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:	2025-08-19
Visit Type:	On-Site
CRA:	CRA-007

SUMMARY OF MONITORING VISIT

This Interim Monitoring Visit (IMV) was conducted on 19-Aug-2025 at California Cancer Associates for Research and Excellence (Site 033) for Protocol M14-359. This visit served as the seventh monitoring visit for the site and the fourth on-site assessment conducted by CRA-007. The primary objectives of this visit were to perform Source Document Verification (SDV) for the three ongoing subjects (SUBJ-019, SUBJ-020, and SUBJ-021), review Investigational Product (IP) accountability, and finalize the resolution of the administrative backlog identified during the post-gap 're-set' visit in March 2025. The Principal Investigator, Dr. Sarah Miller, and the Study Coordinator, Jessica Chen, were available throughout the visit to facilitate document review and address queries.

Following the significant monitoring gap experienced between late 2024 and early 2025, the site has demonstrated a consistent trajectory of operational recovery. During this visit, it was observed that the site is approaching its pre-gap operational baseline. The substantial query backlog and data entry delays that characterized Visits 4 and 5 have been largely resolved. The site staff has successfully addressed the majority of the corrective actions issued during the previous two visits. Currently, the focus has shifted from remediation to routine maintenance of the three ongoing subjects. SDV was completed for all active subjects up to the current date, with 100% verification of safety data and primary efficacy endpoints.

Two legacy administrative items remain open from the post-gap audit: specifically, the retrieval of an updated Financial Disclosure Form (FDF) for a sub-investigator who is on extended leave, and the finalization of end-dates on the Delegation of Authority (DOA) log for former staff members. Aside from these administrative gaps, the site's clinical data integrity appears robust. Three new minor findings were identified during this visit, primarily related to minor transcription errors and a temperature log signature omission. These findings were discussed with the SC and PI during the exit interview, and a plan for resolution was agreed upon.

Overall Impression:

The site has effectively stabilized following the monitoring gap, with operations now approaching the pre-gap baseline and the query backlog substantially reduced.

Exit Interview Comments:

Dr. Miller and Ms. Chen were present. We reviewed the 3 new findings and the 2 legacy items. Dr. Miller acknowledged the outstanding FDF and committed to contacting the sub-investigator personally. Ms. Chen confirmed that the data transcription errors would be corrected in the EDC within 48 hours.

URGENT ISSUES

No

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PERSONS PRESENT

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

ENROLLMENT STATUS

Screened: 30

Consented: 23

Pre Randomization Failure: 7

Randomized: 21

Completed: 18

Ongoing: 3

Withdrawn: 0

Recruitment Plan Notes:

Enrollment is closed. Site met target enrollment (21 randomized). Focus is now on retention and follow-up of the 3 ongoing subjects.

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 current.
2	Was ICF signed prior to any study procedures?	Yes	Verified for all active subjects.
3	Is the correct version of the ICF filed in the subject's source?	Yes	
4	Was re-consent obtained if applicable?	Yes	SUBJ-019 re-consented to v3.0 as required.

Site Staff/Facilities

5	Is the Principal Investigator available for supervision?	Yes	Dr. Miller met with CRA during visit.
6	Are Sub-Investigators qualified and delegated appropriately?	Yes	
7	Is the Study Coordinator trained on the protocol?	Yes	Ms. Chen is well-versed in protocol procedures.
8	Are pharmacy facilities adequate?	Yes	Access restricted, temperature controlled.
9	Is the laboratory certified (CLIA/CAP)?	Yes	Current certifications filed in ISF.
10	Is equipment calibrated and maintained?	Yes	ECG and Centrifuge calibration records current.
11	Is the Delegation of Authority (DOA) log current?	No	PI to sign off end-dates for departed staff.
12	Is the Training Log complete for all staff?	Yes	New phlebotomist training documented.
13	Are CVs and Medical Licenses current?	No	Site to continue attempts to retrieve documents from Dr. Ev

Investigator Site File / Monitoring Activities

14	Is the Investigator Site File (ISF) complete and organized?	Yes	ISF organization has improved significantly since Visit 4.
15	Are essential documents current?	Yes	Aside from the specific CV noted above.
16	Is the Site Visit Log signed by the monitor?	Yes	Signed for today's visit.
17	Have prior visit follow-up items been addressed?	Yes	Majority of outstanding actions now closed. 2 legacy items r

Research Ethics Board

18	Is IRB/EC approval current?	Yes	Continuing Review approval letter dated 10-May-2025 on fil
19	Are protocol amendments approved?	Yes	Amendment 3 approved.
20	Have safety reports been submitted to IRB?	Yes	IND Safety Reports submitted per local requirements.
21	Is annual renewal current?	Yes	
22	Is site-specific consent approved?	Yes	
23	Is SAE reporting compliant with IRB requirements?	Yes	

Safety

24	Is AE reporting timely and accurate?	Yes	AEs for ongoing subjects reviewed against source notes.
25	Are SAEs followed to resolution?	Yes	No new SAEs since last visit.
26	Is pregnancy reporting compliant?	N/A	No pregnancies reported.
27	Are protocol deviations documented?	Yes	Deviations log is up to date.
28	Is the safety database reconciled with the EDC?	Yes	
29	Are SUSAR notifications timely?	Yes	Filed in ISF.
30	Are DSMB recommendations implemented?	Yes	
31	Is the risk-benefit assessment current?	Yes	

Compliance

32	Is protocol compliance acceptable?	Yes	Adherence is high for ongoing subjects.
33	Is GCP compliance maintained?	Yes	ALCOA+ principles observed in source documentation.
34	Is regulatory compliance current?	Yes	

Study Investigational Product

35	Is IP storage adequate?	Yes	Ambient storage 15-25C maintained.
36	Is IP accountability current?	Yes	Logs match physical inventory.
37	Is IP dispensing correct?	Yes	Verified for SUBJ-019 and SUBJ-021.
38	Are IP returns documented?	Yes	Used kits returned and logged.
39	Is temperature monitoring compliant?	No	Pharmacist to review and sign July 2025 temp log.

Study Supplies/Vendors

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40	Are lab kits and supplies adequate?	Yes	Inventory sufficient for remaining 3 subjects.
Source Document Verification & Review			
41	Are source documents available?	Yes	EMR access granted and paper charts available.
42	Is SDV completed per plan?	Yes	100% SDV for active subjects.
43	Are data discrepancies identified?	Yes	Minor transcription error noted.
44	Does CRF data match source?	No	SC to correct ConMed start date in EDC.
45	Is query resolution timely?	Yes	Backlog from Visit 4/5 is cleared. Current queries < 1 week
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-019	Cycle 12 Day 1	No discrepancies. AE #04 (Nausea) resolv	
SUBJ-020	Cycle 11 Day 15	No discrepancies. IP compliance 98%.	
SUBJ-021	Cycle 10 Day 1	ConMed 'Lisinopril' start date entered a	Update EDC to match source.

FOLLOW-UP FROM PRIOR VISIT

Action: Update Delegation Log with new Pharmacist initials | Status: Resolved | Completed on 10-May-2025.
Action: Resolve 15 overdue queries regarding AE start dates | Status: Resolved | All queries closed.
Action: Upload missing lab normal ranges for 2025 | Status: Resolved | Filed in ISF Section 10.
Action: Obtain updated FDF for Sub-I Dr. Evans | Status: Open | Dr. Evans remains on leave; site is attempting contact.
Action: Sign off end-dates on DOA log for departed staff | Status: Open | PI has not yet signed this specific page.

CRA ASSESSMENT

Overall, Site 033 is functioning at a high level and has successfully navigated the transition back to routine monitoring following the operational gap earlier this year. The site is approaching its pre-gap operational baseline, with the Study Coordinator demonstrating renewed confidence in the protocol requirements and data entry timelines. The significant query backlog that was a major concern during the 're-set' Visit 4 and the follow-up Visit 5 has been substantially reduced; the EDC is now current for all active subjects.

The relationship with the site staff is productive and transparent. Ms. Chen has been instrumental in clearing the backlog and was very cooperative during the SDV process today. The PI, Dr. Miller, remains engaged and provides adequate oversight, although the administrative task of signing off on the Delegation Log for past employees remains a lingering action item.

Data quality for the three ongoing subjects is excellent. The source documentation is detailed, ALCOA+ compliant, and tells a clear medical story. The few findings identified today (ConMed transcription error, temperature log signature) are minor and typical of routine monitoring, rather than systemic failures. The two legacy items regarding administrative documentation (Dr. Evans' FDF and the DOA log end-dates) are the only remnants of the previous monitoring gap issues. I will continue to follow up on these remotely, but they do not pose a risk to subject safety or critical data integrity. No critical compliance issues were noted. The site is well-positioned to continue the maintenance phase of the study.