

**ADJUDICATION**

**DEFINITIONS & CODELIST**

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***TALOS:***

**CITALOPRAM IN ACUTE STROKE**

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# Adjudication Definitions

## According to WHO's Adverse Reaction Terminology

### **AE = ADVERSE EVENTS**

- Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have to have a causal relationship with this treatment.

### **AR = ADVERSE REACTION**

- All noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions.

### **SAE = SERIOUS ADVERSE EVENTS**

An adverse event is any undesirable experience associated with the use of a medical product in a patient. The event is serious when the patient outcome is:

- **Death** If you suspect that the death was an outcome of the adverse event, and include the date if known.
- **Life-threatening** If suspected that the patient was at substantial risk of dying at the time of the adverse event, or use or continued use of the device or other medical product might have resulted in the death of the patient.
- **Hospitalization (initial or prolonged)** If admission to the hospital or prolongation of hospitalization was a result of the adverse event. Emergency room visits that do not result in admission to the hospital should be evaluated for one of the other serious outcomes (e.g., life-threatening; required intervention to prevent permanent impairment or damage; other serious medically important event).
- **Disability or Permanent Damage** If the adverse event resulted in a substantial disruption of a person's ability to conduct normal life functions, i.e., the adverse event resulted in a significant, persistent or permanent change, impairment, damage or disruption in the patient's body function/structure, physical activities and/or quality of life.
- **Congenital Anomaly/Birth Defect** If you suspect that exposure to a medical product prior to conception or during pregnancy may have resulted in an adverse outcome in the child.
- **Required Intervention to Prevent Permanent Impairment or Damage (Devices)** If you believe that medical or surgical intervention was necessary to preclude permanent impairment of a body function, or prevent permanent damage to a body structure, either situation suspected to be due to the use of a medical product.
- **Other Serious (Important Medical Events)** If the event does not fit the other outcomes, but the event may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the other outcomes. Examples include allergic bronchospasm (a serious problem with breathing) requiring treatment in an emergency room, serious blood dyscrasias (blood disorders) or seizures/convulsions that do not result in hospitalization. The development of drug dependence or drug abuse would also be examples of important medical events.

### **SAR = SERIOUS ADVERSE REACTION**

- SAE where a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, i.e., the relationship cannot be ruled out.

**SUSAR = SUSPECTED UNEXPECTED SERIOUS ADVERSE REACTION**

- Serious adverse reactions in subjects given a drug, that may or may not be dose related, but are unexpected, as they are not consistent with current information.

## DIAGNOSTIC DEFINITIONS

### ACUTE CORONARY SYNDROMES (ACS)

Divided operationally in:

- Acute myocardial infarction with concomitant ST-segment elevation in the ECG (STEMI)
- Acute myocardial infarction without ST-segment elevation in the ECG (NSTEMI)
- Unstable angina (UAP)

#### **Acute myocardial infarction (AMI)**

Defined according to the *Third universal definition of myocardial infarction*. (1)

The term acute myocardial infarction (MI) is used when there is evidence of myocardial necrosis in a clinical setting consistent with acute myocardial ischaemia.

#### **UAP**

Characterized by (2)

- Angina pectoris occurring during rest or with minimal exertion
- Crescendo angina pectoris in patients with pre-existing chronic stable angina with increase in seizure frequency and/or duration

UAP is a clinical diagnosis made on the basis of medical history. Transient ECG changes support the diagnosis and have prognostic significance, but are not mandatory. The heart-specific biomarkers are by definition normal because the condition would otherwise be classified as NSTEMI.

### ARRHYTHMIA

Any variation from the normal rhythm of the heartbeat - diagnosed using e.g. ECG, Holter monitor and telemetry - including

- Sinus arrhythmia
- Premature beat
- Heart block
- Atrial fibrillation/flutter (3)
- Tachycardia

#### **Serious Arrhythmias**

- Any arrhythmia requiring a) surgical or b) invasive intervention or c) DC cardioversion

#### **Major Arrhythmias**

- Complete heart block, ventricular tachycardia and ventricular fibrillation

#### **Minor Arrhythmias**

- Any arrhythmia that is not listed in the serious or major arrhythmia.

### BLEEDING (4,5)

Bleeding event will be defined according to Global Utilization Of Streptokinase And Tpa For Occluded Arteries (*GUSTO*) definition for bleeding

1. Severe or Life-threatening
  - Intracranial hemorrhage
  - Resulting in substantial hemodynamic compromise requiring treatment
2. Moderate
  - Requiring blood transfusion but not resulting in hemodynamic compromise
3. Mild

- Bleeding that does not meet above criteria

### CARDIAC FAILURE

The table below describes the New York Heart Association (NYHA) Functional Classification, which places patients into one of four categories based on how much they are limited during physical activity. (6)

Class	Functional Capacity: How a patient with cardiac disease feels during physical activity
I	Patients with cardiac disease but resulting in no limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnoea or anginal pain.
II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnoea or anginal pain.
III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnoea or anginal pain.
IV	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases.

### RENAL INSUFFICIENCY

Newly diagnosed (after first dosage project medication) kidney damage or glomerular filtration rate (GFR) <60 mL/min/1.73m<sup>2</sup>. Kidney damage is defined as pathological abnormalities or markers of damage, including abnormalities in blood or urine test or imaging studies.

### DEPRESSION

The World Health Organization (WHO) International Classification of Diseases (ICD) is primarily used in Denmark for depression diagnostics. The treating physician may at his/her discretion independently diagnose depression and evaluate for open-label antidepressant treatment indication. Final study evaluation will be made by the study PI/Sponsor using ICD 10 coding.

#### ***Depressive episode (F32)***

In typical mild, moderate, or severe depressive episodes, the patient suffers from lowering of mood, reduction of energy, and decrease in activity. Capacity for enjoyment, interest, and concentration is reduced, and marked tiredness after even minimum effort is common. Sleep is usually disturbed and appetite diminished. Self-esteem and self-confidence are almost always reduced and, even in the mild form, some ideas of guilt or worthlessness are often present. The lowered mood varies little from day to day, is unresponsive to circumstances and may be accompanied by so-called "somatic" symptoms, such as loss of interest and pleasurable feelings, waking in the morning several hours before the usual time, depression worst in the morning, marked psychomotor retardation, agitation, loss of appetite, weight loss, and loss of libido. Depending upon the number and severity of the symptoms, a depressive episode may be specified as mild, moderate or severe.

#### ***Incl.:***

Single episodes of:

- Depressive reaction
- Psychogenic depression

- Reactive depression

***Excl.:***

- Adjustment disorder
- Recurrent depressive disorder
- When associated with conduct disorders

***F32.0 - Mild depressive episode***

Two or three of the above symptoms are usually present. The patient is usually distressed by these but will probably be able to continue with most activities.

***F32.1 - Moderate depressive episode***

Four or more of the above symptoms are usually present and the patient is likely to have great difficulty in continuing with ordinary activities.

***F32.2 - Severe depressive episode without psychotic symptoms***

An episode of depression in which several of the above symptoms are marked and distressing, typically loss of self-esteem and ideas of worthlessness or guilt. Suicidal thoughts and acts are common and a number of "somatic" symptoms are usually present.

**DIABETES**

Diabetes is diagnosed according to the World Health Organization (7,8).

***HbA1c***

- Diabetes is diagnosed at an A1C of greater than or equal to 6.5%

***Fasting Plasma Glucose (FPG)***

- Diabetes is diagnosed at fasting blood glucose of greater than or equal to 1.26 mg/ml

***Oral Glucose Tolerance Test (OGTT)***

- Diabetes is diagnosed at 2 hour blood glucose of greater than or equal to 2.00 mg/ml

***Random Plasma Glucose Test***

- Diabetes is diagnosed at blood glucose of greater than or equal to 2,0 mg/ml

**DIZZINESS**

- Lightheadness and/or
- Unsteadiness of gait

**DYSPNOEA**

A feeling of difficult or laboured breathing that is out of proportions to the patient's level of physical activity.

**EMBOLISM**

Free flowing blood clot or lesion material that is located in the systemic or pulmonary circulation.

**ENCEPHALOPATHY**

Altered mental state including coma, confusion, delirium, dementia and hallucinations.

Also includes patients with

- Recurrence of initial stroke symptoms and
- No new visible infarctions on cerebral CT/MRI and
- Where other plausible non-neurological reversible cause is found, e.g. urinary tract infection or dehydration

**HEPATIC DYSFUNCTION**

Increase in plasma alanine aminotransferase (ALAT)-concentration  $\geq 2$  times normal<sup>1</sup>

**HYPOTENSION**

Systolic BP < 90 mmHg

**INFECTION**

One or more of the following

- Elevated body temperature<sup>2</sup> (fever)
- Elevated White Blood Count (>12,000/ml and significant leftward shift)
- Positive culture (e.g. urine, blood)

Urinary tract infection can be diagnosed by at least two of following criteria

- Fever<sup>3</sup>
- Increased urinary frequency, urgency, dysuria, suprapubic tenderness, or costovertebral angle pain (not explained by other diagnoses)
- Positive urine culture of at least 10<sup>5</sup> colony-forming units/mL with no more than two species of microorganisms AND/OR positive<sup>4</sup> rapid urine test

**LOW PLASMA SODIUM CONCENTRATION**

- Newly diagnosed (after first dose project medication) P-[Na<sup>+</sup>] values <138 mM.
- Any measured P-[Na<sup>+</sup>] values <130 mM.

**MORTALITY**

A serious adverse event that is classified by the following (adapted from (9)):

**All-cause mortality**

Deaths from any cause (includes all cardiovascular and non-cardiovascular deaths).

**Cardiovascular mortality:**

Any of the following criteria:

- Death due to proximate cardiac cause (e.g. myocardial infarction, cardiac tamponade, worsening heart failure)
- Death caused by non-coronary vascular conditions such as neurological events, pulmonary embolism, ruptured aortic aneurysm, dissecting aneurysm, or other vascular disease
- All procedure-related deaths, including those related to a complication of the procedure or treatment for a complication of the procedure
- All valve-related deaths including structural or non-structural valve dysfunction or other valve-related adverse events
- Sudden or unwitnessed death
- Death of unknown cause

**Non-cardiovascular mortality**

- Any death in which the primary cause of death is clearly related to another condition (e.g. trauma, cancer, suicide)

**MYOCARDIAL INFARCTION (MI)**

Clinical myocardial infarction (1) (if possible classified according to sub-type)

- Type 1: Spontaneous myocardial infarction related to ischemia due to a primary coronary event such as plaque erosion and/or rupture, fissuring, or dissection

- **Type 2:** Myocardial infarction secondary to ischemia due to either increased oxygen demand or decreased supply, e.g. coronary artery spasm, coronary embolism, anaemia, arrhythmias, hypertension, or hypotension
- **Type 3:** Sudden unexpected cardiac death, including cardiac arrest, often with symptoms suggestive of myocardial ischemia, accompanied by presumably new ST elevation, or new LBBB, or evidence of fresh thrombus in a coronary artery by angiography and/or at autopsy, but death occurring before blood samples could be obtained, or at a time before the appearance of cardiac biomarkers in the blood
- **Type 4a:** Myocardial infarction associated with PCI
- **Type 4b:** Myocardial infarction associated with stent thrombosis as documented by angiography or at autopsy
- **Type 5:** Myocardial infarction associated with CABG

### **PSEUDOBULBAR AFFECT**

Emotionalism is a particular feature of neurological disorders and is characterized by a disturbance of the normal control of expression of emotion. It is defined as *“an increase in crying or laughing, where the crying or laughing comes with little or no warning and emotional expression is outside normal control, so that the subject cries or laughs in social situations where he or she would not previously have done so”* (10,11)

### **QTc: Prolonged interval**

- Any corrected-QT (QTc)  $\geq 480$  ms or
- Newly diagnosed (after inclusion)  $\geq 450$  ms

### **RENAL DYSFUNCTION**

Rise in baseline creatinine by  $\geq 25\%$ .

### **SEIZURE/EPILEPSY (12)**

A disorder characterized by recurrent episodes of paroxysmal brain dysfunction due to a sudden, disorderly, and excessive neuronal discharge.

Divided functionally in

1. Partial seizures (i.e., focal or localization-related seizures) and
2. Generalized seizures

### **STROKE AND TIA (9)**

#### **Diagnostic criteria**

- Acute episode of a focal or global neurological deficit with at least one of the following:
  - Change in the level of consciousness
  - Hemiplegia
  - Hemiparesis
  - Numbness /sensory loss affecting one side of the body
  - Dysphasia / aphasia
  - Hemianopia
  - Amaurosis fugax
  - Other neurological signs or symptoms consistent with stroke

- No other readily identifiable non-stroke cause for the clinical presentation (e.g. brain tumour, trauma, infection, hypoglycaemia, peripheral lesion, pharmacological influences), to be determined by or in conjunction with the designated neurologist
- Confirmation of the diagnosis by at least one of the following
  - Neurologist or neurosurgical specialist
  - Neuroimaging procedure (brain CT or MRI), but stroke may be diagnosed on clinical grounds alone

### **Stroke classification** (13)

#### **Stroke**

- Rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than of vascular origin

#### **TIA**

- By applying this definition transient ischemic attack (TIA), which is defined to last less than 24 hours.

#### **Ischaemic**

- An acute episode of focal cerebral dysfunction caused by infarction of the central nervous system tissue.

#### **HAEMORRHAGIC**

- An acute episode of focal or global cerebral or spinal dysfunction caused by intraparenchymal or intraventricular

#### **SAH**

- Sudden bleeding into the subarachnoid space

#### **UNDETERMINED**

- A stroke may be classified as undetermined if there is insufficient information to allow categorization as ischaemic or haemorrhagic

### **Stroke definitions**

- Disabling stroke (at approximately 90 days):
  - A score of  $\geq 3$  on the modified Rankin Scale (mRS)
- Non-disabling stroke (at approximately 90 days):
  - Score of  $\leq 2$  on the mRS

#### **SYNCOPE**

Partial or complete transient loss of consciousness with interruption of awareness of oneself and ones surroundings

## ADJUDICATION CODELIST

Event Code	Description
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### NEUROLOGICAL & PSYCHIATRIC / PSEUDOBULBAR AFFECT

<i><b>Neurovascular</b></i>	
000	Disabling Stroke – Haemorrhagic
001	Disabling Stroke – Ischemic
002	Intracerebral Haemorrhage (Non-Stroke)
003	Non-Disabling Stroke – Haemorrhagic
004	Non-Disabling Stroke – Ischemic
005	Subarachnoid hemorrhage (SAH)
006	Transient Ischemic Attack (TIA)
007	Neurovascular - Other (Specify)
<i><b>Encephalopathy</b></i>	
008	Coma
009	Delirium
010	Seizure
011	Encephalopathy - Other (Specify)
<i><b>Psychiatric / Pseudobulbar affect</b></i>	
012	Depression
013	Laugh Lability
014	Pathological Crying
015	Psychiatric - Other (Specify)
<i><b>Other Neurological</b></i>	
016	Headache
017	Dizziness – non-cardiovascular
018	Syncope – non-cardiovascular
019	Neurological - Other (Specify)

### CARDIOVASCULAR

<i><b>Cardiac Ischemia</b></i>	
100	ACS: Myocardial Infarction – STEMI
101	ACS: Myocardial Infarction – NSTEMI
102	ACS: Unstable Angina
103	Stable Angina
104	Cardiac Ischemia - Other (Specify)
<i><b>Arrhythmia (New Onset Only)</b></i>	
105	Arrhythmia – Severe
106	Arrhythmia – Major
107	Arrhythmia – Minor
108	Permanent Pacemaker Implant
109	Tachycardia – Sinus
110	Atrial Fibrillation

111	Arrhythmia – Other (Specify)
<b>Heart Failure</b>	
112	Left Ventricular Insufficiency (Specify NYHA-Class)
113	Right Ventricular Insufficiency
114	Heart Failure – Other (Specify)
<b>Peripheral Vascular (Specify Site)</b>	
115	Claudication
116	New Extremity Ischemia
117	Peripheral Vascular – Other (Specify)
<b>Other Cardiovascular</b>	
118	Bleeding – See <i>Bleeding Category</i>
119	Cardiogenic Shock
120	Cardiopulmonary Bypass
121	Chest Pain
122	Electrocardiogram – Other Abnormal Findings (Specify)
123	Electrocardiogram – Elongated QTc-Interval <ul style="list-style-type: none"> <li>• Newly diagnosed partially prolonged (<math>\geq 450</math> ms) and</li> <li>• All absolute prolonged (<math>\geq 480</math> ms)</li> </ul>
124	Endovascular Or Surgical Intervention – Planned (Specify Site)
125	Endovascular Or Surgical Intervention – Unplanned (Specify Site)
126	Orthoestatism
127	Peripheral Edema
128	Pulmonary Edema
129	Dizziness – cardiovascular
130	Syncope – cardiovascular
131	Cardiovascular – Other (Specify)
<b>BLEEDING (Specify Site)</b>	
232	Bleeding - Severe or Life-threatening
233	Bleeding - Moderate
234	Bleeding - Mild

<b>MORTALITY</b>	
<b>Proximate Cardiac Cause</b>	
300	Death, Cardiovascular, Proximate Cardiac Cause – Myocardial Infarction
301	Death, Cardiovascular, Proximate Cardiac Cause – Other (Specify)
<b>Non-Coronary</b>	
302	Death, Cardiovascular, Non-Coronary Vascular Conditions – Neurological Event
303	Death, Cardiovascular, Non-Coronary Vascular Conditions – Pulmonary Embolism
304	Death, Cardiovascular, Non-Coronary Vascular Conditions – Dissecting Aneurysm
305	Death, Cardiovascular, Non-Coronary Vascular Conditions – Other (Specify)
<b>Cardiovascular - Other</b>	
306	Death, Cardiovascular – Non-Structural Valve Dysfunction
307	Death, Cardiovascular – Sudden Or Unwitnessed
308	Death, Cardiovascular – Death Of Unknown Cause

309	Death, Cardiovascular – Other (Specify)
<b>Non-Cardiovascular</b>	
310	Death, Non-Cardiovascular – Malignancy
311	Death, Non-Cardiovascular – Accidental
312	Death, Non-Cardiovascular – Infection/Sepsis
313	Death, Non-Cardiovascular – Renal Disease
314	Death, Non-Cardiovascular – Hepatic Failure
315	Death, Non-Cardiovascular – COPD
316	Death, Non-Cardiovascular – Other (Specify)

<b>GASTRO-INTESTINAL, RESPIRATORY, URINARY / GENITAL ORGANS, INFECTION AND SKIN</b>	
<b>Gastro-intestinal</b>	
400	Diarrhoea
401	Hematemesis
402	Ventricle Ulcus
403	Biochemical - Hepatic Dysfunction
404	Gastro-Intestinal - Other (Specify)
<b>Respiratory</b>	
405	Respiratory Insufficiency/Failure
406	Respiratory - Other (Specify)
<b>Urinary / Genital</b>	
407	Renal Insufficiency (newly diagnosed)
408	Biochemical - Renal Dysfunction
409	Urinary And Genital Organs - Other (Specify)
<b>Infection</b>	
410	Infection – Pulmonary
411	Infection – Urinary
412	Infection – Gastrointestinal
413	Infection – Other (Specify)
<b>Skin</b>	
414	Mild To Moderate Bruising Or Ecchymosis
415	<i>Peripheral Edema</i> (See Vascular)
416	Sweating
417	Skin – Other (Specify)
<b>Bone</b>	
418	Fall causing bone fracture

<b>ABNORMAL PARACLINICAL FINDINGS CATEGORY</b>	
501	Biochemical - Low Plasma Sodium Concentration
502	Paraclinical - Other (Specify)

<b>NEOPLASM, ENDOCRINE, BLOOD AND BLOOD FORMING ORGANS &amp; NUTRITIONAL AND METABOLIC DISEASES (Newly Diagnosed)</b>	
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<b>Neoplasm</b>	
601	Carcinoma In Situ
602	Benign Neoplasms
603	Neoplasm - Other (Specify)
<b>Blood and blood forming organs</b>	
604	Haemolysis
605	Anaemia
606	Diseases In Blood And Blood Forming Organs - Other (Specify)
<b>Endocrine, nutritional and metabolic diseases</b>	
607	Diabetes
608	Endocrine, nutritional and metabolic – Other (Specify)

<b>SURGERY</b>	
701	Carotid Endarectomy
702	Carotid Artery Stenting
<b>Other Surgery</b>	
703	Surgery – Other (Specify)

<b>OTHER</b>	
801	Other, specify

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<sup>1</sup> Alanine Aminotransferase

<sup>2</sup> Single oral temperature >37.8°C AND/OR Persistent oral or tympanic membrane temperature ≥37.2°C AND/OR Rectal temperature ≥37.5°C AND/OR Rise in temperature of ≥1.1°C above baseline temperature

<sup>3</sup> Single oral temperature >37.8°C AND/OR Persistent oral or tympanic membrane temperature ≥37.2°C AND/OR Rectal temperature ≥37.5°C AND/OR Rise in temperature of ≥1.1°C above baseline temperature

<sup>4</sup> Leukocytes and nitrite can indicate a bacterial infection – final diagnostics made by the treating clinician