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 #:	Highlands Oncology Group / SITE-055
Site Address:	Springdale, USA
Site Activation Date:	2024-05-06
Monitoring Visit Date:	2025-04-08
Visit Type:	On-Site
CRA:	CRA-003

SUMMARY OF MONITORING VISIT

On-Site Monitoring Visit 7 was conducted at Highlands Oncology Group (SITE-055) on 08-Apr-2025 to review study progress, data quality, and regulatory compliance for Protocol M14-359. The monitor arrived at the site at 09:00 and met with the Study Coordinator (SC), Sarah Jenkins, and Sub-Investigator (Sub-I), Dr. Emily Chen. The Principal Investigator (PI), Dr. Alistair Thorne, was not present at the site and was unavailable for the exit interview or ad-hoc questions. This marks the second consecutive monitoring visit (following Remote Visit 6 on 09-Feb-2025) where the PI has been unavailable to meet with the CRA. Site staff indicated Dr. Thorne is currently prioritizing other competing clinical commitments.

The primary focus of this visit was to address the stalling enrollment rates, review the Investigator Site File (ISF), and perform Source Document Verification (SDV) for query resolution on completed subjects. No new subjects have been screened or consented since the previous visit. The site remains at 5 randomized subjects against a target of 28, with activation having occurred nearly a year ago. During the discussion regarding recruitment, Sub-I Dr. Chen expressed frustration, noting that while she is managing the active patient load, she lacks the referral network access required to identify new eligible NSCLC patients, which is typically managed by Dr. Thorne.

Data quality for the 5 completed subjects remains high, with minimal queries generated. Regulatory binders are largely up to date, though the Delegation of Authority log required a minor update regarding the Sub-I's expanded scope during the PI's absence. The visit concluded with an exit interview with SC Sarah Jenkins and Sub-I Dr. Chen. The critical issue of PI oversight and the lack of new enrollment was discussed, and the site was informed that this would be escalated to the Sponsor.

Overall Impression:

While data quality and retention of completed subjects are excellent, the site is critically failing to meet enrollment targets due to a lack of Principal Investigator engagement and referral pipeline activity.

Exit Interview Comments:

Discussed the urgent need for PI re-engagement. Dr. Chen acknowledged the recruitment stall but stated she cannot force referrals from the PI's network. SC Jenkins confirmed no new potential subjects are currently in prescreening.

URGENT ISSUES

Yes

A. Principal Investigator (Dr. Thorne) unavailable for second consecutive visit; lack of oversight is directly impacting recruitment pipeline.

B. Enrollment has stalled completely (0 ongoing, 0 screened since last visit). Site is significantly behind the target of 28 subjects.

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PERSONS PRESENT

Name	Position/Title
Dr. Emily Chen	Sub-Investigator
Sarah Jenkins	Study Coordinator

ENROLLMENT STATUS

Screened: 6

Consented: 5

Pre Randomization Failure: 1

Randomized: 5

Completed: 5

Ongoing: 0

Withdrawn: 0

Recruitment Plan Notes:

Recruitment rate has fallen below target (0.45 subjects/month vs target 2.0). Sub-I expressed concern about PI engagement and its impact on the recruitment pipeline. The site has exhausted their internal database and relies on PI referrals which have ceased.

Recruitment Rate Adequate? No

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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	
3	Was the correct version of the ICF signed?	Yes	
4	Is re-consent required for any subjects?	N/A	No protocol amendments requiring re-consent since last vis

Site Staff/Facilities

5	Is the Principal Investigator available and involved in the study?	No	Escalate PI availability concerns to sponsor.
6	Are Sub-Investigators qualified and delegated appropriately?	Yes	Dr. Chen is managing all study activities.
7	Is the Study Coordinator trained and familiar with the protocol?	Yes	SC Jenkins is well versed in the protocol.
8	Are pharmacy facilities adequate and secure?	Yes	
9	Are laboratory facilities certified and adequate?	Yes	CAP/CLIA current.
10	Is equipment calibrated and maintained?	Yes	
11	Is the Delegation of Authority Log current?	No	SC to update DOA log to reflect current responsibilities.
12	Is the Training Log complete for all staff?	Yes	
13	Are CVs and medical licenses current?	Yes	

Investigator Site File / Monitoring Activities

14	Is the Investigator Site File (ISF) complete and organized?	Yes	
15	Are all essential documents current and filed?	Yes	
16	Is the Site Visit Log signed by the monitor and staff?	Yes	
17	Have action items from prior visits been resolved?	Yes	No open actions from Visit 6.

Research Ethics Board

18	Is IRB/EC approval current for protocol and ICF?	Yes	Annual renewal approved 15-Jan-2025.
19	Have all protocol amendments been approved?	Yes	
20	Have safety reports been submitted to the IRB/EC?	Yes	
21	Is the annual renewal current?	Yes	
22	Is site-specific consent wording approved?	Yes	
23	Is SAE reporting to IRB compliant with local requirements?	Yes	

Safety

24	Are Adverse Events (AEs) reported in a timely manner?	Yes	No new AEs since last visit.
25	Are SAEs followed to resolution?	Yes	All prior SAEs resolved.
26	Is pregnancy reporting compliant?	N/A	No pregnancies reported.
27	Are protocol deviations documented?	Yes	
28	Is the safety database reconciled with source documents?	Yes	
29	Are SUSAR notifications acknowledged and filed?	Yes	
30	Have DSMB recommendations been implemented?	N/A	
31	Is the risk-benefit assessment current?	Yes	

Compliance

32	Is protocol compliance acceptable?	No	Site to revise recruitment plan.
33	Is GCP compliance maintained?	Yes	
34	Is regulatory compliance current?	Yes	

Study Investigational Product

35	Is IP storage adequate and secure?	Yes	Ambient storage 15-25C maintained.
36	Is IP accountability current?	Yes	100% accountability performed for returned kits.
37	Is IP dispensing correct per protocol?	Yes	
38	Are IP returns documented?	Yes	
39	Is temperature monitoring compliant?	Yes	Temp logs reviewed; no excursions.

Study Supplies/Vendors

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40	Are lab kits and supplies adequate?	Yes	Inventory sufficient for 2 potential subjects.
Source Document Verification & Review			
41	Are source documents available?	Yes	EMR access granted.
42	Was SDV completed per the monitoring plan?	Yes	100% SDV for completed subjects.
43	Were data discrepancies identified?	Yes	SC to correct EDC.
44	Does CRF data match source documents?	Yes	Generally matches; see finding.
45	Is query resolution timely?	Yes	All queries <14 days old.
46	Are data corrections documented?	Yes	

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
055-005	End of Treatment	Stop date for Ondansetron in EDC (12-Mar	SC to update EDC.
N/A	N/A	Recruitment log has not been updated sin	SC to update recruitment log weekly
N/A	N/A	Dr. Chen's expanded duties regarding rec	PI to sign updated DOA log upon ret

CRA ASSESSMENT

Site 055 demonstrates strong data management capabilities for the subjects currently enrolled and completed. The Study Coordinator and Sub-Investigator are diligent in maintaining regulatory compliance and data integrity. However, the site's performance is critically threatened by the continued disengagement of the Principal Investigator, Dr. Thorne. This is the second consecutive visit where the PI was unavailable. The lack of PI oversight is directly correlating with the complete stall in recruitment (0 screened since last visit). The Sub-Investigator is capable of clinical management but lacks the authority and network to drive recruitment. Immediate Sponsor intervention or a PI-to-Medical Monitor call is recommended to address the enrollment stagnation.