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:	2025-02-09
Visit Type:	On-Site
CRA:	CRA-003

SUMMARY OF MONITORING VISIT

Remote Interim Monitoring Visit (IMV) 6 was conducted for Highlands Oncology Group (SITE-055) on 09-Feb-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. Notably, the Principal Investigator (PI), Dr. Alistair Thorne, was unavailable for the duration of the visit due to competing study commitments; Sub-Investigator Dr. Emily Chen conducted all monitoring activities and the close-out discussion in his stead. The primary focus of this visit was the review of the Investigator Site File (ISF), remote Source Document Verification (SDV) for ongoing data cleaning, and a review of the current enrollment stagnation.

Enrollment has decelerated significantly since the previous visit. While the site has successfully randomized and completed 5 subjects, no new subjects have been screened in the last three months. During the discussion regarding recruitment, the SC indicated that Dr. Thorne's focus on a competing Phase 3 trial has reduced the referral pipeline for this protocol. The Sub-I expressed difficulty reaching the PI for specific protocol eligibility questions, which has further hesitated screening efforts. A recruitment plan was discussed to re-engage the PI, though the SC noted his availability remains limited.

Remote SDV was performed for all randomized subjects with a focus on safety data and concomitant medications. Data quality remains high with minimal queries. The ISF was reviewed via the site's eReg binder; the Delegation of Authority Log was found to be updated to reflect Dr. Chen's increased responsibilities, but the PI's oversight signature was pending on recent logs due to his absence. No critical findings were identified, but the lack of PI oversight is a developing concern.

Overall Impression:

Site operations are well-managed by the SC and Sub-I, but PI disengagement due to competing priorities is negatively impacting recruitment momentum and oversight visibility.

Exit Interview Comments:

Exit interview conducted with SC Sarah Jenkins and Sub-I Dr. Emily Chen. Dr. Thorne was not present. Discussed the urgent need for PI oversight on the Delegation Log and the need to revitalize recruitment efforts.

URGENT ISSUES

Yes

A. Principal Investigator unavailable for monitoring visit and reportedly difficult to contact for study oversight due to competing trial commitments.

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 has stalled. SC attributes this to PI's focus on a competing study. Action item assigned to schedule a call between the Medical Monitor and PI to discuss engagement.

Recruitment Rate Adequate? Borderline -- screening volume declining

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

Site Staff/Facilities

5	Is the Principal Investigator available and involved in the study?	No	CRA to escalate to Study Manager.
6	Are Sub-Investigators qualified and delegated appropriately?	Yes	Dr. Chen is fully qualified and handling PI duties.
7	Is the Study Coordinator trained and familiar with the protocol?	Yes	Sarah Jenkins remains highly knowledgeable.
8	Are pharmacy facilities adequate and secure?	Yes	Verified via remote tour/photos in previous visit; no change
9	Is the Delegation of Authority Log current and signed?	No	PI to sign updated DOA log.
10	Are laboratory facilities certified and accreditation current?	Yes	CAP/CLIA current in ISF.
11	Is site equipment calibrated and maintained?	Yes	Calibration logs for centrifuge and freezer reviewed.
12	Is the Site Training Log complete and up to date?	Yes	
13	Are CVs and Medical Licenses current for all staff?	Yes	

Investigator Site File / Monitoring Activities

14	Is the Investigator Site File (ISF) complete and organized?	Yes	eISF reviewed remotely.
15	Are all essential documents current and filed?	Yes	
16	Is the Site Visit Log/Monitoring Log signed by site staff and CRA?	Yes	Electronic signature applied.
17	Have action items from the prior visit been resolved?	Yes	No open actions from Visit 4.

Research Ethics Board

18	Is IRB/EC approval current for protocol and ICF?	Yes	Continuing Review approval filed.
19	Have all protocol amendments been approved by the IRB/EC?	Yes	
20	Have safety reports been submitted to the IRB/EC as required?	Yes	IND safety reports submitted per local requirements.
21	Is the annual renewal/continuing review current?	Yes	Next renewal due May 2025.
22	Is site-specific consent language approved?	Yes	
23	Is SAE reporting to IRB/EC compliant with local regulations?	Yes	

Safety

24	Are Adverse Events (AEs) reported in a timely manner?	Yes	Source data matches EDC entries.
25	Are Serious Adverse Events (SAEs) followed to resolution?	Yes	No active SAEs at this time.
26	Is pregnancy reporting compliant with protocol?	N/A	No pregnancies reported.
27	Are protocol deviations documented and reported?	Yes	Minor deviation log reviewed.
28	Is the safety database reconciled with the clinical database?	Yes	
29	Are SUSAR notifications acknowledged and filed timely?	Yes	
30	Have DSMB recommendations been implemented?	N/A	No new DSMB directives.
31	Is the risk-benefit assessment current?	Yes	

Compliance

32	Is protocol compliance acceptable?	Yes	Generally good, though PI oversight documentation is laggi
33	Is GCP compliance maintained?	Yes	
34	Is regulatory compliance current?	Yes	FDA 1572 is current.

Study Investigational Product

35	Is IP storage adequate and secure?	Yes	Temperature logs reviewed remotely; no excursions.
36	Is IP accountability current and accurate?	Yes	Logs match IWRS dispensing records.
37	Is IP dispensing correct per protocol?	Yes	
38	Are IP returns documented?	Yes	Used kits quarantined for destruction.
39	Is temperature monitoring compliant?	Yes	Digital logs uploaded to portal.

Study Supplies/Vendors

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40	Are lab kits and study supplies adequate?	Yes	Inventory sufficient for current patient load.
Source Document Verification & Review			
41	Are source documents available and accessible?	Yes	Remote EMR access granted.
42	Was SDV completed per the monitoring plan?	Yes	100% SDV for randomized subjects.
43	Were data discrepancies identified?	No	Data aligns with source.
44	Does CRF data match source documents?	Yes	
45	Is query resolution timely?	Yes	SC is very responsive to DM queries.
46	Are data corrections documented properly?	Yes	Audit trails visible in EDC.

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
055-004	Visit 6 (End of Treatment	Verified stop date of IP. No issues.	
055-005	Visit 5	Source data verified against EDC. Clean.	

CRA ASSESSMENT

Highlands Oncology Group continues to execute the protocol with high data quality, largely due to the diligence of the Study Coordinator and the Sub-Investigator, Dr. Chen. However, the continued absence and lack of engagement from the PI, Dr. Thorne, is becoming a critical issue. The site has not screened a new patient in months, and the SC explicitly linked this to the PI's focus on a competing trial. While the Sub-I is capable of medical oversight for current patients, the lack of PI drive is stalling enrollment. I recommend a peer-to-peer discussion between the Sponsor Medical Monitor and the PI to re-establish expectations, otherwise, the site is unlikely to meet its enrollment target of 28 subjects.