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:	2025-07-16
Visit Type:	On-Site
CRA:	CRA-003

SUMMARY OF MONITORING VISIT

Remote Interim Monitoring Visit (IMV) 9 was conducted for Highlands Oncology Group (SITE-055) on 16-Jul-2025 to review study progress, data quality, and regulatory compliance for Protocol M14-359. The monitor met remotely with the Study Coordinator (SC), Sarah Jenkins, via video conference. The primary objective of the visit was to assess the status of the Principal Investigator's (PI) oversight, review recent enrollment metrics, and conduct Source Document Verification (SDV) for ongoing data queries.

Significantly, the Principal Investigator, Dr. Alistair Thorne, was not available for the visit, nor was he available for the exit interview. This marks the third consecutive monitoring visit (following Visit 6 and Visit 7) where the PI has been absent. SC Jenkins indicated that Dr. Thorne is currently prioritizing a competing high-volume Phase 3 study. Consequently, PI oversight appears compromised, and site leadership is actively discussing the formal delegation of PI responsibilities to the current Sub-Investigator, Dr. Emily Chen.

Enrollment has effectively stalled, with zero new screenings recorded in the past four weeks. The correlation between the PI's lack of engagement and the decline in recruitment is evident. While data quality for the five randomized subjects remains acceptable, the lack of PI involvement raises significant GCP concerns regarding supervision. Immediate Sponsor intervention is recommended to facilitate the transition of the PI role or to re-engage Dr. Thorne.

Overall Impression:

Critical concerns regarding PI oversight and enrollment stagnation require immediate escalation; site operations are otherwise functional under the SC and Sub-I.

Exit Interview Comments:

Discussed the critical nature of the PI's continued absence with SC Sarah Jenkins and Sub-I Dr. Emily Chen. Dr. Chen acknowledged the issue and confirmed that site administration is drafting a plan to formally transfer PI responsibilities to her, pending Sponsor approval. The SC was reminded that enrollment cannot remain at zero indefinitely without risking site closure.

URGENT ISSUES

Yes

A. Principal Investigator (Dr. Thorne) unavailable for third consecutive visit; lack of documented oversight.

B. Enrollment stalled; zero screenings in the past 4 weeks.

C. Potential administrative hold required pending PI change/succession plan.

PERSONS PRESENT

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

ENROLLMENT STATUS

Screened: 6

Consented: 5

Pre Randomization Failure: 1

Randomized: 5

Completed: 5

Ongoing: 0

Withdrawn: 0

Recruitment Plan Notes:

Recruitment is critically behind target. The site has screened 0 subjects in the last month. The SC attributes this to the PI's focus on a competing study. A revised recruitment plan was requested but not provided.

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 the ICF signed prior to any study-related procedures?	Yes	
3	Is the correct version of the ICF signed and dated by the subject and person obt	Yes	
4	Is re-consent required for any subjects?	N/A	No new protocol amendments requiring re-consent.

Site Staff/Facilities

5	Is the Principal Investigator available for the visit?	No	Sponsor to issue formal warning letter; Site to finalize PI
6	Is the Sub-Investigator qualified and available?	Yes	Dr. Chen was available and is handling clinical decisions in
7	Is the Study Coordinator trained and familiar with the protocol?	Yes	SC Jenkins remains very knowledgeable.
8	Are pharmacy facilities adequate?	Yes	Remote review of temp logs confirms adequacy.
9	Is the laboratory certified and adequate?	Yes	CAP/CLIA current.
10	Is equipment calibrated and maintained?	Yes	
11	Is the Delegation of Authority Log current?	No	Update DOA log pending PI change.
12	Is the Training Log complete and current?	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	eISF reviewed remotely.
15	Are essential documents current?	Yes	
16	Is the Site Visit Log signed?	Yes	Electronic signature applied.
17	Have action items from prior visits been resolved?	Yes	No overdue actions from Visit 7.

Research Ethics Board

18	Is IRB/EC approval current?	Yes	Continuing Review approved 15-May-2025.
19	Are protocol amendments approved?	Yes	
20	Have safety reports been submitted to the IRB/EC?	Yes	
21	Is the annual renewal current?	Yes	
22	Is the site-specific consent form approved?	Yes	
23	Is SAE reporting compliant with IRB 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	
26	Is pregnancy reporting compliant?	N/A	No pregnancies reported.
27	Are protocol deviations documented?	Yes	Deviation log reviewed.
28	Is the safety database reconciled with the CRF?	Yes	
29	Are SUSAR notifications acknowledged in a timely manner?	Yes	
30	Are DSMB recommendations implemented?	Yes	
31	Is the risk-benefit assessment current?	Yes	

Compliance

32	Is protocol compliance acceptable?	Yes	Clinical compliance is good; administrative oversight is the
33	Is GCP compliance maintained?	No	PI to re-engage or delegate authority.
34	Is regulatory compliance current?	Yes	

Study Investigational Product

35	Is IP storage adequate?	Yes	Temperature logs reviewed; no excursions.
36	Is IP accountability current?	Yes	Logs updated for all dispensed kits.
37	Is IP dispensing correct?	Yes	
38	Are IP returns documented?	Yes	
39	Is temperature monitoring compliant?	Yes	

Study Supplies/Vendors

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40	Are lab kits and supplies adequate?	Yes	Inventory sufficient given stalled enrollment.
Source Document Verification & Review			
41	Are source documents available?	Yes	EMR access granted for remote review.
42	Was SDV completed per the monitoring plan?	Yes	100% SDV for critical data points.
43	Were data discrepancies identified?	No	Data quality remains high despite PI absence.
44	Does CRF data match source documents?	Yes	
45	Is query resolution timely?	Yes	SC is responsive to queries.
46	Are data corrections documented?	Yes	

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
055-004	End of Treatment	Verified stop dates for concomitant medi	
055-005	Follow-up Visit 1	Confirmed subject status via EMR notes.	

CRA ASSESSMENT

While the site staff (SC and Sub-I) continue to perform high-quality data entry and subject management for the existing cohort, the site is functionally operating without a Principal Investigator. Dr. Thorne's repeated absence and the subsequent halt in enrollment (zero screenings in 4 weeks) indicate that the site is no longer prioritizing Protocol M14-359. The site leadership's proposal to delegate PI responsibilities to Dr. Chen is a necessary step if the site is to remain active. I recommend the Sponsor immediately pause new enrollment at this site until the PI succession plan is formalized and approved by the IRB. Continued operation under the current conditions poses a GCP compliance risk regarding investigator supervision.