Sample – Safety Narrative Writing

Seriousness criterion of the event

Death:	☐
Serious adverse event:	☐
Involved or Prolonged inpatient Hospitalisation	☒
Discontinuation due to laboratory abnormality:	☐
Life Threatening	☒

Protocol:	Gxxxxxx
Subject identifier:	Y
Subject demographics:	66-year-old of unknown male
Treatment group:	Drug P: z mg x y days
Date of first dose of study drug:	DD-MM - YYYY
Date of last dose of study drug:	DD-MM - YYYY
Serious adverse event (Preferred Term):	Superventricular Tachycardia

Narrative: This is the report from the clinical study entitled "A Long-term, Multi-centre, International, Randomised Double-blind, Placebo-controlled Trial to Determine Drug P Effects on Cardiovascular Events" carried out by healthcare professionals (HCP). Subject Mr.D had type 2 diabetes mellitus which was diagnosed in 1996. The subject had co morbid conditions like hyperlipidaemia, hypertension, bowel obstruction and also partial pancreatectomy and splenectomy was done. During the study the subject haven't received any relevant concomitant medication associated with the event. The patient had a no history of tobacco use.

On DD-MM - YYYY the patient was treated with trial drug P Vs. Placebo and on-going for type 2 diabetes mellitus. On DD-MM - YYYY, during the routine follow up with a doctor the medical assistant visualized a rapid, fast heart rate and reported to the doctor. The doctor examined the subject heart rate to be at 150 beats/min and the blood pressure (B/P) was 118/80.An electrocardiogram (ECG) examination revealed cardiac arrhythmia, possible sinus tachycardia, left axis deviation, right bundle branch block (RBBB) with left anterior fascicular block, inferior infarct-age undetermined, lateral T wave changes may be an indicative of myocardial ischemia. Meanwhile, on DD-MM - YYYY Electrocardiogram (EKG) examination showed cardiac arrhythmia. The subject was asymptomatic and administered with Aspirin (acetylsalicylic acid) and water, then admitted to the hospital. Further to confirm, the cardiac biomarkers analysis was performed on DD-MM - YYYY and results were as follows, Blood creatine phosphokinase (CPK) was 109.0 U/L, CPKMB was 1.2 ng/mL, CPK-MB repeat was <0.01 ng/mL, Troponin I was <0.05 ng/mL and finally Troponin I repeat was <0.02 ng/mL. The subject was monitored overnight, but no cause of cardiac arrhythmia was found. On DD-MM - YYYY the patient had recovered and was discharged. Based on the medical records, the investigator indicated as supraventricular tachycardia. The cardiac biomarkers were found to be in the normal clinical range. The event was not associated with acute coronary syndrome but with trifascicular block and aortic valve sclerosis. The action taken to trial drug was reported as dose not changed. Dechallenge and Re-challenge was missing. Finally, on DD-MM - YYYY trial drug was un-blinded according to regulatory requirements.

In the opinion of the sponsor, array of clinical scenarios can lead to or cause arrhythmia (supraventricular tachycardia) including high blood pressure, diabetes, stress, alcohol and coronary artery disease. The patient had been treated with trial drug for almost two years before the event which does not indicate a chronological relationship. Furthermore the patient recovered without changes made to trial drug administration. With the provided information the sponsor assesses the event and trial drug as unlikely related.

In the opinion of the investigator, the event assessed as possibly related.