



Drop-out Log

Protocol ID:	H-34	Principal Investigator:	Dr Jerzy Bialecki
Protocol short title:	Delta Revision CUP	Study site ID:	01
Study site name:	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP	Country:	Poland

Subject ID	Subject Withdrawn? (yes/no)	If withdrawn, record the date of withdrawn (dd/mmm/yyyy)	If withdrawn, record reason for withdrawn (specify)	Subject Lost Follow Up? (yes/no)	If lost follow up, record the date of lost follow up (dd/mmm/yyyy)	If lost follow up, record the date of last contact and the reason for lost follow up (dd/mmm/yyyy)
A01-12	Y <input checked="" type="checkbox"/> N <input checked="" type="checkbox"/>	22 FEB 2022	intraoperative damage of iliac vessels	Y <input checked="" type="checkbox"/> N <input checked="" type="checkbox"/>		
A01-09	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>	03 DEC 2021	cup loosening	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>	04.11.22	04.11.2027
A01-14	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>	28 JUL 2022	cup loosening	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>	04.11.2021	PATIENT DOES NOT WANT TO CONTACT
A01-6	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>	01 DEC 2021	lost to follow up	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>	01 DEC 2021	01 DEC 2021
	Y <input type="checkbox"/> N <input type="checkbox"/>			Y <input type="checkbox"/> N <input type="checkbox"/>		
	Y <input type="checkbox"/> N <input type="checkbox"/>			Y <input type="checkbox"/> N <input type="checkbox"/>		
	Y <input type="checkbox"/> N <input type="checkbox"/>			Y <input type="checkbox"/> N <input type="checkbox"/>		
	Y <input type="checkbox"/> N <input type="checkbox"/>			Y <input type="checkbox"/> N <input type="checkbox"/>		
	Y <input type="checkbox"/> N <input type="checkbox"/>			Y <input type="checkbox"/> N <input type="checkbox"/>		



Protocol Deviation Log

Protocol ID:	H-34	Principal Investigator:	Dr Jerzy Bialecki
Protocol short title:	Delta Revision CUP	Study site ID:	101
Study site name:	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP	Country:	Poland

Site ID	Subject ID	Date of deviation (dd/mmm/yyyy)	Category of deviation (Minor, major, critical)	Description of deviation	Reason for deviation and corrective measures taken	IRB/IEC Notification (yes/no)	Date of closure (dd/mmm/yyyy)
101	101-02	30/SEP/2021	MAJOR	THE DATE OF ICF SIGNATURE THE SITE STAFF WAS WRITTEN BY SJ, NOT SUBJECT. WAS RETRAINED	Y <input type="checkbox"/> N <input type="checkbox"/>		
101	101-03	11/OCT/2021	MAJOR	THE DATE OF ICF SIGNATURE THE SITE STAFF WAS WRITTEN BY SJ, NOT SUBJECT. WAS RETRAINED	Y <input type="checkbox"/> N <input type="checkbox"/>		
101	101-04	20/OCT/2021	MAJOR	IF NOT SIGNED BY THE SUBJECT TO SIGN THE ICF THE DATE WRITTEN BY SJ, NOT SUBJECT SITE WAS RETRAINED	Y <input type="checkbox"/> N <input type="checkbox"/>	03/NOV/2021	
101	101-05	26/OCT/2021	MAJOR	THE DATE OF ICF SIGNATURE THE SITE STAFF WRITTEN BY SJ, NOT SUBJECT. WAS RETRAINED	Y <input type="checkbox"/> N <input type="checkbox"/>		
101	101-06	25/OCT/2021	MAJOR	THE DATE OF ICF SIGNATURE THE SITE STAFF WRITTEN BY SJ, NOT SUBJECT. WAS RETRAINED	Y <input type="checkbox"/> N <input type="checkbox"/>		
101	101-07	11/NOV/2021	MAJOR	THE DATE OF ICF SIGNATURE THE SITE STAFF WRITTEN BY SJ, NOT SUBJECT. WAS RETRAINED	Y <input type="checkbox"/> N <input type="checkbox"/>		
101	101-07-101-16	09/NOV/2021	MAJOR	CONSENT PROCESS NOT DOCUMENTED THE SITE WAS ADVISED TO PROVIDE SUPPLEMENT	Y <input type="checkbox"/> N <input type="checkbox"/>	04/NOV/2021	
101	101-14	17/NOV/2021	MAJOR	DELAYED SAFE REPORTING THE SITE WAS ADVISED TO REPORT SAER WITHIN 24H	Y <input type="checkbox"/> N <input type="checkbox"/>	09/NOV/2021	
101	101-07	20/NOV/2021	MINOR	OUT OF WINDOW VISIT	THE VISIT IS OUT OF SCHEDULE	Y <input type="checkbox"/> N <input type="checkbox"/>	09/NOV/2021
101	101-07	20/NOV/2021	MINOR	OUT OF WINDOW VISIT	THE VISIT IS OUT OF SCHEDULE	Y <input type="checkbox"/> N <input type="checkbox"/>	09/NOV/2021
101	101-2	29/MAY/2022	MAJOR	6 MFU VISIT WAS NOT DONE	LACK OF CONTACT WITH PATIENT	Y <input type="checkbox"/> N <input type="checkbox"/>	29 MAY 2022
101	101-17	26 APR 2023	MAJOR	LATE SAER REPORTING	OMISSION	Y <input type="checkbox"/> N <input type="checkbox"/>	17 MAY 2023
						Y <input type="checkbox"/> N <input type="checkbox"/>	