Monitoring Report

1. General information	
Study ID:	**H-34 DELTA REVISION**
Principal Investigator:	**Dr. Jerzy Białecki**
Study site ID:	**101**
Study site:	**Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Grucy CMKP** **Księdza Stanisława Konarskiego, 13 - 05-400 Otwock, Poland**

Attendees, Site/Role		Attendees, Monitor (Sponsor/CRO/other)
Dr Jerzy Białecki (PI) **Dr Julia Macias (SI)**		**Adam Kogut**
Visit #: **2**	Date of Visit: **03 Feb 2022**	Date of previous visit: **18 Nov 2021**

SUBJECT ENROLMENT INFORMATION

Target Number of subjects:

Number Screened from logs (including failures)	Number Screened failure	Number Enrolled	Number Ongoing	Number Completed	Number withdrawn	
					AE	Other
10	0	10	9	0	1	

Is the recruitment rate satisfactory?	Yes	No	NA
	☒	☐	☐
Comments			

2. Site Staff			
Changes to SSDDL since previous visit (if “Yes”, please specify below)?	Yes	No	NA
	☐	☒	☐
Comments	There were no changes in site staff since the previous visit.		
Has the assignment of all study personnel remained consistent and the Responsibilities /Signature Log been maintained?	Yes	No	NA
	☒	☐	☐
Comments			
Are training logs completed and available at the site? (if “No”, please specify below)	Yes	No	NA
	☒	☐	☐
Comments	The training logs are present in the ISF, including the new training on ICF process performed on the last MV.		
Are CV and GCP certificates completed and available at the	Yes	No	NA
	☐	☒	☐

site? (if “No”, please specify below)			
Comments	CVs are present for the whole study staff, however, only Dr. Macias’ GCP certificate was provided so far to the CRA. The remaining site staff will provide the current GCP certificates for filling after the visit. See CAPA #5		
Are Financial Disclosure (if applicable) completed and available at the site? (if “No”, please specify below)	Yes	No	NA
	☒	☐	☐
Comments	FD forms were collected from all site team members and filed in ISF.		

3. Administration & Regulatory			
Confirm adequate storage space for site records			
Location of Investigator Site File (ISF)	Locked shelf in the medical office available to the study site staff.		
Is the ISF up-to-date (list below the new documents in the ISF if applicable)?	Yes	No	NA
	☒	☐	☐
Comments	The following documents were filed during the visit: EC notification, IMV2 confirmation letter, MV1 follow-up letter, correspondence with the site, GCP certificate of Dr. Macias, FD forms signed by all site staff, Declaration of conformity and the updated insurance policy. See CAPA #4		
Has the Site Monitoring Log been updated?	Yes	No	NA
	☒	☐	☐
Comments			
Is the current protocol filled in the ISF?	Yes	No	NA
	☒	☐	☐
Comments	The most current protocol version is 1.1 dated 28 Sep 2020.		
Has the PI signed the protocol signature page and amendments (if applicable)?	Yes	No	NA
	☒	☐	☐
Comments	All protocol signature pages are filed in ISF. The most current protocol version is 1.1 dated 28 Sep 2020.		
Is the current ICF filled in the ISF?	Yes	No	NA
	☒	☐	☐
Comments	The current ICF version 1.0 dated 4 Feb 2020..		
Has EC approval of the protocol and amendments (if available) been filed in the ISF?	Yes	No	NA
	☒	☐	☐
Comments	The initial EC approval granted on 9 Sep 2020. A protocol non substantial amendment sent to EC on 26 Nov 2020. The confirmation of receipt dated 26 Nov 2020 and EC notification dated on November 2021 filed in the ISF.		

Is the insurance current and filed in the ISF?	Yes	No	NA
	☒	☐	☐
Comments	The updated insurance policy no. ITLSCC13149 valid till 30Jun2022 is filed in the ISF. See CAPA #4		

4. Medical Device			
Study Medical Device:			
Is the Declaration of Conformity current and filed in the ISF?	Yes	No	NA
	☒	☐	☐
Comments			
Is the IDE/510(k) or CE certificate current and filed in the ISF?	Yes	No	NA
	☒	☐	☐
Comments			
Is the device accountability reviewed?	Yes	No	NA
	☐	☐	☒
Comments			No accountability required since this study is post market.

5. Subject Logs			
Has the Screening/Enrolment Log been checked and is it up-to-date?	Yes	No	NA
	☒	☐	☐
Comments			
Has the Identification Log up-to-date?	Yes	No	NA
	☒	☐	☐
Comments			

6. Consent Form			
Is there a signed, and dated consent form for each subject enrolled?	Yes	No	NA
	☐	☒	☐
Comments	The following ICFs were reviewed during the visit: Subject 101-02 (#101/02): - 18Nov2021: signed the ICF on 30Sep2021, however no printed name was written by the subject.		

	The date of signature was written by SI instead of the subject. The site staff was retrained and instructed to collect a statement from the subject confirming that the subject agreed to participate in the study. The statement should be signed with the current date by the subject. See CAPA #3 - Update 03Feb2022: the ICF was updated by the subject's statement documenting that on 30Sep2021 he/she agreed to participate in the study (statement personally dated by the subject on 06Dec2021), however, no subject's signature was placed under the statement. The printed name was completed by the subject, however, no date and signature was placed next to that change. See CAPA #3 Subject 101-03 (#101/04): - 18Nov2021: signed the ICF on 11Oct2021, however no printed name was written by the subject on ICF enclosures. The date of signature was written by SI instead of the subject. The site staff was retrained and instructed to collect a statement from the subject confirming that the subject agreed to participate in the study. The statement should be signed with the current date by the subject. See CAPA #3 - Update 03Feb2022: no changes from the previous visit. See CAPA #3 Subject 101-04 (#101/05): - 18Nov2021: no signature was placed by the subject. The subject personally printed his/her name on the ICF, however, the date was written by SI instead of the subject. The site staff was retrained and instructed to collect a statement from the subject confirming that the subject agreed to participate in the study. The statement should be signed with the current date by the subject. See CAPA #2 - Update 03Feb2022: the ICF was updated by the subject's statement documenting that he/she agreed to participate in the study. The ICF was signed by the subject with the exception of "Secondary use of data" part of the ICF. Subject 101-05 (#101/06): - 18Nov2021: signed the ICF on 26Oct2021, however the date of signature was written by SI instead of the subject. The site staff was retrained and instructed to collect a statement from the subject confirming that the subject agreed to participate in the study. The statement should be signed with the

	current date by the subject. See CAPA #3- Update 03Feb2022: no changes from the previous visit. Subject 101-06 (#101/07): - 18Nov2021: signed the ICF on 25Oct2021, however the date of signature was written by SI instead of the subject. The site staff was retrained and instructed to collect a statement from the subject confirming that the subject agreed to participate in the study. The statement should be signed with the current date by the subject. See CAPA #3- Update 03Feb2022: no changes from the previous visit. Subject 101-07 (#101/08): - 18Nov2021: signed the ICF on 11Nov2021, however the date of signature and subject's printed name was written by SI instead of the subject. The site staff was retrained and instructed to collect a statement from the subject confirming that the subject agreed to participate in the study. The statement should be signed with the current date by the subject. See CAPA #3 - Update 03Feb2022: the ICF was updated by the subject on 04Jan2022 by crossing out the printed name previously completed by SI. The change was signed and dated by the subject. No subject's statement was obtained documenting that he/she agreed to participate in the study. See CAPA #3 Subject 101-08 (#101/09) correctly signed and personally dated the ICF and enclosures on 21Nov2021. No issues were noted. Subject 101-09 (#101/10) correctly signed and personally dated the ICF and enclosures on 04Jan2022. No issues were noted. Subject 101-10 (#101/11) correctly signed and personally dated the ICF and enclosures on 19Jan2022. No issues were noted.		
Has consent been documented in the subject notes?	Yes	No	NA
	☒	☐	☐
Comments	The supplementary notes with the current date documenting the whole consenting process were completed during the MV. See CAPA #7		
Has a consent form been signed and dated by the subject/s before or on the day that any study-related	Yes	No	NA
	☒	☐	☐

procedures were performed?			
Comments	All subjects enrolled since the last visit correctly signed the ICF. The consenting process was documented in medical documentation during the MV. The site staff was reminded that the consenting process must be documented for each subject.		
Is the Informed Consent Process conducted by site staff delegated per SSDDL (if "No", please provide a comment below)?	Yes	No	NA
	☒	☐	☐

7. Source Data Review: Confirm subject eligibility							
New patients since previous MV							
Subject #	ICF V.#	Date of consent	Surgery Date	ICP appropriate	Subject meets all Inclusion criteria	Subject does not meet all Exclusion criteria	Comments
101-08	1.0	21Nov2021	22Nov2021	☒	☒	☒	
101-09	1.0	04Jan2022	10Jan2022	☒	☒	☒	
101-10	1.0	19Jan2022	19Jan2022	☒	☒	☒	

8. Source Data Verification			
Confirm source documents are accurate, complete and current			
Nature of source data (electronic vs. paper; access; etc.)	The SD was printed out for all subjects, however, the consenting process and eligibility was documented as a supplementary documentation during the MV. eCRF was used as SD for some of the data. Including race, intensity of activity daily living, work status, smoking habits, alcohol drinking habits and radiographical description including presence of osteophytes and presence of cystis. The site staff will provide the updated medical documentation signed with the current date to support the data completed into the eCRF.		
Are the source documents adequate, available and up-to-date?	Yes	No	NA
	☐	☒	☐
Comments	The consenting process and subjects' eligibility was documented during the MV (See CAPA #7). The eCRF was used as SD for race, intensity of activity daily living, work status, smoking habits, alcohol drinking habits and radiographical description including presence of osteophytes and presence of cystis. The site staff was retrained and asked to provide supplementary notes with the current date.		
Source data entries are consistent with SSDDL? (if "No",	Yes	No	NA
	☒	☐	☐

please provide a comment below)			
Comments			
Is each subject in compliance with the protocol and amendments (if applicable)?	Yes	No	NA
		☒	☐
Comments	See CAPA #3 and #7		
Are the CRFs properly completed, in compliance with CRF guidelines and are they up-to-date?	Yes	No	NA
	☐	☒	☐
Comments	Due to lack of SI's time no all queries were resolved and CRF corrected during the visit. The SI was asked to correct the CRF as soon as possible after the visit.		
Have CRF corrections been made in the proper manner by authorised personnel?	Yes	No	NA
	☒	☐	☐
Comments			
Has SDV been performed as agreed (and documented)?	Yes	No	NA
	☒	☐	☐
Comments	Due to a large size of past and current medical documentation (approx. 150 pages per subject) mostly the Pre-Operative visit and eligibility verification was performed.		
Have SDV discrepancies been noted? Please list in the comment box if any.	Yes	No	NA
	☒	☐	☐
Comments			
Have any withdrawals been noted in the subject notes?	Yes	No	NA
	☐	☒	☐
Comments			
Have any data queries been addressed at this visit?	Yes	No	NA
	☒	☐	☐
Comments	Due to lack of SI's time no all queries were resolved and CRF corrected during the visit. All other open queries will be resolved after the visit.		

Verify overall data reported is reflective of source data			
Subject #	Visit	Checked	Comment
101-1	Pre-operative Visit	☒	Eligibility review.
101-1	Intraoperative Visit	☒	Partial review
101-2	Pre-operative Visit	☒	Eligibility review.

101-2	Intraoperative Visit	☒	Partial review
101-3	Pre-operative Visit	☒	Eligibility review.
101-3	Intraoperative Visit	☒	Partial review
101-4	Pre-operative Visit	☒	Eligibility review.
101-4	Intraoperative Visit	☒	Partial review
101-5	Pre-operative Visit	☒	Eligibility review.
101-5	Intraoperative Visit	☒	Partial review
101-6	Pre-operative Visit	☒	Eligibility review.
101-6	Intraoperative Visit	☒	Partial review
101-7	Pre-operative Visit	☒	Eligibility review.
101-7	Intraoperative Visit	☒	Partial review
101-8	Pre-operative Visit	☒	Eligibility review.
101-8	Intraoperative Visit	☒	Partial review
101-9	Pre-operative Visit	☒	Eligibility review.
101-9	Intraoperative Visit	☒	Partial review
101-10	Pre-operative Visit	☒	Eligibility review.
101-10	Intraoperative Visit	☒	Partial review

9. Adverse Events (AE)			
New Adverse Events occurred since last MVR?	Yes	No	NA
	☐	☒	☐

Subject #	Description (i.e. diagnosis, onset & end date, outcome, therapy, MD relationship, comments)

10. Serious Adverse Events (SAE)			
Has a New Serious Adverse Events occurred since last MVR? (please provide information in table **below**)	Yes	No	NA
	☒		☐
Was the Sponsor notified within the timelines as per protocol?	Yes	No	NA
	☐	☒	☐
Comment	**The Sponsor was informed with a delay about the SAE due to site's staff mistake.**		
Was the EC/IRB notified by clinical site?	Yes	No	NA
	☐	☒	☐
Comment	The EC will be informed about the protocol deviation due to ICF process.		
Is there appropriate documentation regarding SAEs (how to report them, blank forms and any completed forms) contained within the ISF and SD?	Yes	No	NA
	☒	☐	☐
Comment			

Subject #	Description (e.g.: onset & end date, outcome, diagnosis, therapy, comments)
101/09	

Onset date	End date	Status	Intensity	Relation with MD
01Dec2021	10Dec2021	Resolved	Severe	Not related

Diagnosis	Cup loosening
Therapy	Revision surgery
Sponsor notified	07Dec2021
Comment	Patient withdrawn

101/05

Onset date	End date	Status	Intensity	Relation with MD
20Oct2021	27Oct2021	Resolved	Severe	Not related

Diagnosis	Intraoperative fracture of femur shaft
Therapy	intraoperative reduction and fixation of the fracture
Sponsor notified	03Feb2022
Comment	CAPA #9

101/10	

Onset date	End date	Status	Intensity	Relation with MD
14Jan2022	NA	Ongoing	Moderate	Not related

Diagnosis	Chronic heart failure
Therapy	Concomitant medication
Sponsor notified	19Jan2022
Comment	

10.1 New Information on previous Serious Adverse Events (SAE)

	Yes	No	NA
New information available for previous SAEs (please provide information in section **10.1**)?	☐	☐	☒

#	Description

Reference MVR	Reference SAE #

Onset date	End date	Status	Intensity	Relation with MD

Diagnosis	
Therapy	
Sponsor notified	
Comment	

11. Corrective and preventive actions (Follow-up Items)

Ensure appropriate corrections, additions, or deletions are made, dated, explained and signed

Are issues identified during the MV? Please update the table below with the issues	Yes	No	NA
	☒	☐	☐

#	Issue Date	Finding	Action Required	Action Taken	Status (closed/open)
1	**18Nov2021**	**Subject 101/3 doubled in the e-CRF**	**Subject 101/3 should be removed from e-CRF**	**Informing the Sponsor to remove the subject from the list of subjects**	**Closed**

2	**18Nov2021**	**Subject 101-4 did not sign ICF**	**To collect from the subject a statement confirming that the subject agreed to participate in the study. The statement should be signed with the current date by the subject.** **To check with the subject the reason why "Secondary use of data" part of the ICF was not signed.**	**The site staff was retrained and instructed to collect a statement from the subject.** **Update 03Feb2022: the ICF was updated by the subject's statement documenting that he/she agreed to participate in the study. The ICF was signed by the subject with the exception of "Secondary use of data" part of the ICF.**	**Open**
3	**18Nov2021**	**Subjects 101-2 – 101-7 did not personally date the ICF**	**To collect from the subject a statement confirming that the subject agreed to participate in the study. The statement should be signed with the current date by the subject.**	**The site staff was retrained and instructed to collect a statement from the subject.** **Update 03Feb2022: the statement collected from subjects 101-2 and 101-4.** **The missing signed statement that have not been collected during the recent visits of the patients at site, will be collected during their next visit at site.**	**Open**
4	**18Nov2021**	**Updated insurance policy not filed in the ISF**	**To file the updated version of the insurance policy**	**Sponsor was informed about the need of the copy of updated insurance policy.** **Update: The updated insurance policy was filed in the ISF.**	**Closed**

5	**18Nov2021**	**Lack of copies of current GCP certificates from the site staff**	**To file the current GCP certificates in ISF**	**Site staff was asked to provide the GCP certificates.** **Update: The GCP certificate of Dr. Macias was collected and filed in ISF.**	**Open**
6	**18Nov2021**	**Lack of printed out SD**	**To print out the SD of all subjects**	**The site staff was asked to provide printed out SD**	**Closed**
7	**18Nov2021**	**Consent process not documented in subjects notes from patients 101-01 to 101-07**	**To provide supplementary notes with the current date documenting the whole consenting process.**	**The site staff was retrained and instructed to provide supplementary notes.** **Update: The consenting process was documented during the MV.**	**Closed**
8	**11Jun2021**	**Missing laboratory certificates**	**To collect the missing laboratory certificates from the site local laboratory.**	**The site staff was asked to collect the laboratory certificates.**	**Closed**
9	**3 Feb2022**	**SAE communication and process for subject number 101-**	**The site should be retrained on SAE communication process.**	**The site has been retrained.**	**Closed**
10	**03Feb2022**	**Pending queries**	**To resolve pending queries**	**The site staff was asked to resolve pending queries not resolved during the visit.**	**Open**

11	**03Feb2022**	**eCRF was used as SD for some of the data. Including race, intensity of activity daily living, work status, smoking habits, alcohol drinking habits and radiographical description including presence of osteophytes and presence of cystis.**	**To provide the updated medical documentation signed with the current date to support the data completed in eCRF.**	**Site staff was asked to provide the updated medical documentation.**	

12. Discussion with Principal investigator	
Ensure appropriate corrections, additions, or deletions are made, dated, explained and signed	
Topics	The current open issues were discussed with PI.

13. Closure of Monitoring Visit Report	
Comment	The purpose of this monitoring visit was to perform SDV on completed CRFs as well as consenting procedures and overall site performance with respect to ICH-GCP and ISO 14155 requirement. During the visit the consenting process was verified, subjects' eligibility was checked as well as SDV was performed.

	Role	Name and Surname	Date	Signature
Written by:	CRA	Adam Kogut	18/2/2022 | 15:01 CET	DocuSigned by: Adam Kogut Signer Name: Adam Kogut Signing Reason: I am the author of this document Signing Time: 18/2/2022 | 15:01 CET 9D23805603764291AFE4F20144B06401
Approved by:	CMCL	Federica Azzimonti	18/2/2022 | 15:58 CET	DocuSigned by: Federica Azzimonti Signer Name: Federica Azzimonti Signing Reason: I approve this document Signing Time: 18/2/2022 | 15:58 CET F76117269A994B43A353A3F6CBA0F6D9

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In Person Signer Events	Signature	Timestamp

Editor Delivery Events	Status	Timestamp

Agent Delivery Events	Status	Timestamp

Intermediary Delivery Events	Status	Timestamp

Certified Delivery Events	Status	Timestamp

Carbon Copy Events	Status	Timestamp

Witness Events	Signature	Timestamp

Notary Events	Signature	Timestamp

Envelope Summary Events	Status	Timestamps
Envelope Sent	Hashed/Encrypted	2/18/2022 2:45:42 PM
Certified Delivered	Security Checked	2/18/2022 3:58:40 PM
Signing Complete	Security Checked	2/18/2022 3:58:55 PM
Completed	Security Checked	2/18/2022 3:58:55 PM

Payment Events	Status	Timestamps

Electronic Record and Signature Disclosure

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