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:	2024-09-29
Visit Type:	On-Site
CRA:	CRA-006

SUMMARY OF MONITORING VISIT

This Remote Monitoring Visit (RMV) was conducted on 29-Sep-2024 for Site SITE-033 (California Cancer Associates for Research and Excellence) regarding Protocol M14-359. The visit was conducted by CRA-006 via remote access to the site's Electronic Medical Record (EMR) system and electronic Investigator Site File (eISF), followed by a teleconference with the Study Coordinator, Jessica Chen. The primary objectives of this visit were to perform Source Document Verification (SDV) for all randomized subjects, review Investigational Product (IP) accountability logs, and ensure ongoing regulatory compliance. As noted in the previous visit report, the site has been active since May 2024 and has rapidly reached its initial recruitment targets.

During this visit, 100% SDV was performed for the three (3) randomized subjects (SUBJ-001, SUBJ-002, SUBJ-003), all of whom have now moved to the 'Completed' status in the EDC system. The review focused on end-of-treatment visits, survival follow-up data, and the resolution of queries generated during the previous interim visit. Overall, the data quality remains high, with source documents clearly supporting the eCRF entries. There were no new Serious Adverse Events (SAEs) reported since the last visit. A review of the eISF revealed that while most essential documents are up to date, there is a lapse in the updated medical license for one Sub-Investigator, which requires immediate attention. Additionally, a minor discrepancy was noted in the temperature excursion log acknowledgement.

This visit also served as the transition visit for the current monitor (CRA-006). The Principal Investigator, Dr. Sarah Miller, and the study staff were informed that monitoring responsibilities will be transferred to a new CRA effective 01-Oct-2024. The site was instructed to maintain all study logs and continue data entry as per protocol during the interim period while the new monitor is assigned. The site staff expressed understanding of the transition process. No specific date for the next monitoring visit was scheduled during this interaction; the incoming CRA will contact the site to arrange the next visit once assignment is finalized.

Overall Impression:

The site is performing well with high enrollment velocity and good data quality, though administrative attention is required regarding the upcoming CRA transition.

Exit Interview Comments:

The exit interview was conducted via teleconference with Ms. Chen (SC) and briefly with Dr. Miller (PI). We discussed the three findings identified during the visit: the expired medical license for Sub-I Dr. Evans, the missing signature on the September temperature log, and the transcription error for SUBJ-002's concomitant medication. Ms. Chen agreed to address the data query immediately. Dr. Miller acknowledged the transition of monitoring responsibilities and confirmed that the site will continue to submit safety reports to the sponsor portal during the handover period. The site was thanked for their rapid enrollment and cooperation.

MONITORING VISIT REPORT

URGENT ISSUES

Yes

A. None. Routine findings only.

PERSONS PRESENT

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

ENROLLMENT STATUS

Screened: 5

Consented: 3

Pre Randomization Failure: 2

Randomized: 3

Completed: 3

Ongoing: 0

Withdrawn: 0

Recruitment Plan Notes:

The site has met its initial recruitment target of 3 subjects for this competitive enrollment phase. All 3 randomized subjects have completed the primary study phase. No further screening is anticipated at this time unless the sponsor re-opens enrollment slots.

Recruitment Rate Adequate? Yes

MONITORING VISIT REPORT

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 3 subjects.
3	Is the correct version of the ICF signed?	Yes	
4	Is re-consent required and completed if applicable?	N/A	No new ICF amendments since last visit.

Site Staff/Facilities

5	Is the PI available for supervision?	Yes	Dr. Miller joined the exit call.
6	Are Sub-Investigators qualified and delegated?	Yes	
7	Is the Study Coordinator trained and familiar with the protocol?	Yes	Ms. Chen is very knowledgeable.
8	Are pharmacy facilities adequate?	Yes	Access controlled, temperature monitored.
9	Is the laboratory certified/accredited?	Yes	CLIA/CAP current.
10	Is equipment calibrated and maintained?	Yes	
11	Is the Delegation of Authority Log current?	Yes	Reviewed in eISF.
12	Is the Training Log complete for all staff?	Yes	
13	Are CVs and medical licenses current?	No	Site to obtain and file current license for Dr. Evans.

Investigator Site File / Monitoring Activities

14	Is the ISF complete and organized?	Yes	eISF is well maintained.
15	Are essential documents current?	Yes	Aside from the finding noted in item 13.
16	Is the Monitoring Visit Log signed?	Yes	Electronic signature applied.
17	Are prior visit follow-up items complete?	Yes	All 4 items from Visit 2 are closed.

Research Ethics Board

18	Is IRB/EC approval current?	Yes	WIRB approval valid.
19	Are protocol amendments approved?	Yes	
20	Are safety reports submitted to IRB/EC?	Yes	IND safety reports submitted per local requirements.
21	Is annual renewal current?	Yes	Not due yet.
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 SUBJ-002 reviewed against source.
25	Are SAEs followed to resolution?	Yes	No open SAEs.
26	Is pregnancy reporting compliant?	N/A	No pregnancies reported.
27	Are protocol deviations documented?	Yes	Minor deviation log reviewed.
28	Is the safety database reconciled with the site?	Yes	
29	Are SUSAR notifications timely?	Yes	
30	Are DSMB recommendations implemented?	N/A	No new recommendations.
31	Is the risk-benefit assessment current?	Yes	

Compliance

32	Is protocol compliance acceptable?	Yes	Adherence is good.
33	Is GCP compliance maintained?	Yes	
34	Is regulatory compliance current?	Yes	

Study Investigational Product

35	Is IP storage adequate?	Yes	Ambient storage 15-25C.
36	Is IP accountability current?	Yes	Logs updated for returned kits.
37	Is IP dispensing correct?	Yes	IWRS confirmations match source.
38	Are IP returns documented?	Yes	Returns from SUBJ-003 verified.
39	Is temperature monitoring compliant?	No	Site to sign and date September temp log.

Study Supplies/Vendors

MONITORING VISIT REPORT

40	Are lab kits/supplies adequate?	Yes	Inventory sufficient for follow-up visits.
Source Document Verification & Review			
41	Are source documents available?	Yes	EMR access provided.
42	Was SDV completed per plan?	Yes	100% SDV for randomized subjects.
43	Are data discrepancies identified?	Yes	One discrepancy noted.
44	Does CRF data match source?	No	Query issued.
45	Is query resolution timely?	Yes	Previous queries resolved.
46	Are data corrections documented?	Yes	Audit trails visible.

MONITORING VISIT REPORT

SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
SUBJ-001	Visit 6 (End of Treatment	Subject completed treatment. No issues n	
SUBJ-002	Visit 5, Visit 6	Transcription error: Ondansetron stop da	Site to correct EDC to match source
SUBJ-003	Visit 4, Visit 5, Visit 6	Disease progression documented per RECIS	

FOLLOW-UP FROM PRIOR VISIT

Action: Update Delegation Log with new Phlebotomist | Status: Resolved | Log updated and signed 15-Aug-2024.
Action: Upload missing lab normal ranges for local lab | Status: Resolved | Uploaded to eISF.
Action: Resolve query regarding AE start date for SUBJ-001 | Status: Resolved | Data corrected.
Action: Complete GCP training for Sub-I Dr. Evans | Status: Resolved | Certificate filed 20-Aug-2024.

CRA ASSESSMENT

Site SITE-033 continues to demonstrate a high level of engagement and competence in the execution of Protocol M14-359. The study coordinator, Jessica Chen, is highly organized and responsive to queries, which has facilitated a smooth remote monitoring process. The Investigator Site File is largely compliant, with the exception of the expired medical license noted in this report. From a data perspective, the site is performing well; the three randomized subjects have completed the treatment phase, and the data entry is timely. The discrepancy rate is low, and the site's adherence to the protocol, particularly regarding dosing modifications and safety reporting, is commendable.

As this is the final visit for the current CRA, a significant portion of the visit was dedicated to ensuring the site is prepared for the transition. The site has been instructed on the communication pathways during the interim period before the new CRA is fully onboarded. The site understands that while the specific date of the next visit is currently To Be Determined (TBD), they must maintain the ISF and EDC currency in the interim. The gap in monitoring assignment should not impact site operations provided they adhere to the instructions given during the exit interview. I have prepared handover notes for the incoming CRA to ensure they are aware of the license renewal issue and the minor data query pending for SUBJ-002. Overall, the site is in a stable condition to be handed over.