



# Monitoring Report

1. General information		
Study ID:	<b>H-34 DELTA REVISION</b>	
Principal Investigator:	<b>Dr. Jerzy Bialecki</b>	
Study site ID:	<b>101</b>	
Study site:	<b>Samodzielny Publiczny Szpital Kliniczny im. Prof. Adama Gruicy CMKP Księda Stanisława Konarskiego, 13 - 05-400 Otwock, Poland</b>	
Attendees, Site/Role	Attendees, Monitor (Sponsor/CRO/other)	
<b>Dr Julia Macias (SI)</b>	<b>Adam Kogut</b>	
Visit #: 3	Date of Visit: <b>09 Jun 2022</b>	Date of previous visit: <b>03 Feb 2022</b>

## 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Screened from logs (including failures)	Number Screened failure	Number Enrolled	Number Ongoing	Number Completed	Number withdrawn	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
13	1	12	11	0	1	
Is the recruitment rate satisfactory?		Yes		No		NA
		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>		<input type="checkbox"/>
Comments		The enrolment is slightly below the expectations infact the planned patients agreed with the PI are 2 patients per months, whereas here we have 1,3 patients per month The site staff is looking for potential eligible subjects.				

## 2. Site Staff

Changes to SSDDL since previous visit (if "Yes", please specify below)?	Yes	No	NA
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
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
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments			
Are training logs completed and available at the site? (if "No", please specify below)	Yes	No	NA
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments	The training logs dated 11Jun2021, 18Nov2021 and 03Feb2022 are present in the ISF.		
Are CV and GCP certificates completed and available at the site? (if "No", please specify below)	Yes	No	NA
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>



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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. Dr. Macias was reminded to provide the GCP certificates of all remaining site staff. See <b>CAPA #5</b>		
Are Financial Disclosure (if applicable) completed and available at the site? (if "No", please specify below)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
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 <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA <input type="checkbox"/>
Comments	The following documents were filed during the visit: IMV3 confirmation letter, MV2 follow-up letter and correspondence with the site. Protocol Deviation log is missing ( <b>See CAPA #14</b> )		
Has the Site Monitoring Log been updated?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
Comments			
Is the current protocol filled in the ISF?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
Comments	All protocol signature pages are signed and filed in ISF. The most current protocol version is 1.1 dated 28 Sep 2020.		
Is the current ICF filled in the ISF?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
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 <input type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
Comments	The initial EC approval granted on 9 Sep 2020. A protocol non substantial amendment package sent to EC on 26 Nov 2020. The confirmation of non substantial amendment receipt dated 26 Nov 2020 and EC notification dated on November 2021 are filed in the ISF.		
Is the insurance current and filed in the ISF?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>



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Comments	The updated insurance policy no. ITLSCC13149 valid till 30Jun2022 is filed in the ISF. <b>See CAPA #4</b>		
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4. Medical Device			
Study Medical Device:			
Is the Declaration of Conformity current and filed in the ISF?	Yes	No	NA
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments			
Is the IDE/510(k) or CE certificate current and filed in the ISF?	Yes	No	NA
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments			
Is the device accountability reviewed?	Yes	No	NA
	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
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
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments		The reason of non-eligibility for screen failure subject (101-11) to be provided in the log.	
Has the Identification Log up-to-date?	Yes	No	NA
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments			

6. Consent Form			
Is there a signed, and dated consent form for each subject enrolled?	Yes	No	NA
		<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments	<p>In general yes, however, below issues for the following ICFs reviewed during the visit were noted:</p> <p>Subject 101-02 (#101/02):</p> <ul style="list-style-type: none"><li>- 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. <b>See CAPA #3</b></li><li>- Update 03Feb2022: the ICF was updated by the subject's statement</li></ul>		



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	<p>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. <b>See CAPA #3</b></p> <p>- Update 09Jun2022: no changes from the previous visit. <b>See CAPA #3</b></p> <p><b>Subject 101-03 (#101/04):</b></p> <ul style="list-style-type: none"><li>- 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. <b>See CAPA #3</b></li><li>- Update 03Feb2022: no changes from the previous visit. <b>See CAPA #3</b></li><li>- Update 09Jun2022: no changes from the previous visit. <b>See CAPA #3</b></li></ul> <p><b>Subject 101-04 (#101/05):</b></p> <ul style="list-style-type: none"><li>- 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. <b>See CAPA #2</b></li><li>- 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.</li><li>- Update 09Jun2022: no changes from the previous visit.</li></ul> <p><b>Subject 101-05 (#101/06):</b></p> <ul style="list-style-type: none"><li>- 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. <b>See CAPA #3</b></li><li>- Update 03Feb2022: no changes from the previous visit.</li><li>- Update 09Jun2022: no changes from the previous visit.</li></ul> <p><b>Subject 101-06 (#101/07):</b></p> <ul style="list-style-type: none"><li>- 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. <b>See CAPA #3</b></li><li>- Update 03Feb2022: no changes from the previous visit.</li><li>- Update 09Jun2022: no changes from the previous visit.</li></ul> <p><b>Subject 101-07 (#101/08):</b></p> <ul style="list-style-type: none"><li>- 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</li></ul>
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	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. <b>See CAPA #3</b> - 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. <b>See CAPA #3</b> - Update 09Jun2022: On ICF signature pages subject placed the signature and current date (04Jan2022).  The EC will be informed about the deviation. <b>CAPA #2 and #3</b>		
	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.		
	Subject 101-11 (#101/12) correctly signed and personally dated the ICF and enclosures on 22Feb2022, however, the subject did not select the option about subject's agreement on informing the GP and using collected data for future studies. The subject is a SCF and will not come back to the site for updating the ICF.		
	Subject 101-12 (#101/13) correctly signed and personally dated the ICF and enclosures on 12Apr2022. No issues were noted.		
	Subject 101-13 (#101/14) correctly signed and personally dated the ICF and enclosures on 26Apr2022. No issues were noted.		
Has consent been documented in the subject notes?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA <input type="checkbox"/>
Comments	The supplementary notes with the current date documenting the whole consenting process were completed for the subjects 1-7. For the next subjects the consenting process was not documented. The site staff was reminded that the consenting process must be documented for each subject <b>See CAPA #12</b>		
Has a consent form been signed and dated by the subject/s before or on the day that any study-related procedures were performed?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA <input type="checkbox"/>
Comments	All subjects enrolled since the last visit correctly signed the ICF but there are deviations regarding the first 7 patients to the date of ICF <b>See CAPA #2 and #3</b>		
Is the Informed Consent Process conducted by site staff delegated per SSDDL (if "No", please provide a comment below)?	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>

### 7. Source Data Review: Confirm subject eligibility



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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
101-11	1.0	22Feb2022	NA	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	SCF - correctly signed and personally dated the ICF and enclosures on 22Feb2022, however, the subject did not select the option about subject's agreement on informing the GP and using collected data for future studies. Only brief review was performed due to the lack of SD documenting the procedures performed at screening visit and confirmation of non-eligibility of the subject.
101-12	1.0	12Apr2022	12Apr2022	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	80% of SDV was performed and confirmation of eligibility of the subject was confirmed.
101-13	1.0	26Apr2022	26Apr2022	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	80% of SDV was performed and



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						confirmation of eligibility of the subject was confirmed.
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## 8. Source Data Verification

Confirm source documents are accurate, complete and current

Nature of source data (electronic vs. paper; access; etc.)	The SD from first visits was printed out for subjects 1-7, the data from follow-up visits in a limited form was available in electronic version, however, the consenting process ( <b>See CAPA #12</b> )  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 evaluation. A NTF will be prepared and archived in the ISF for the patients already enrolled. For new enrolled patients worksheets will be utilized. <b>See CAPA #11</b>		
Are the source documents adequate, available and up-to-date?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA <input type="checkbox"/>
Comments	The consenting process was not documented since the last MV ( <b>See CAPA #12</b> ). The eCRF was used as SD for race, intensity of activity daily living, work status, smoking habits, alcohol drinking habits and radiographical evaluation. <b>See CAPA #11</b>  The site staff was reminded to provide supplementary notes including Medical history from the previous visit documented with the current date, the information about consenting of the subjects with the current date. <b>CAPA #12</b>		
Source data entries are consistent with SSDDL? (if "No", please provide a comment below)	Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	NA <input type="checkbox"/>
Comments			
Is each subject in compliance with the protocol and amendments (if applicable)?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA <input type="checkbox"/>
Comments	<b>See CAPA #3 and #12</b> The out of window visits of subject 101/7 FU 6 Months was noted. The site was reminded to perform the visit within the protocol defined timeframe. <b>See CAPA #14</b> The subject 101-5 (#101/6) missed the FU2 Months FU visit, the site was not able to reach subject so far to schedule the visit.		
Are the CRFs properly completed, in compliance with CRF guidelines and are they up-to-date?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>	NA <input type="checkbox"/>
Comments	Most of queries were resolved during the MV, the remaining queries will be resolved after the MV. <b>See CAPA #10</b>		
Have CRF corrections been made	Yes	No	NA



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in the proper manner by authorised personnel?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Comments			
Has SDV been performed as agreed (and documented)?	Yes	No	NA
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments	Due to missing SD with data covering large amount of study specific data only partial SDV was performed. During the MV the site staff was instructed to document all data completed into the CRF. The supplementary notes were created with the current date to document missing information. The site staff was asked to complete the remaining supplementary notes for the rest of the subjects. Due to lack of time there was no possibility to resolve all SD issues during the visit.		
<b>Update after MV of 09June2022</b> A NTF will be prepared and archived in the ISF for the patients already enrolled. For new enrolled patients worksheets will be utilized. <b>See CAPA #11</b>			
Have SDV discrepancies been noted? Please list in the comment box if any.	Yes	No	NA
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments			
Have any withdrawals been noted in the subject notes?	Yes	No	NA
	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
Comments			
Have any data queries been addressed at this visit?	Yes	No	NA
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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	Intraoperative visit	<input checked="" type="checkbox"/>	surgery and implant data checked, ConMeds need to be double checked during the next visit.
101-1	FU at Discharge	<input checked="" type="checkbox"/>	All fields according to the MP from FU at Discharge visit was reviewed.
101-1	FU 2 Months	<input checked="" type="checkbox"/>	All fields
101-1	FU 6 Months	<input checked="" type="checkbox"/>	All fields
101-2	Intraoperative visit	<input checked="" type="checkbox"/>	surgery and implant data checked, ConMeds need to be double checked during the next visit.
101-2	FU at Discharge	<input checked="" type="checkbox"/>	All fields
101-2	FU 2 Months	<input checked="" type="checkbox"/>	All fields
101-3	Intraoperative visit	<input checked="" type="checkbox"/>	surgery and implant data checked, ConMeds need to be double checked during the next visit.



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101-3	FU at Discharge	<input checked="" type="checkbox"/>	All fields
101-3	FU 2 Months	<input checked="" type="checkbox"/>	Partial review – HHS and Oxford not completed in CRF. The data will be SDV'd during the next visit.
101-4	Intraoperative visit	<input checked="" type="checkbox"/>	surgery and implant data checked, ConMeds need to be double checked during the next visit.
101-5	Intraoperative visit	<input checked="" type="checkbox"/>	surgery and implant data checked, ConMeds need to be double checked during the next visit.
101-6	Intraoperative visit	<input checked="" type="checkbox"/>	surgery and implant data checked, ConMeds need to be double checked during the next visit.
101-7	Intraoperative visit	<input checked="" type="checkbox"/>	surgery and implant data checked, ConMeds need to be double checked during the next visit.
101-9	Intraoperative visit	<input checked="" type="checkbox"/>	surgery and implant data checked, ConMeds need to be double checked during the next visit.
101-9	FU at discharge	<input checked="" type="checkbox"/>	Date of visit, AEs
101-11	Pre-operative Visit	<input checked="" type="checkbox"/>	Eligibility review.
101-12	Pre-operative Visit	<input checked="" type="checkbox"/>	Eligibility review.
101-12	Intraoperative Visit	<input checked="" type="checkbox"/>	surgery and implant data checked, ConMeds need to be double checked during the next visit.



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<b>9. Adverse Events (AE)</b>																												
New Adverse Events occurred since last MVR?		Yes	No	NA																								
		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																								
Subject #	Description (i.e. diagnosis, onset & end date, outcome, therapy, MD relationship, comments)																											
101/13	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Onset date</td> <td style="width: 20%;">End date</td> <td style="width: 20%;">Status</td> <td style="width: 20%;">Intensity</td> <td style="width: 20%;">Relation with MD</td> </tr> <tr> <td>11Apr2022</td> <td>19Apr2022</td> <td>Recovered</td> <td>Mild</td> <td>Not related</td> </tr> <tr> <td colspan="5"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Diagnosis</td> <td>Intraoperative fracture of great trochanter</td> </tr> <tr> <td>Therapy</td> <td>Not pharmacological</td> </tr> <tr> <td>Sponsor notified</td> <td>09Jun2022</td> </tr> <tr> <td>Comment</td> <td></td> </tr> </table> </td> </tr> </table>					Onset date	End date	Status	Intensity	Relation with MD	11Apr2022	19Apr2022	Recovered	Mild	Not related	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Diagnosis</td> <td>Intraoperative fracture of great trochanter</td> </tr> <tr> <td>Therapy</td> <td>Not pharmacological</td> </tr> <tr> <td>Sponsor notified</td> <td>09Jun2022</td> </tr> <tr> <td>Comment</td> <td></td> </tr> </table>					Diagnosis	Intraoperative fracture of great trochanter	Therapy	Not pharmacological	Sponsor notified	09Jun2022	Comment	
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Comment																												

<b>10. Serious Adverse Events (SAE)</b>					
Has a New Serious Adverse Events occurred since last MVR? (please provide information in table below)		Yes	No	NA	
		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Was the Sponsor notified within the timelines as per protocol?		Yes	No	NA	
		<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Comment		<b>The Sponsor was informed with a delay about the SAE due to site's staff mistake. See CAPA #9 and #13</b>			
Was the EC/IRB notified by clinical site?		Yes	No	NA	
		<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	
Comment		The EC will be informed about the SAE and the delays of SAE reporting			
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	
		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Comment		<b>Printed out SAE reports were filed in the ISF and a note about the events placed in the SD.</b>			

Subject #	Description (e.g.: onset & end date, outcome, diagnosis, therapy, comments)																											
101/09	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Onset date</td> <td style="width: 20%;">End date</td> <td style="width: 20%;">Status</td> <td style="width: 20%;">Intensity</td> <td style="width: 20%;">Relation with MD</td> </tr> <tr> <td>01Dec2021</td> <td>10Dec2021</td> <td>Resolved</td> <td>Severe</td> <td>Not related</td> </tr> <tr> <td colspan="5"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Diagnosis</td> <td>Cup loosening</td> </tr> <tr> <td>Therapy</td> <td>Revision surgery</td> </tr> <tr> <td>Sponsor notified</td> <td>07Dec2021</td> </tr> <tr> <td>Comment</td> <td>Patient withdrawn</td> </tr> </table> </td> </tr> </table>					Onset date	End date	Status	Intensity	Relation with MD	01Dec2021	10Dec2021	Resolved	Severe	Not related	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Diagnosis</td> <td>Cup loosening</td> </tr> <tr> <td>Therapy</td> <td>Revision surgery</td> </tr> <tr> <td>Sponsor notified</td> <td>07Dec2021</td> </tr> <tr> <td>Comment</td> <td>Patient withdrawn</td> </tr> </table>					Diagnosis	Cup loosening	Therapy	Revision surgery	Sponsor notified	07Dec2021	Comment	Patient withdrawn
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Comment	Patient withdrawn																											

| 101/05 | |            |          |        |           |                  | |------------|----------|--------|-----------|------------------| | Onset date | End date | Status | Intensity | Relation with MD | |------------|----------|--------|-----------|------------------| | | | | |



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	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				
101/14	Onset date	End date	Status	Intensity	Relation with MD
	04Jun2022	NA	Ongoing	Severe	Probable
	Diagnosis	Dislocation of left hip			
	Therapy	Not pharmacological			
	Sponsor notified	17Jun2022			
	Comment	CAPA #13			

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)?		<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
#	Description				
101/10	Reference MVR	Reference SAE #			
	3	101/10-1			
	Onset date	End date	Status	Intensity	Relation with MD
	14Jan2022	09Jun2022	Recovered	Moderate	Not Related
	Diagnosis	Chronic heart failure			
	Therapy	Concomitant medication			
	Sponsor notified	09Jun2022 (about the outcome)			
	Comment				



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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
	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

#	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.  Update 09Jun2022: no changes were made since the last visit  To inform the EC about the deviation.	Open



## Monitoring Report

#	Issue Date	Finding	Action Required	Action Taken	Status (closed/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.  Update 09Jun2022: Subject 101-07. On ICF signature pages subject placed the signature and current date (04Jan2022).  To inform the EC about the deviation.	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. The GCP certificates for the rest of site team are pending	Open



## Monitoring Report

#	Issue Date	Finding	Action Required	Action Taken	Status (closed/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.  Update: The consenting process was documented during the MV.	The site staff was retrained and instructed to provide supplementary notes.	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 101-05	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.  Update 09June2022: Instead of to provide the updated medical documentation signed with the current date, to provide a NTF clarifying that eCRF is the source document.	Site staff was asked to provide the updated medical documentation.  Update 09June2022: for future patients it is requested to provide source documents (worksheet)	Open



## Monitoring Report

#	Issue Date	Finding	Action Required	Action Taken	Status (closed/open)
12	09Jun2022	Consent process not documented in subjects notes from patients 101-07 to 101-014	To provide supplementary notes with the current date documenting the whole consenting process.	The site staff was instructed to provide supplementary notes.	Open  (Same of CAPA #7)
13	17Jun2022 Post meeting CAPA	Delayed of SAE reporting of the event for subject number 101-14	The site should be retrained on SAE communication process.	The site will be retrained.  To inform the EC about the deviation	Open  (Same of CAPA #9)
14	09Jun2022.	The out of window visits of subject 101/7 FU 6 Months was noted.	The site should be reminded to perform the visit within the timeframe defined by the protocol	The site was reminded to perform the visit within the protocol defined timeframe	Open

### 12. Discussion with Principal investigator

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

Topics	PI was not present during the monitoring visit. The current open issues will be discussed with PI after the visit.
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# Monitoring Report

13. Closure of Monitoring Visit Report	
Comment	<p>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.</p> <p>During the visit the consenting process was verified, subjects' eligibility was checked as well as SDV was performed based on partially available SD.</p> <p>The Radiographic evaluation was verified for subjects 1-4, due to the lack of SD only partial SD was performed as described in section 8. The Protocol Deviations including Out of Window visit, the ICF consent process documentation, the ICF not properly completed and signed by the subjects and the delayed SAE reporting needs to be completed in the PD log.</p>

Role	Name and Surname	Date	Signature
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Written by: CRA Adam Kogut

28/6/2022 | 11:42 CEST

DocuSigned by:

Adam Kogut



Signer Name: Adam Kogut  
Signing Reason: I am the author of this  
Signing Time: 28/6/2022 | 11:42 CEST  
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Approved by: CMCL Federica Azzimonti

28/6/2022 | 14:30 CEST

DocuSigned by:

Federica Azzimonti



Signer Name: Federica Azzimonti  
Signing Reason: I approve this document  
Signing Time: 28/6/2022 | 14:30 CEST  
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