MONITORING VISIT REPORT

VISIT INFORMATION

Protocol Title:	A Randomized, Open-Label, Multicenter, Phase 3 Trial Comparing Veliparib Plus Carboplatin and Paclitaxel Versus Investigator's Choice of Standard Chemotherapy in Subjects Receiving First Cytotoxic Chemotherapy for Metastatic or Advanced Non-Squamous Non-Small Cell Lung Cancer (NSCLC) and Who Are Current or Former Smokers
Protocol Name:	M14-359
Site Name / Site #:	California Cancer Associates for Research and Excellence / SITE-033
Site Address:	Encinitas, USA
Site Activation Date:	2024-05-11
Monitoring Visit Date:	2024-08-14
Visit Type:	On-Site
CRA:	CRA-006

SUMMARY OF MONITORING VISIT

This Interim Monitoring Visit (IMV) was conducted on 14-Aug-2024 at California Cancer Associates for Research and Excellence (Site 033) to review study progress, data quality, and regulatory compliance for Protocol M14-359. This was the second visit to the site following the Site Initiation Visit (SIV) and subsequent activation on 11-May-2024. The Principal Investigator, Dr. Sarah Miller, and Study Coordinator, Jessica Chen, were available throughout the visit to facilitate document review and answer queries. The site has screened two (2) subjects and randomized one (1) subject (SUBJ-033-002) since activation. One screen failure (SUBJ-033-001) occurred due to inclusion criterion #4 (prior chemotherapy wash-out period).

Source Document Verification (SDV) was performed for 100% of the data for the randomized subject, who has completed the study treatment phase as of this visit. The subject's medical history, concomitant medications, and adverse events were cross-referenced against the Electronic Medical Records (EMR) and the EDC system. Overall, the data quality is high, with source documents clearly narrating the patient journey. One minor data discrepancy regarding a concomitant medication start date was identified and discussed with the Coordinator for correction. Informed Consent Forms (ICF) for both screened subjects were reviewed for completeness and Good Documentation Practice (GDP); all were signed prior to any study-specific procedures using the correct version (v3.0).

The Investigator Site File (ISF) was reviewed for currency. The regulatory binder is generally well-maintained. However, it was noted that the local laboratory CAP/CLIA certifications expired at the end of July 2024 and the new certificates had not yet been filed. Additionally, the Delegation of Authority Log requires an update to reflect the end date of a Sub-Investigator who left the practice last month. Investigational Product (IP) accountability was reviewed; storage conditions remain within protocol-defined limits (controlled room temperature), and temperature logs showed no excursions. The site staff remains engaged, and the PI expressed continued commitment to the enrollment target despite the slow start.

Overall Impression:

The site is performing well with high-quality data entry and strong PI oversight, though minor administrative maintenance of the ISF is required.

Exit Interview Comments:

Discussed the three action items with Dr. Miller and Ms. Chen. Ms. Chen agreed to upload the new lab certifications by Friday. Dr. Miller confirmed the data entry error regarding the concomitant medication and instructed the SC to correct it immediately. The PI also noted that two potential candidates are identified for screening next week.

URGENT ISSUES

No

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PERSONS PRESENT

Name	Position/Title
Dr. Sarah Miller	Principal Investigator
Jessica Chen	Study Coordinator

ENROLLMENT STATUS

Screened: 2

Consented: 1

Pre Randomization Failure: 1

Randomized: 1

Completed: 1

Ongoing: 0

Withdrawn: 0

Recruitment Plan Notes:

The site has randomized 1 subject against a target of 21. While the current rate is slightly below the initial projection of 1 subject/month, the PI attributes this to a temporary lull in eligible NSCLC referrals during the summer months. Pre-screening logs indicate active review of pathology reports. No changes to the recruitment plan are recommended at this time.

Recruitment Rate Adequate? Yes

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MONITORING CHECKLIST

Informed Consent

1	Is the current IRB/EC-approved ICF version being used?	Yes	Version 3.0 is currently in use.
2	Was ICF signed prior to any study procedures?	Yes	Verified for SUBJ-033-001 and SUBJ-033-002.
3	Is the correct version of the ICF signed and dated by the subject and person obt	Yes	All signatures and dates present.
4	Is re-consent required and has it been obtained?	N/A	No new ICF amendments since activation.

Site Staff/Facilities

5	Is the Principal Investigator available for supervision?	Yes	Dr. Miller met with CRA during the visit.
6	Are Sub-Investigators qualified and available?	Yes	CVs and medical licenses on file are current.
7	Is the Study Coordinator trained and familiar with the protocol?	Yes	Ms. Chen demonstrates excellent protocol knowledge.
8	Are pharmacy facilities adequate?	Yes	Access restricted, temperature controlled.
9	Is the laboratory certified and adequate?	No	SC to obtain and file current CAP/CLIA certifications.
10	Is equipment calibrated and maintained?	Yes	Centrifuge and ECG calibration records are current.
11	Is the Delegation of Authority Log current?	No	PI/SC to update Delegation Log with end date for Dr. Evans
12	Is the Training Log complete for all staff?	Yes	All active staff have completed required EDC training.
13	Are CVs current for all staff?	Yes	Reviewed.

Investigator Site File

14	Is the ISF complete and organized?	Yes	Aside from the specific findings noted in items 9 and 11, th
15	Are essential documents current?	Yes	FDA 1572 and Financial Disclosure Forms are current.
16	Is the Site Visit Log signed by the monitor?	Yes	Signed at conclusion of visit.
17	Are follow-up items from the prior visit complete?	Yes	Action items from SIV (May 2024) regarding initial supply re

Research Ethics Board

18	Is IRB/EC approval current?	Yes	Initial approval valid until May 2025.
19	Are protocol amendments approved?	N/A	No amendments released since site activation.
20	Are safety reports submitted to IRB?	Yes	IND safety reports submitted via central IRB portal.
21	Is annual renewal current?	N/A	Not yet due.
22	Is site-specific consent approved?	Yes	Approved 01-May-2024.
23	Is SAE reporting compliant with IRB requirements?	Yes	No SAEs to report to date.

Safety

24	Is AE reporting timely and accurate?	Yes	AEs for SUBJ-033-002 (Grade 1 Nausea, Grade 1 Fatigue)
25	Are SAEs followed to resolution?	N/A	No SAEs reported.
26	Is pregnancy reporting compliant?	N/A	No pregnancies reported.
27	Are protocol deviations documented?	Yes	No deviations noted for the randomized subject.
28	Is the safety database reconciled with EDC?	Yes	No discrepancies.
29	Are SUSAR notifications timely?	Yes	Filed in ISF.
30	Are DSMB recommendations implemented?	N/A	No new DSMB letters issued.
31	Is the risk-benefit assessment current?	Yes	IB v4.0 in use.

Compliance

32	Is protocol compliance acceptable?	Yes	Procedures performed within window.
33	Is GCP compliance maintained?	Yes	Source documentation meets ALCOA+ standards.
34	Is regulatory compliance current?	Yes	Site is compliant with FDA regulations.

Study Investigational Product

35	Is IP storage adequate?	Yes	Stored in locked pharmacy, ambient temperature.
36	Is IP accountability current?	Yes	Logs updated upon dispensing to SUBJ-033-002.
37	Is IP dispensing correct?	Yes	Correct kit dispensed via IWRS.
38	Are IP returns documented?	Yes	Used kits returned by subject and quarantined.
39	Is temperature monitoring compliant?	Yes	Min/Max recorded daily. No excursions.

Study Supplies/Vendors

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40	Are lab kits/supplies adequate?	Yes	Inventory sufficient for next 3 subjects.
Source Document Verification			
41	Are source documents available?	Yes	EMR access provided.
42	Was SDV completed per plan?	Yes	100% SDV for randomized subject.
43	Were data discrepancies identified?	Yes	One discrepancy in ConMed start date.
44	Does CRF data match source?	No	SC to correct Lisinopril start date in EDC.
45	Is query resolution timely?	Yes	No outstanding queries prior to visit.
46	Are data corrections documented?	Yes	Audit trails visible in EDC.

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
SUBJ-033-001	Screening	Confirmed screen failure due to Inclusio	
SUBJ-033-002	Screening, Cycle 1, Cycle	100% SDV completed. Subject completed tr	Query issued in EDC.

FOLLOW-UP FROM PRIOR VISIT

Action: Confirm receipt of initial IP shipment and file acknowledgement in ISF (from SIV) | Status: Resolved | Acknowledgement of Receipt filed in ISF Section 8.

CRA ASSESSMENT

This was a routine and productive monitoring visit. Site 033 is operating in compliance with the protocol and GCP. The staff is well-organized, and the facilities remain adequate for the study. While enrollment is currently at 1 randomized subject, the quality of the data is high, and the PI is actively screening. The only findings noted were administrative in nature (Delegation Log update and Lab Certification filing) and a single data entry error. The site staff was cooperative and receptive to the findings. I am confident in the site's ability to continue the study successfully. The next visit is tentatively scheduled for November 2024.