Serious Adverse Event Report

Event 14-Jan-2022 - report of 19-Jan-2022 - 06:46 UTC, revision 1

Initial Report Date	19-Jan-2022
Date of this report	19-Jan-2022
Investigator/reporter	Pawel Bartosz
Study Protocol (Id and Title)	H-34 - DELTA Revision study
Site Information	101 - Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Patient ID	10
Event onset	14-Jan-2022
Report type	Initial
Date of Study Team Aware	14-Jan-2022 08:51
Title of clinical study	H-34 - DELTA Revision study
Name of the healthcare facility	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP
Name of the Principal Investigator	Jerzy Białecki
Name of the medical device involved	N/A
Components involved	N/A
ID number of study subject	101 - 10
Age	76
Gender	Male
Attribution within the clinical investigation	TreatmentGroup

Adverse Event (diagnosis, if known, or signs/symptoms)	Dyspnoea, fluid collection in lungs
Event narrative	Chronic heart failure exacerbation
Admission date (dd-mmm-yyyy)	30-Dec-2021
Discharge date (dd-mmm-yyyy)	18-Jan-2022
Classification of the adverse event	Hospitalization
Outcome of the event	Ongoing
Relevant concomitant drugs and date of administration	Furosemid 40mg 2xday from 14.01.2022.
Detail all possible and suspected causes including relevant medical histor	Chronic heart failure
Current clinical status	Good
Severity	Moderate
Causality: relationship to study medical device	NotRelated
Causality: relationship to study procedure	NotRelated
Expectedness	NA
Action taken	Pharmacological
Was the device permanently removed?	No
Detailed treatment	
Relevant medical history	None
Relevant medical records	None

10 Report

Laboratory Results	None
Imaging Methods (e.g., X-ray, CT-scan)	None
Other (please specify)	None
Submitter	Investigator
Name of submitter	Pawel Bartosz