2)
Respiratory, thoracic, and mediastinal disorders / Chronic obstructive pulmonary disease	2 (6.5)
Cardiac disorders / Left atrial dilatation	1 (3.2)
Atrial fibrillation	1 (3.2)
Neoplasms benign, malignant and unspecified (incl. cysts and polyps) / Breast cancer recurrent	2 (6.5)
Vascular disorders / Peripheral vascular disorder	1 (3.2)
Hypertension	2 (6.5)
Metabolism and nutrition disorders / Diabetes Mellitus Type 2 Diabetes	1 (3.2)
Nervous System Disorders / Peripheral neuropathy	1 (3.2)
Cerebrovascular accident	1 (3.2)
Infections And Infestations / Hepatitis C	1 (3.2)
<b>Other reasons</b>	

**Comorbidities by SOC and Preferred Term (< 75 years)**

<b>Comorbidity (as documented on the Subject Eligibility Review Form [SERF])</b>	<b>Age&lt;75 Years (N=31) n (%)</b>
Patient's strong wish against intensive chemotherapy	2 (6.5)
Performance status decreased	1 (3.2)
Not a candidate for intensive chemotherapy in the Czech Republic (age > 65 years)	7 (22,6)