	Monitoring Oversight Visit (MOV) Report
Protocol Number: A multicenter, randomized, open-label, blinded endpoint evaluation, phase 3 study comparing the effect of abelacimab relative to apixaban on venous thromboembolism (VTE) recurrence and bleeding in patients with cancer associated VTE (ASTER)	
Site Number: 725006	Country: FRANCE
Principal Investigator: Dr. Ygal Benhamou	
Date(s) of the visit:17/JULY/2025	

Protocol Short Title	Abelacimab versus apixaban in the treatment of cancer associated VTE
Site Address	CHU de Rouen - Charles Nicolle 1 rue de Germont 76 031 ROUEN Cedex
Satellite Address(es)	N/A ☒ Not visited ☐
Satellite Site Number(s)	N/A ☒
ANTHOS Staff	Katia NEDJMA (Clinical Oversight Manager)
Study Site Staff	• Dr. Ygal BENHAMOU (Principal Investigator) • Mrs Ouahmi Ketteb (Study coordinator)
Other Attendees	NA
Visit accompanied by ESP staff	Yes ☐ No☒ If Yes, specify:
Type of Oversight Visit	SIV MOV ☐ IMV MOV ☐ COV MOV ☐ Other ☐ specify:

Key:	N/A = Not Applicable NR = Not Reviewed

Site Recruitment Status	
# screened	10
# screen failures	0
# randomized enrolled	10

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# early discontinued (including randomized but not dosed)	0
# completed treatment	1
# completed study	6

Site Personnel		
1. Does the site have **adequate resources** allocated to conduct the study procedures effectively?	☒Yes ☐No ☐N/A ☐NR	The site has adequate resources allocated to conduct the study. The PI has more than ten years of experience in clinical research. In addition to his participation in the clinical trial, Dr Benhamou is the coordinator of the Rare Autoimmune and Auto-inflammatory Diseases Competence Center for adults in the North, Northwest, Mediterranean, and Guadeloupe - CeRAINOM. The study staff is composed of the following: • 8 sub-investigators; • 1 central study coordinator; • 2 pharmacists; • 1 healthcare framework.
2. Is the **Site Delegation Log** (or equivalent) accurate, complete, and up to date?	☐Yes ☒No ☐N/A ☐NR	The COM noticed that the site delegation log is not complete, and all delegated tasks are assigned to appropriately qualified and trained personnel. Please see below: The start date indicated in the site delegation log for Mrs. Alexandra Bougeard, laboratory

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Site Personnel		
		technician (12 April 2023), is inconsistent with the CV's date (18 March 2022). The start date indicated in the site delegation log for Mrs. Elise Duhamel, pharmacist (23 January 2023), is inconsistent with the CV's date (30 January 2024). The start date indicated in the site delegation log for Mr. Sebastien Normant, radiologist (19 June 2023), is inconsistent with the CV's date (23 June 2022). The CRA Mrs. Mounia Godwin was not present during the MOV to discuss this issue. Also, the study coordinator was not present during the SIV to provide information regarding this topic.. Please see related action item #1 Moreover, the COM still does not have access to eTMF to verify the filing of interim DOA and site personnel documents (CV, FDF, Training certificates, etc).
3. Is the site staff adequately trained in **GCP, study procedures, and site-specific procedures**, and is training documentation available for all delegated personnel?	☐Yes ☒No ☐N/A ☐NR	The COM noticed that the certificate ICH-GCP is missing in the investigator file for Mrs.Gaelle Boulet (the study coordinator). The CRA, Mrs. Mounia Godwin, was not present during the MOV to discuss this issue. Also, the study coordinator was not present during the SIV to provide information regarding this topic. Please see related action item #2. The COM does not have access to the eTMF to verify the filing of the ICH-GCP certificates.

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Site Personnel		
4. Is the personnel qualification documentation **filed, accurate, and up to date** (including CVs, medical licenses, and any other required documents per local regulatory requirements)?	☐Yes ☒No ☐N/A ☐NR	The COM noticed that the personnel qualification documentation for the site staff is inaccurate. Please see below: For Mrs. Alexandra Bougeard, the laboratory technician, the CV's date (18 March 2022) is not consistent with the date of the SIV (23 January 2023). For Mr.Sebastien Normant the radiologist, the CV's date (23 June 2022) is not consistent with the date of the SIV (23 January 2023). For Mrs. Elise Duhamel, the pharmacist, the CV's date (30 January 2024) is not consistent with the date of the SIV (23 January 2023). The CV mentions personal data such as date of birth and personal address. Please see related action item #3. For Mrs Jennifer Guillerme, the laboratory technician, the CV mentions personal data such as date of birth and nationality. Please see related action item #4 For Dr. Sebastien Miranda, the sub-investigator, the CV mentions personal data such as date of birth. Please see related action item #5.
5. Is the **Site Training Log** and its documentation **accurate and complete**?	☐Yes ☒No ☐N/A ☐NR	The COM noticed that the site training logs are neither accurate nor complete. Please see below a list of missing trainings: • For the SIV: Dr. Salome Bougerolle (the sub-investigator), Mrs Nathalie Donnadieu (the pharmacist), Mrs

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Site Personnel		
		Elise Duhamel (the pharmacist), Mrs Karole Lassale (the pharmacist), Mrs Brigitte Mansard (the nurse), Sébastien Normant (the radiologist), Mrs Melody Aroma (the radiologist), Mr Jacques Morillon (the radiologist) ; • For the amendment protocol V4.2: Mrs Alexandra Bougeard (the laboratory technician), Mrs Nathalie Donnadieu (the pharmacist), Mrs Elise Duhamel (the pharmacist), Mrs Karole Lassale, Mrs Brigitte Mansard (the nurse), Mr Sebastian Normant (the radiologist), Mrs Melody Aroma (the radiologist), Mr Jacques Morillon (the radiologist), Dr Sebatien Miranda (the sub-investigator) ; • For the manual pharmacy V8: Mrs Nathalie Donnadieu (the pharmacist), Mrs Elise Duhamel (the pharmacist), Mrs Karole Lassale (the pharmacist), Mrs Delphine Simon (the sub-investigator). The CRA, Mrs. Mounia Godwin, was on sick leave. It was not possible to provide these documents at the time of the MOV. Please see related action items #6, #7, and #8.
6. Does the **Principal Investigator (PI)** demonstrate appropriate oversight, such as	☒Yes ☐No ☐N/A ☐NR	The COM noticed that the PI demonstrates appropriate oversight of the study. The PI has a good knowledge of the issues, such as

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Site Personnel		
knowledge of the study and active involvement in its conduct?		the wrong inclusion of the patient. Please see related action items #9.

Protocol Processes and Site Facilities		
7. Does the site have **SOPs or documented processes** for key study activities, and are they readily available? (E.g., recruitment, informed consent, patient retention, personnel qualification, etc.)	☐Yes ☒No ☐N/A ☐NR	The COM noticed that the site didn't encounter any difficulties in recruiting patients. The site does not have a procedure in place for patient recruitment for this study.
8. Have the **site facilities** been inspected and deemed suitable for conducting the study?	☒Yes ☐No ☐N/A ☐NR	The COM noticed that the site facilities had been inspected and deemed suitable for conducting the study. There is a room dedicated to clinical research where the monitoring visits take place. The room is secured.
9. Are the **calibration certificates** available, properly **filed, and up to date**?	☐Yes ☒No ☐N/A ☐NR	The calibration certificates are missing for the fridges, freezer and centrifuges. The CRA is following up with the site on this issue that is still pending since the SIV was made on 23 January 2023. The calibration certificate is missing for the examination equipment: e.g. scales, blood pressure cuff, body thermometers. The site explained that they can´t provide these documents because they don´t exist. The site regrets that this topic has not been discussed during the site initiation visit. Also, the PI expressed his dissatisfaction because this issue is open since January 2023 and the CRA reminds to provide these documents at each monitoring visit without proposing a solution. Please see related action item #10.

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Protocol Processes and Site Facilities		
10. Is the **approved process and manual for home visits** available **onsite**?	☐Yes ☒No ☐N/A ☐NR	The COM noticed that there is no home visit expected.

Investigational Medicinal Product (IMP) Management		
11. Are all versions of the **Site IMP/Pharmacy Manual (or equivalent)** available, properly filed, and up to date?	☐Yes ☐No ☐N/A ☒NR	
12. Is the **Investigational Medicinal Product (IMP)** stored in compliance with the **protocol and study requirements**?	☐Yes ☐No ☐N/A ☒NR	
13. Is there any **expired IMP** present at the study site?	☐Yes ☐No ☐N/A ☒NR	
14. Are **IMP receipt and shipping records** properly filed, complete, and up to date?	☐Yes ☐No ☐N/A ☒NR	
15. Are all **IMP temperature excursions** properly **documented, reported, and managed** in accordance with the **study procedures and IMP handling instructions**?	☐Yes ☐No ☐N/A ☒NR	
16. Have any **Product Technical Complaints (PTCs)** been reported, properly managed, and documented accordingly?	☐Yes ☐No ☐N/A ☒NR	
17. Is **IMP dispensation and accountability documentation** available, accurate, and up to date?	☐Yes ☐No ☐N/A ☒NR	

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Investigational Medicinal Product (IMP) Management		
18. Are the requirements for **IMP destruction on-site** or **return to ANTHOS (or delegate) for destruction** being properly followed?	☐Yes ☐No ☐N/A ☒NR	
19. Is IMP accountability complete in the IRT, covering the full lifecycle from receipt through return to depot or destruction?	☐Yes ☐No ☐N/A ☒NR	
20. If **IMP is provided for home treatment**, has the study site ensured that subjects receive **adequate instructions** on **use, storage, administration, accountability, and expiration**? Additionally, is the site using the Dosing Diaries for abelacimab, apixaban, and dalteparin?	☐Yes ☐No ☐N/A ☒NR	

Laboratory Sample Management		
21. Are all versions of the **Laboratory Manual (or equivalent)** properly **filed**?	☒Yes ☐No ☐N/A ☐NR	The laboratory manual V3 dated 12 Dec 2024 is filed in ISF.
22. Are the **laboratory certificates, accreditations, normal values, and reference ranges** properly **filed**?	☒Yes ☐No ☐N/A ☐NR	The laboratory certificate and the accreditation are filed in the investigator file. The accreditation is valid until the 31th of July 2027.
23. Have all **lab samples** been **collected, processed, and shipped** according to the protocol and by **delegated site staff**?	☒Yes ☐No ☐N/A ☐NR	The site confirmed the process for lab draws, processing, storage and shipment. The blood samples are collected by the study nurse. Then, the laboratory technician takes care of sending the blood sample according to study procedures. Requisition forms are filed in the patient's file.

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Laboratory Sample Management		
		The lab kits are stored in the study coordinator's office on a shelf. The study coordinator's office is secured with an access code on the door. The expired lab kits are destroyed on site. The site provides certificates of destruction for expired lab kits. The site confirmed all lab samples have been collected, processed and shipped according to the protocol. There is no lab kit that expired on site.
24. Are all **sample logs and forms** properly **filed, complete, and up to date**?	☐Yes ☒No ☐N/A ☐NR	The COM noticed that the site hasn't sample logs and forms for the traceability of shipment samples. The site files all requisition form in the patient medical file for the traceability of shipment samples.
25. Are all **sample temperature deviations** properly **documented, reported, and managed** in accordance with the **study procedures**?	☐Yes ☒No ☐N/A ☐NR	The COM didn´t have access to eTMF to ensure all sample temperature deviations are documented, reported, and managed in accordance with the study procedures.
26. Are the **records of retained body samples** properly **filed and up to date**?	☐Yes ☐No ☒N/A ☐NR	Body samples are not required for this study.

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Protocol Deviation Management		
27. Is a **Protocol Deviation (PD) list** available at the site?	☐Yes ☒No ☐N/A ☐NR	The list of protocol deviations is not filed in ISF.The CRA Mrs. Mounia Godwin was not present during the MOV to discuss this topic. The CRA was on sick leave from the 14th of July 2025. Please, see related action item #11.
28. Are **Protocol Deviations (PDs)** reported to the **IRB/Ethics Committee** as per local requirements, and is the documentation properly **filed**? Additionally, is the IRB policy on reporting PDs filed, and has the CRA confirmed awareness of this policy?	☐Yes ☐No ☒N/A ☐NR	Not applicable in France. The PDs are reported by the sponsor.
29. Are all **Protocol Deviations (PDs) and issues** properly **managed, documented, and closed**? Additionally, were major PDs escalated according to the Clinical Monitoring Plan (CMP) and as applicable?	☐Yes ☒No ☐N/A ☐NR	The COM noticed the last protocol deviation has been declared by the CRA responsible for the site. Please find below the protocol deviation : • Subject #725006009 was enrolled in the study even though exclusion criteria "Primary brain cancer or untreated intracranial metastasis" was met. The site explained that it's a misinterpretation of the protocol. The site thought that the patient who had a resected brain tumor or brain tumor under treatment can be included. The COM noticed a training log dated on 15 April 2024 regarding the inclusion and the exclusion criteria. The study coordinator has been retrained to the study protocol but Dr.Ygal Benhamou (the PI) was missing from the training log.Please, see related action item #9.

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Safety Management		
30. Are all **SAEs** reported to the sponsor **accurately and within the required timelines**, in accordance with the protocol?	☒Yes ☐No ☐N/A ☐NR	The COM noticed that the SAE "pertrochanteric fracture" for the subject #725006010 has been reviewed and was reported to the sponsor within the required timelines.
31. Are **SAEs/AEs** properly documented in the **source notes**, including initial and follow-up reports?	☐Yes ☒No ☐N/A ☐NR	The COM noticed that the relationship to treatment for the SAE "pertrochanteric fracture" is not documented for the subject #725006010. Please, see related action item #12.
32. Are **SAEs/AEs** reported to the **Regulatory Authorities (RA), Institutional Review Board (IRB), or Ethics Committees (ECs)** in accordance with country-specific reporting requirements? Additionally, are the RA, IRB, or EC reporting requirements filed in the ISF, and has the CRA confirmed awareness of this policy?	☐Yes ☐No ☒N/A ☐NR	Not applicable in France. SAEs/AEs are reported by the sponsor.
33. Are **Suspected Unexpected Serious Adverse Reactions (SUSARs)** properly **filed in the ISF** and reported in compliance with regulatory requirements?	☐Yes ☒No ☐N/A ☐NR	The SUSARs and the safety reports are downloaded by the study coordinator on Drug Dev and then will be shared with the PI and all other study teams. The CRA provides paper form every monitoring visit and will be signed by the PI to confirm the acknowledgment for the reported safety notification. The SUSARs filed in the ISF. The COM noticed that the following SUSARs are signed but not dated by the PI : • Recurrent pulmonary embolism ; • Suspected Recurrent pulmonary embolism ;

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Safety Management		
		• Abdominal pain and fever ; • Diverticular abscess ; • Right lower limb arterial thrombosis ; • Vasculitis ; • Cervical erythema • Suspicion of active bleeding ; • Pancytopenia ; • Acute on chronic anemia. Also, the following SUSARs were signed by the PI three years after the notification sent to the sites: • Traumatic subarachnoid hemorrhage; • Pancytopenia; Acute on chronic anemia.Please see related action item #13.
34. Were any **SAEs/AEs** discovered during this visit that had not been previously reported?	☐Yes ☒No ☐N/A ☐NR	

Investigator Site File		
35. Are all **Regulatory Authority submissions and approvals** (in accordance with country and site-specific regulations) **complete and properly filed**?	☒Yes ☐No ☐N/A ☐NR	The COM noticed that all regulatory authority submissions and approvals are complete and properly filed in ISF.
36. Are all **Regulatory Authority correspondences** properly **filed and up to date**?	☒Yes ☐No ☐N/A ☐NR	The COM noticed that all regulatory authority correspondences are complete and properly filed in ISF.
37. Are all **IRB/EC submissions and approvals** (in accordance with country and site-specific regulations) **complete and properly filed**?	☒Yes ☐No ☐N/A ☐NR	The COM noticed that all IRB/EC submissions and approvals are complete and properly filed.

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Investigator Site File		
38. Is the **IRB/EC composition** properly **filed and up to date**?	☒Yes ☐No ☐N/A ☐NR	The COM noticed that all IRB/EC composition is filed .
39. Are all **IRB/EC correspondences** properly **filed and up to date**?	☒Yes ☐No ☐N/A ☐NR	The COM noticed that all IRB/EC correspondences is filed.
40. Are the **interim and/or annual reports** available, including supporting documentation confirming submission to the relevant authorities?	☐Yes ☒No ☐N/A ☐NR	There were no interim or annual reports available in ISF.
41. Are all **safety notifications** to the **Regulatory Authority (RA) or IRB/EC** properly **filed, complete, and up to date**?	☒Yes ☐No ☐N/A ☐NR	All safety notifications to the Regulatory Authority (RA) or IRB/EC are filed in ISF.
42. Are all **financial agreements** properly **filed, complete, and up to date**?	☒Yes ☐No ☐N/A ☐NR	The COM noticed that all financial agreements are properly filed, complete, and up to date.
43. Is the **Investigator Brochure (all versions) or equivalent**, along with relevant **receipt and review documentation**, properly **filed**?	☒Yes ☐No ☐N/A ☐NR	The COM noticed the list of the following IBs available in ISF: V6; V7; V8.
44. Are all **revisions** of the **Study Protocol** properly **filed**?	☒Yes ☐No ☐N/A ☐NR	The COM noticed the list of the following study protocols available in ISF: • Version 4.1 dated 7 September 2023 ; • Version 3.1 dated 1 February 2023 ; • Version 1.1 dated 14 October 2021.
45. Are the **Protocol Acceptance Pages** signed and dated by the PI and filed in the eTMF?	☒Yes ☐No ☐N/A ☐NR	The COM noticed that all protocol acceptances pages were signed.

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Investigator Site File		
46. Are all **subject materials submitted and approved** (including advertisements, if applicable) properly **filed**?	☐Yes ☒No ☐N/A ☐NR	The patient emergency card is missing in the ISF.Please see related action item #14.
47. Are all versions of the **subject insurance documentation** properly **filed**?	☒Yes ☐No ☐N/A ☐NR	The subject insurance is filed in ISF and is valid until 31 December 2026.
48. Are all **relevant communications** (e.g., letters, meeting notes, phone contacts) properly **filed**?	☒Yes ☐No ☐N/A ☐NR	The COM noticed that all relevant communications are filed in the ISF.
49. Is the **Clinical Study Report (CSR) or summary** available at the site?	☐Yes ☒No ☐N/A ☐NR	The Clinical Study Report (CSR) or summary is not yet available.
50. Are the **completed Case Report Forms (CRFs)** available and accessible?	☒Yes ☐No ☐N/A ☐NR	
51. Is the **study contact list** properly **filed at the site**?	☒Yes ☐No ☐N/A ☐NR	The study contact list is filed in the ISF.
52. Is the **Subject (Pre)Screening and Enrollment Log (or equivalent)** properly **filed, complete, and up to date**?	☐Yes ☒No ☐N/A ☐NR	The subjects #725006011 and the #725006012 are missing from the Subject (Pre)Screening and Enrollment Log. Please see related action item #15.
53. Is the **Subject Identification Code List (or equivalent)** properly **filed, complete, and up to date**?	☒Yes ☐No ☐N/A ☐NR	The Subject Identification Code List is complete and filed in ISF.
54. Is the **site Informed Consent Form (ICF) consent log** (listing approved and used ICF versions) properly **filed, complete, and up to date**?	☒Yes ☐No ☐N/A ☐NR	Informed Consent Form (ICF) consent log is complete and filed in ISF.

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Investigator Site File		
55. Are **Informed Consent Forms (ICFs) for each subject** (including all signed ICFs) properly **filed and up to date**?	☒Yes ☐No ☐N/A ☐NR	The Informed Consent Forms (ICFs) for each subject are properly filed in the patient's medical record and up to date.
56. Is the **Informed Consent process** thoroughly **documented in the source documents**, including all relevant details?	☐Yes ☒No ☐N/A ☐NR	The COM noticed the Informed Consent process is well documented in the source documents for subjects #725006001, #725006002, #725006003, #725006005, #725006006, #725006009, #725006011. For the subject #725006004, the ICF V6.1.0 of February 20, 2023 has been signed on February 1st, 2024. The consent collection process is documented for the signing of ICF but the version number of the consent is missing. Please see open action item #16. For the subject #725006007, the ICF V6.2.0 of October 28, 2024 has been signed on May 14, 2025. The consent collection process is not available for the signing of addendum V6.2.0 of October 28, 2024. Please see open action item #17. For the subject #725006008, the ICF V6.2.0 of October 28, 2024 has been signed on April 30, 2025. The consent collection process is not available for the signing of addendum V6.2.0 of October 28, 2024. Please see open action item #18. For the subject #725006010, the ICF V6.2.0 of October 28, 2024 has been signed on May 12, 2025. The consent collection process is documented for the signing of the addendum

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Investigator Site File		
		but the version number and the rational are missing. Please see open action item #19.
57. Have **new Informed Consent Form (ICF) versions** been **implemented in a timely manner**?	☒Yes ☐No ☐N/A ☐NR	The ICFs have been implemented in a timely manner.

Source Documents		
58. Are all **the original source documents** available?	☒Yes ☐No ☐N/A ☐NR	The original source documents are in paper format and are available.
59. If **original source documents** are unavailable, are **certified copies** properly **filed, accurate, and complete**?	☒Yes ☐No ☐N/A ☐NR	The site can provide certified copies if original source documents are unavailable.
60. Are **source document archiving and retrieval arrangements** properly established?	☒Yes ☐No ☐N/A ☐NR	The source document are archived two years on site after the close-out visit. Then, the source documents are archived at the adress below : LOCARCHIVES Xelians archivage Route de chateauneuf - Garnay 28501 VERNOUILLET
61. Is the **Source Document Location Agreement (or equivalent)** properly **filed, accurate, and up to date**?	☐Yes ☒No ☐N/A ☐NR	The source data identification log is filed in ISF and was signed by the PI on 18 September 2023. The document was not signed at the time of the SIV (23 January 2023). The CRA was not present during the MOV to discuss this topic. CRA was on sick leave. Please see related open action item #20.

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Principal Investigator: Dr. Ygal Benhamou	
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Source Documents		
62. Are **source documents** (both **paper and electronic medical records**) compliant with **ALCOA+ principles** and other relevant **GCP and regulatory requirements**?	☐Yes ☒No ☐N/A ☐NR	The data sources were not compliant with the ALCOA+ principles. For the subject #725006011, for the screening visit and the D1 visit, the site created a summary worksheet with all study procedures required by the protocol. Regarding the vital signs, there is also a specific worksheet created by the site to collect this data. The study coordinator rewrites in the summary worksheet the vital signs measured by the nurses. This summary worksheet is stapled, initialed, signed, and dated by the investigator. Therefore, this data from the nurses rewritten on this summary worksheet are not compliant with the ALCOA+ principles. This data on the summary worksheet cannot be used in the clinical trial because it's not contemporaneous and not attributable. The COM retrained the study coordinator on the ALCOA+ principles and the ICH-GCP. The study coordinator understood that the duplicate of data is not allowed. The study coordinator will stop duplicating the data to be in accordance with the ICH-GCP and the ALCOA+ principles. The COM noticed for the subject #725006010 that the ECG performed at the screening visit has been reviewed by the sub-investigator but the date, the initials and the signature were missing. Please see related open action item #21. The COM noticed for the subject #725006004 that the medical report from the emergency department dated February 1, 2024 was not dated and signed by the sub-

	Monitoring Oversight Visit (MOV) Report
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Principal Investigator: Dr. Ygal Benhamou	
Date(s) of the visit:17/JULY/2025	

Source Documents		
		investigator. Please see related open action item #22. The COM noticed for the subject #725006004 that the laboratory results from the screening are not signed by the sub-investigator. Please see related open action item #23. The COM noticed for the subject #725006012 that the date, the initials and the signature are missing on the vital signs for the D31 visit. Please see related open action item #24.
63. Have the **Inclusion/Exclusion criteria** been **reviewed and documented** in the **source documents** for selected subjects?	☐Yes ☒No ☐N/A ☐NR	The inclusion/exclusion criteria have been reviewed and documented in the medical report for the subjects #725006004 and #725006009. No deviation observed for the subject #725006004. • The subject #725006009 was enrolled in the study even though exclusion criteria "Primary brain cancer or untreated intracranial metastasis" was met. The site explained that it's a misinterpretation of the protocol. The site thought that the patient who had a brain tumor can be included. Please see related action item #9.
64. Are the **Case Report Forms (CRFs)** completed based on the **relevant source documents** by **delegated personnel** and signed by the **Principal Investigator (PI)**?	☐Yes ☐No ☐N/A ☒NR	

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Source Documents		
65. Have any **discrepancies** between the **source documents** and **Case Report Forms (CRFs)** been identified for the reviewed subjects?	☐Yes ☐No ☐N/A ☒NR	
66. Is **data entry into the Electronic Data Capture (EDC) system** completed on time, and are **queries resolved within the specified timelines**?	☐Yes ☐No ☐N/A ☒NR	

Monitoring		
67. Have there been any **significant changes** (e.g., **change in location, Principal Investigator (PI), primary Sub-Investigator (SI), primary Study Coordinator (SC) or primary unblinded staff**) or any other concerns?	☐Yes ☒No ☐N/A ☐NR	There are no significant changes.
68. Have **regular monitoring visits** been conducted at this study site **post-SIV**, in accordance with the **monitoring plan (or equivalent)**?	☐Yes ☐No ☒N/A ☐NR	The COM needs to review the QB RAMP (IQVIA Biotech Risk Assessment Mitigation Plan) to ensure the monitoring visits have been conducted according to the monitoring plan. Please see related open action item #25.
69. Has there been a **Clinical Research Associate (CRA) change** at this study site since the **Site Initiation Visit (SIV)** was conducted?	☒Yes ☐No ☐N/A ☐NR	There has been a change of Clinical Research Associate (CRA) since February 2025. The new CRA taking over the site is Mrs. Mounia Godwin.
70. Has a **Monitoring Oversight Visit** for this study previously been conducted at this study site?	☐Yes ☒No ☐N/A ☐NR	There is no monitoring oversight visit for this study previously been conducted at this study site.

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Monitoring		
71. Is the **overall quality** of **monitoring visit reports**, including **follow-up letters**, acceptable at this study site?	☐Yes ☒No ☐N/A ☐NR	The COM can't judge the quality of monitoring visit reports, including follow-up letters as few documents are not provided. Please find the documents below: • SIV report January 23, 2023; • IMV report January 12, 2024; • IMV report January 8, 2025 and the corresponding IMV Follow-up letter • IMV's Follow-up letter dated February 18, 2025; • IMV report March 27, 2025 and the corresponding IMV Follow-up letter; • IMV report April 17, 2025 and the corresponding IMV Follow-up letter.
72. Is the **Monitoring Visit Log** properly **filed, complete, and up to date**?	☒Yes ☐No ☐N/A ☐NR	The monitoring visit log is properly filed, complete, and up to date. The COM signed the monitoring visit log. Therefore, the verification of the consistency of the data between the monitoring visit log and the monitoring visit report is pending.
73. Is the **site selection letter** properly **filed**?	☒Yes ☐No ☐N/A ☐NR	The selection letter is filed in ISF.
74. Is the **Site Initiation Visit (SIV) report** or equivalent properly **filed**?	☒Yes ☐No ☐N/A ☐NR	The site initiation visit report is filed in ISF.
75. Are the **Confirmation and Follow-up Letters** properly **filed, complete, and up to date**?	☒Yes ☐No ☐N/A ☐NR	The confirmation and follow-up letters are filed in ISF.

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Monitoring		
76. Is a **pandemic plan/disaster recovery process** available?	☐Yes ☒No ☐N/A ☐NR	There is no pandemic plan established because the study started after the lockdown.
77. Have **remote monitoring arrangements** been agreed upon, and are the processes adequate to **mitigate risks during the pandemic or disaster**?	☐Yes ☒No ☐N/A ☐NR	There is no monitoring arrangements established because the study started after the lockdown.

Prior Site Inspection Experience		
78. Has the site been **previously inspected**?	☐Yes ☒No ☐N/A ☐NR	The site has not been inspected.
79. Were there any **major or critical findings** during the **previous inspections**?	☐Yes ☐No ☒N/A ☐NR	
80. Have the **personnel** previously **participated in an inspection**?	☐Yes ☒No ☐N/A ☐NR	The personnel didn´t participate in an inspection.

Study Site Feedback		
81. Has any **feedback** been received from the **site**?	☒Yes ☐No ☐N/A ☐NR	Dr. Benhamou is very open-minded to discussion and receptive to suggestions for improvement. Dr. Benhamou expressed his dissatisfaction regarding the behavior of IQVIA Biotech. For example: • the PI sent an email to the CTM Mouna Tabakh to discuss the issues encountered in the study, but the PI never received a response. The PI wanted to explain to the CTM that

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Principal Investigator: Dr. Ygal Benhamou	
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Study Site Feedback		
		both Aster and Magnolia study takes a lot of time; • the data manager sent irrelevant re-queries regarding unknown dates which are not in accordance with the eCRF guidelines.the CRA reminds the site to provide the calibration certificates for the examination equipment (e.g. scales, blood pressure cuff, body thermometers) since the SIV (23 January 2023) while the site can´t provide these documents.
82. Did the CRA adequately perform oversight and issue resolution in accordance with the monitoring plan?	☐Yes ☐No ☒N/A ☐NR	COM has not enough information to assess whether CRA adequately performs oversight and issue resolution in accordance with the monitoring plan. COM still needs: • to review all reports and FULs provided from the SIV to present; • to verify if all reports and FULs are available for this site; • to retrieve the QB RAMP; • to access eTMF; • to retrieve all I-Site Pack from the beginning of the study.
83. Does the **study site** feel **adequately supported by the CRA and IQB**?	☐Yes ☒No ☐N/A ☐NR	The site doesn't feel supported by the CRA and IQB from the SIV until January 2025. For example, when the site asks a question to the CRA regarding the study procedure or the protocol, the expected response is not fast enough.

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Study Site Feedback		
		The site regrets that the new CRA must review some items that have already been monitored in the past by the previous CRA. Also, the site regrets that there was a delay in SDV from the previous CRA. So, the new CRA must come several times in few month to catch up on the delay. There were not enough monitoring visits at the beginning of the study. The site did not feel supported.

Visit Summary with Impact / Risk Level of Observations		
84. Have any **risks** been **identified at the site level**?	☐Yes ☒No	If yes, confirm if any impact on: ☐ country level ☐ study level Describe any risks in the Narrative section.
85. Have any risks been identified at the CRA level (e.g., monitoring gaps, delayed issue resolution, inadequate site oversight)?	☒Yes ☐No	COM provides any answer for the reasons detailed at question 82.

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Narratives

- The MOV was focus on the ISF because the COM didn´t have time to review it during the MOV on 3 and 4 July 2025.The pharmacy was already visited on 3 July 2025.
- According the training log filed in ISF, the previous CRA Mrs.Sawssen Ben Romdhan trained the study coordinator and not the PI on important topics. For example: inclusion/exclusion criteria, schedule of assessment. The COM has no access to eTMF to verify if the CRA used to train only the study coordinator.
- Some trainings were done long after the deviation. For example, schedule of assessment, visit window.
- Some issues have been open for too long. For example, the issue regarding of the calibration certificate is open since 23 January 2023, some SUSARs since 2023 are signed but they are not yet dated by the PI.
- The site needs to be retrained to the ALCOA+ principles and ICH-GCP because the site uses of not dating, of not signing data source, to duplicate data source since the SIV (23 January 2023). The COM didn´t found any training in ISF regarding the ALCOA+ principles and ICH-GCP. The COM spent one hour to retrain the site to the ALCOA+ principles and ICH-GCP.
- There is a lack of rigor for the following of some important topics. Some issues were noticed during the MOV and it seems to be open for too long without corrective action. For example, the subject signed the ICF V6.1.0 on 1 February 2024 and the consent collection process is partially documented (the version number of the consent is missing). The subject #725006007 signed the ICF V6.2.0 but the consent collection process is not available. These issues should not be opened in 2025.

Issues identified/ Action items

Item #	Description of Issue	Action to be taken	Responsible	Due Date
#1	There are discrepancies regarding the dates of the CVs for Mrs Alexandra Bougeard, Mrs. Elise Duhamel, Mr. Sebastien Normant and those provided in the site delegation form.	. To discuss with the CRA remotely.	CRA	30 August 2025

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Item #	Description of Issue	Action to be taken	Responsible	Due Date
#2	The certificate ICH-GCP is missing in the investigator file for Mrs Gaelle Boulet (the study coordinator).	To provide the certificate ICH-GCP of Mrs Gaelle Boulet	CRA	30 August 2025
#3	The CV of Mrs. Elise Duhamel mentions personal data such as date of birth and personal address.	To provide the CV of Mrs. Elise Duhamel without personal data.	Site	30 August 2025
#4	The CV of Mrs Jennifer Guillerme the laboratory technician mentions personal data such as date of birth and the nationality.	To provide the CV of Mrs Jennifer Guillerme without personal data.	Site	30 August 2025
#5	The CV of Dr. Sebastien Miranda the sub-investigator mentions personal data such as date of birth.	To provide the CV of Dr. Sebastien Miranda without personal data.	Site	30 August 2025
#6	The SIV training is missing for Dr. Salome Bougerolle (the sub-investigator), Mrs Nathalie Donnadieu (the pharmacist), Mrs Elise Duhamel (the pharmacist), Mrs Karole Lassale (the pharmacist),Mrs Brigitte Mansard (the nurse),Sébastien Normant (the radiologist),Mrs Melody Aroma (the radiologist),Mr Jacques Morillon (the radiologist)	To provide the SIV training for Dr. Salome Bougerolle, Mrs Nathalie Donnadieu, Mrs Elise Duhamel, Mrs Karole Lassale, Mrs Brigitte Mansard, Sébastien Normant, Mrs Melody Aroma ,Mr Jacques Morillon.	CRA	30 August 2025
#7	The training for the amendment protocol	To provide training for the amendment protocol V4.2 for	CRA	30 August 2025

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Site Number: 725006	Country: FRANCE
Principal Investigator: Dr. Ygal Benhamou	
Date(s) of the visit:17/JULY/2025	

Item #	Description of Issue	Action to be taken	Responsible	Due Date
	V4.2 is missing for Mrs Alexandra Bougeard (the laboratory technician), Mrs Nathalie Donnadieu (the pharmacist), Mrs Elise Duhamel (the pharmacist), Mrs Karole Lassale, Mrs Brigitte Mansard (the nurse), Mr Sebastian Normant (the radiologist), Mrs Melody Aroma (the radiologist),Mr Jacques Morillon (the radiologist) Dr Sebatien Miranda (the sub-investigator).	Mrs Alexandra Bougeard, Mrs Nathalie Donnadieu, Mrs Elise Duhamel, Mrs Karole Lassale, Mrs Brigitte Mansard, Mr Sebastian Normant, Mrs Melody Aroma,Mr Jacques Morillon, Dr Sebatien Miranda.		
#8	The training for the manual pharmacy V8 is missing for Mrs Nathalie Donnadieu (the pharmacist), Mrs Elise Duhamel (the pharmacist), Mrs Karole Lassale (the pharmacist), Mrs Delphine Simon (the sub-investigator).	To provide training for the manual pharmacy V8 for Mrs Nathalie Donnadieu, Mrs Elise Duhamel, Mrs Karole Lassale, Mrs Delphine Simon.	CRA	30 August 2025
#9	Subject 725006009 was enrolled in the study even though exclusion criteria "Primary brain cancer or untreated intracranial metastasis" was meet. The site explained that it's a misinterpretation of the protocol. The site thought that the patient who had a resected brain tumor or brain tumor under treatment can be included.	To verify with the CRA if Dr Ygal Benhamou (the PI) and Ouahmi Ketteb (the study coordinator) have been retrained to the study protocol at the time of protocol deviation.	CRA	30 August 2025

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Item #	Description of Issue	Action to be taken	Responsible	Due Date
#10	The calibration certificates are missing for the fridges, freezer and centrifuges. The calibration certificate is missing for the examination equipment: e.g. scales, blood pressure cuff, body thermometers. The site explained that they can´t provide these documents because they don´t exist.	To provide the calibration certificates for the fridges, freezer and centrifuges. To make a note to file to explain the reason why it´s not possible to provide the calibration certificates for examination equipment.	Site Site	30 August 2025 30 August 2025
#11	The list of protocol deviations is not filed in ISF.	To be discussed with the CRA and to be filed in the ISF.	CRA	30 August 2025
#12	For the subject #725006010, the relationship to treatment for the SAE “pertrochanteric fracture” is not documented.	To document the relationship to treatment for the SAE “pertrochanteric fracture” is not documented.	Site	30 August 2025
#13	The SUSARs below are signed but not dated by the PI : • Recurrent pulmonary embolism ; • Suspected Recurrent	The SUSARs to be signed by the PI.	Site	30 August 2025

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Item #	Description of Issue	Action to be taken	Responsible	Due Date
	pulmonary embolism ; • Abdominal pain and fever ; • Diverticular abscess ; • Right lower limb arterial thrombosis ; • Vasculitis ; • Cervical erythema • Suspicion of active bleeding ; • Pancytopenia ; • Acute on chronic anemia. The SUSARs below were not signed on time: • Traumatic subarachnoid hemorrhage; • Pancytopenia; • Acute on chronic anemia.	To provide the reason why the following SUSARs were not signed on time: • Traumatic subarachnoid hemorrhage; • Pancytopenia; • Acute on chronic anemia.	CRA	30 August 2025
#14	The patient emergency card is missing from the ISF.	To be sent to the site.	CRA	30 August 2025
#15	The subjects #725006011 and the #725006012 are missing from the Subject	To add the subjects #725006011 and the #725006012 on the Subject	Site	30 August 2025

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Item #	Description of Issue	Action to be taken	Responsible	Due Date
	(Pre)Screening and Enrollment Log.	(Pre)Screening and Enrollment Log.		
#16	For the subject #725006004, the ICF V6.1.0 of February 20, 2023 has been signed on February 1st, 2024. The consent collection process is documented for the signing of ICF but the version number of the consent is missing.	To provide the version number of the consent.	Site	30 August 2025
#17	For the subject #725006007, the ICF V6.2.0 of October 28, 2024 has been signed on May 14, 2025. The consent collection process is not available for the signing of addendum V6.2.0 of October 28, 2024.	To provide the consent collection process for the signing of addendum V6.2.0 of October 28, 2024.	Site	30 August 2025
#18	For the subject #725006008, the ICF V6.2.0 of October 28, 2024 has been signed on April 30, 2025. The consent collection process is not available for the signing of addendum V6.2.0 of October 28, 2024.	To provide the consent collection process for the signing of addendum V6.2.0 of October 28, 2024.	Site	30 August 2025
#19	For the subject #725006010, the ICF V6.2.0 of October 28, 2024 has been signed on May 12, 2025. The consent collection	To provide the version number and the rational.	Site	30 August 2025

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Item #	Description of Issue	Action to be taken	Responsible	Due Date
	process is documented for the signing of the addendum but the version number and the rational are missing.			
#20	The source data identification log was not signed at the time of the SIV (23 January 2023).	To discuss with the CRA remotely why the source data identification log was not signed on time.	CRA	30 August 2025
#21	For the subject #725006010, the ECG performed at the screening visit has been reviewed by the sub-investigator but the date, the initials and the signature were missing.	To provide the ECG the date, the initials, the signature.	Site	30 August 2025
#22	For the subject #725006004, the medical report from the emergency department dated February 1, 2024 was not dated and signed by the sub-investigator.	To provide the medical report dated and signed by the sub-investigator.	Site	30 August 2025
#23	For the subject #725006004, the laboratory results from the screening are not signed by the sub-investigator.	To provide the laboratory results dated and signed by the sub-investigator.	Site	30 August 2025
#24	For the subject #725006012, the date, the initials, and the signature are missing on the vital signs for the D31 visit.	To provide the date, the initials, the signature on the vital signs for the D31 visit.	Site	30 August 2025
#25	The QB RAMP (IQVIA Biotech Risk Assessment	To provide the QB RAMP (IQVIA Biotech Risk Assessment Mitigation Plan).	LCOM	30 August 2025

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Item #	Description of Issue	Action to be taken	Responsible	Due Date
	Mitigation Plan) was not provided before the MOV.			

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Site Number: 725006	Country: FRANCE
Principal Investigator: Dr. Ygal Benhamou	
Date(s) of the visit:17/JULY/2025	

Signatures

Katia Nedjma	Elizabeth Alicot
Report Author Name/ Role	Reviewer Name/ Role
Signé par : Katia Nedjma 421CE4B0707F494...	Signed by: Elizabeth Alicot 9F6A7610352C41E...
Signature	Signature
10-sept.-2025	10-Sep-2025
Date (dd/mmm/yyyy)	Date (dd/mmm/yyyy)