



## 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Subject ID	Subject Withdrawn?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 <u>withdrawn</u> , record the date of withdrawn (dd/mm/yyyy)	If <u>withdrawn</u> , record reason for withdrawn (specify)	Subject Lost Follow Up? (yes/no)	If lost follow up, record the date of lost follow up (dd/mm/yyyy)	If lost follow up, record the date of last contact and the reason for lost follow up (dd/mm/yyyy)
101-12	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"/>		
101-09	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>	03 DEC 2021	cup loosening	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>		
101-14	Y <input checked="" type="checkbox"/> N <input type="checkbox"/>	28 JUL 2022	cup loosening	Y <input type="checkbox"/> N <input checked="" type="checkbox"/>	<del>01 DEC 2021</del>	<del>01 DEC 2021</del>
101-6	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	PATIENT DOES NOT WANT TO CONTACT 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

<b>Protocol ID:</b>	H-34	<b>Principal Investigator:</b>	Dr Jerzy Bialecki
<b>Protocol short title:</b>	Delta Revision CUP	<b>Study site ID:</b>	101
<b>Study site name:</b>	Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP	<b>Country:</b>	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/JER/2021	MAJOR	THE DATE OF ICF SIGNATURE WAS WRITTEN BY SI, NOT BY SUBJECT. WAS RETAINED	THE SITE STAFF	Y <input type="checkbox"/> N <input type="checkbox"/>	
101	101-03	11/OCT/2021	MAJOR	THE DATE OF ICF SIGNATURE WAS WRITTEN BY SI, NOT BY SUBJECT. WAS RETAINED	THE SITE STAFF	Y <input type="checkbox"/> N <input type="checkbox"/>	
101	101-04	20/OCT/2021	MAJOR	ICF NOT SIGNED BY THE SUBJECT. THE DATE WRITTEN BY SI, NOT BY SUBJECT. SITE WAS RETAINED	THE SITE STAFF	Y <input type="checkbox"/> N <input type="checkbox"/>	03/PRP/2022
101	101-05	26/OCT/2021	MAJOR	THE DATE OF ICF SIGNATURE WAS WRITTEN BY SI, NOT BY SUBJECT. WAS RETAINED	THE SITE STAFF	Y <input type="checkbox"/> N <input type="checkbox"/>	
101	101-06	25/OCT/2021	MAJOR	THE DATE OF ICF SIGNATURE WAS WRITTEN BY SI, NOT BY SUBJECT. WAS RETAINED	THE SITE STAFF	Y <input type="checkbox"/> N <input type="checkbox"/>	
101	101-07	11/NOV/2021	MAJOR	THE DATE OF ICF SIGNATURE WAS WRITTEN BY SI, NOT BY SUBJECT. WAS RETAINED	THE SITE STAFF	Y <input type="checkbox"/> N <input type="checkbox"/>	
101	101-07-10-14	09/NOV/2021	MAJOR	CONSENT PROCESS NOT DOCUMENTED	THE SITE WAS ALERTED TO PROVIDE SUPPLEMENT	Y <input type="checkbox"/> N <input type="checkbox"/>	04/NOV/2022
101	101-14	17/NOV/2022	MAJOR	DELAYED SAE REPORTING	THE SITE WAS ALERTED TO REPORT SAE WITHIN 24H	Y <input type="checkbox"/> N <input type="checkbox"/>	09/NOV/2022
101	101-07	20/NOV/2022	MINOR	OUT OF WINDOW VISIT	THE SITE STAFF SCHEDULED THE VISITS AS PER PROTOCOL	Y <input type="checkbox"/> N <input type="checkbox"/>	09/NOV/2022
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"/>	23/MAY/2022
101	101-17	26/APR/2023	MAJOR	LATE SAE REPORTING	OMISSION	Y <input type="checkbox"/> N <input type="checkbox"/>	17/MAY/2023
						Y <input type="checkbox"/> N <input type="checkbox"/>	