

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:	2025-05-05
Visit Type:	On-Site
CRA:	CRA-007

SUMMARY OF MONITORING VISIT

This Interim Monitoring Visit (IMV) was conducted on 05-May-2025 at California Cancer Associates for Research and Excellence (Site 033) for Protocol M14-359. This visit served as the second on-site assessment by CRA-007 following the significant monitoring gap identified earlier this year. The primary objectives of this visit were to verify the resolution of action items generated during the 're-set' Visit 4 (22-Mar-2025), perform Source Document Verification (SDV) for the two ongoing subjects, and finalize the data review for the recently completed subjects. The Principal Investigator, Dr. Sarah Miller, and Study Coordinator, Jessica Chen, were available to facilitate the review. The site has made commendable progress in addressing the administrative backlog accumulated during the 6-month monitoring hiatus; however, full recovery to a steady state of compliance has not yet been achieved.

During the visit, the monitor focused heavily on the data query backlog and the documentation of data corrections. At the conclusion of Visit 4, there were 12 overdue queries and significant gaps in source-to-EDC entry. As of this visit, the query backlog has been reduced to 7 overdue items, indicating active engagement by the study coordinator. However, the documentation regarding the 'late entry' of data during the monitoring gap remains incomplete. Specifically, the required Note to File (NTF) explaining the retrospective data entry for subjects SUBJ-008 through SUBJ-012 has not been finalized or signed by the PI. Additionally, while 3 of the 8 major action items identified at Visit 4 have been fully resolved (specifically regarding temperature excursion logs and regulatory binder currency), 5 actions remain open. These open items primarily concern the aforementioned data correction documentation and the reconciliation of Safety Reports in the ISF.

Overall, the site is trending in a positive direction. The immediate safety oversight is robust, and the two ongoing subjects are being managed compliantly with no new protocol deviations observed. The 'Partial Recovery' status reflects that while the critical backlog is shrinking, the administrative hygiene required to close out the gap period is still a work in progress. The focus for the next interim visit will be the complete closure of the remaining Visit 4 action items and the finalization of the retrospective data entry explanations to ensure ALCOA+ standards are met for the audit trail.

Overall Impression:

The site is showing signs of partial recovery following the monitoring gap; while the query backlog has decreased significantly, administrative documentation regarding data corrections remains incomplete.

Exit Interview Comments:

Discussed the remaining open action items with Dr. Miller and Ms. Chen. Dr. Miller acknowledged the delay in signing the Note to File regarding late data entry and committed to reviewing it by Friday. Ms. Chen explained that the remaining 7 queries require input from the sub-investigator who was on leave, but they are prioritized for next week. The site staff was cooperative and receptive to the plan for closing the gap-related findings.

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URGENT ISSUES

No

PERSONS PRESENT

Name	Position/Title
Dr. Sarah Miller	Principal Investigator
Jessica Chen	Study Coordinator
Dr. Mark Reynolds	Sub-Investigator

ENROLLMENT STATUS

Screened: 21
Consented: 16
Pre Randomization Failure: 5
Randomized: 15
Completed: 13
Ongoing: 2
Withdrawn: 0

Recruitment Plan Notes:

Enrollment is closed. The site met 71% of the original target (15/21). Focus is now on retention of the 2 ongoing subjects and data cleaning for the 13 completed 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 currently active. No new subjects consented.
2	Was the ICF signed prior to any study-related procedures?	Yes	Verified for ongoing subjects SUBJ-014 and SUBJ-015.
3	Is the correct version of the ICF signed and dated by the subject and person obtaining consent?	Yes	All signatures present and dated correctly.
4	Is re-consent required and has it been obtained?	Yes	SUBJ-014 re-consented to v3.0 on 15-Apr-2025. SUBJ-015 re-consented to v3.0 on 15-Apr-2025.

Site Staff/Facilities

5	Is the Principal Investigator (PI) available for supervision?	Yes	Dr. Miller was present for the exit interview and available.
6	Are Sub-Investigators qualified and listed on the 1572?	Yes	Dr. Reynolds and Dr. Patel are listed. CVs are current.
7	Is the Study Coordinator trained and familiar with the protocol?	Yes	Jessica Chen demonstrates strong protocol knowledge, though not explicitly listed.
8	Are pharmacy facilities adequate and secure?	Yes	Access restricted to authorized personnel. Temperature logs reviewed.
9	Is the laboratory certified (CLIA/CAP) and are normal ranges current?	Yes	Current CAP/CLIA valid through Dec 2025.
10	Is equipment calibrated and maintained?	Yes	ECG and Centrifuge calibration records verified.
11	Is the Delegation of Authority Log current and signed?	No	SC to update DOAL to include Mark Lewis; PI to sign off.
12	Is the Training Log complete for all staff?	Yes	GCP training certificates on file for all active staff.
13	Are CVs current and signed for all key staff?	Yes	Verified.

Investigator Site File / Monitoring Activities

14	Is the Investigator Site File (ISF) complete and organized?	No	SC to draft and PI to sign NTF regarding retrospective data review.
15	Are essential documents current (1572, FDF, etc.)?	Yes	1572 updated 10-Jan-2025 is on file.
16	Is the Site Visit Log signed by the monitor?	Yes	Signed for today's visit.
17	Have action items from the prior visit been resolved?	No	Site to prioritize remaining 5 open actions from Visit 4.

Research Ethics Board

18	Is IRB/EC approval current for protocol and ICF?	Yes	Approval letter dated 15-Jan-2025 on file.
19	Have all protocol amendments been approved?	Yes	Amendment 4 approved.
20	Have safety reports been submitted to the IRB/EC as required?	Yes	IND safety reports submitted in batch on 30-Mar-2025.
21	Is the annual renewal current?	Yes	Next renewal due Dec 2025.
22	Is site-specific consent approved?	Yes	Verified.
23	Is SAE reporting to IRB compliant?	Yes	No local SAEs since last visit.

Safety

24	Are Adverse Events (AEs) reported in a timely manner?	Yes	AEs for ongoing subjects are current. Retrospective entry for previous visits.
25	Are SAEs followed to resolution?	Yes	All SAEs for completed subjects are closed.
26	Is pregnancy reporting compliant?	N/A	No pregnancies reported.
27	Are protocol deviations documented?	Yes	Deviations related to missed windows during the monitoring period.
28	Is the safety database reconciled with the clinical database?	No	SC to correct SAE onset dates in EDC to match Safety Data.
29	Are SUSAR notifications acknowledged and filed?	Yes	Filed electronically.
30	Have DSMB recommendations been implemented?	Yes	No new recommendations.
31	Is the risk-benefit assessment current?	Yes	PI confirms continued benefit for ongoing subjects.

Compliance

32	Is protocol compliance acceptable?	Yes	Current compliance is good. Historical non-compliance during V4.
33	Is GCP compliance maintained?	Yes	General adherence is observed.
34	Is regulatory compliance current?	Yes	Regulatory binder is now up to date (Action from V4 resolved).

Study Investigational Product

35	Is IP storage adequate and secure?	Yes	Ambient storage 15-25C maintained.
36	Is IP accountability current?	Yes	Logs updated for recent dispenses.
37	Is IP dispensing correct per protocol?	Yes	Verified for SUBJ-014 Visit 12.
38	Are IP returns documented?	Yes	Returns counted and verified.
39	Is temperature monitoring compliant?	Yes	Excursion log issue from Visit 4 has been resolved.

Study Supplies/Vendors

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40	Are lab kits and supplies adequate?	Yes	Inventory sufficient for remaining 2 subjects.
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Source Document Verification & Review

41	Are source documents available for all subjects?	Yes	EMR access functional.
42	Has SDV been completed per the monitoring plan?	Yes	100% SDV performed for new data.
43	Have data discrepancies been identified?	Yes	Minor transcription errors noted in concomitant meds.
44	Does CRF data match source documents?	Yes	Generally yes, after recent clean-up.
45	Is query resolution timely?	No	SC to resolve remaining 7 overdue queries by 15-May-2025
46	Are data corrections documented?	No	See Item 14.

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
SUBJ-014	Cycle 12 Day 1	Data entered timely. No new issues.	
SUBJ-015	Cycle 10 Day 1	Query regarding AE start date remains op	SC to answer Query #4492.
SUBJ-009	End of Treatment	SAE onset date in EDC does not match sou	Update EDC to match source.

FOLLOW-UP FROM PRIOR VISIT

Action: Update Regulatory Binder with current lab certs and CVs | Status: Resolved | Binder is now current.

Action: Address temperature excursion log gaps | Status: Resolved | Logs retrieved and filed.

Action: Resolve 12 overdue queries from Visit 4 | Status: Partially Resolved | 5 queries answered; 7 remain open.

Action: Create Note to File for retrospective data entry | Status: Open | Drafted but not signed.

Action: Update Delegation Log for new staff | Status: Open | Pending signature.

Action: Reconcile SAEs for SUBJ-009 and SUBJ-011 | Status: Open | Pending EDC updates.

Action: Complete missing SDV for SUBJ-012 | Status: Resolved | Completed during this visit.

Action: Upload missing financial disclosure forms | Status: Open | Still missing for Dr. Reynolds.

CRA ASSESSMENT

Site 033 is in a state of partial recovery. The transition from the monitoring gap (Visit 3 to Visit 4) created a significant administrative burden that the site is slowly working through. The reduction of the query backlog from 12 to 7 is a positive indicator of effort, but the persistence of open actions regarding data correction documentation (ALCOA+ compliance) and SAE reconciliation prevents the site from being considered 'clean.' The clinical care of the remaining subjects appears excellent, and safety reporting is timely. The primary risk remains the data integrity documentation for the period where oversight was absent. I will continue to work closely with the SC to close the remaining 5 open actions from Visit 4 before the next visit.