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 #:	Clearview Cancer Institute / SITE-012
Site Address:	Huntsville, USA
Site Activation Date:	2024-03-09
Monitoring Visit Date:	2024-10-02
Visit Type:	On-Site
CRA:	CRA-001

SUMMARY OF MONITORING VISIT

This Interim Monitoring Visit (IMV) was conducted at Clearview Cancer Institute on 02-Oct-2024 to review study progress, verify source data, and ensure compliance with the protocol and GCP. The Principal Investigator, Dr. Reynolds, and Study Coordinator (SC), Ms. Davis, were present and available throughout the visit. The primary focus of this visit was the Source Document Verification (SDV) of newly randomized subjects (101-006 and 101-007) and the review of the Investigator Site File (ISF). Recruitment is tracking well against the target, with 7 subjects randomized to date.

A key objective of this visit was to follow up on the data entry findings from Visit 3 regarding the Lab Results eCRF pages. The site has successfully resolved the specific queries identified during the previous visit, correcting the 3 flagged CRF entries. However, during the SDV of the new subjects (101-006 and 101-007), two new queries were generated regarding the same Lab Results domain. Specifically, there appear to be persistent discrepancies between the local lab reports and the values entered into the EDC, particularly regarding unit conversions for hematology parameters. While the previous specific errors were fixed, the root cause--likely a data entry workflow issue--remains unaddressed.

Investigational Product (IP) accountability was reviewed for all active subjects with no discrepancies noted. Regulatory documents are current, including the recent IRB approval for the protocol amendment. The site staff remains cooperative, but the recurrence of data entry errors requires immediate attention to prevent data quality issues from compounding as enrollment continues.

Overall Impression:

The site is enrolling well and staff are engaged; however, recurrent data entry errors in the laboratory module suggest a need for targeted re-training to ensure data integrity.

Exit Interview Comments:

Discussed the recurrence of lab data entry errors with Ms. Davis and Dr. Reynolds. Dr. Reynolds acknowledged the issue and stated that a secondary check will be implemented for all future lab data entries. Ms. Davis requested a refresher on the specific unit requirements for the EDC lab module.

URGENT ISSUES

Yes

A. Recurrent data entry discrepancies in Lab Results eCRF module despite resolution of prior queries. Potential impact on safety monitoring (ANC values).

PERSONS PRESENT

MONITORING VISIT REPORT

Name	Position/Title
Dr. Reynolds	Principal Investigator
Ms. Davis	Study Coordinator

ENROLLMENT STATUS

Screened: 12

Consented: 8

Pre Randomization Failure: 4

Randomized: 7

Completed: 6

Ongoing: 1

Withdrawn: 0

Recruitment Plan Notes:

The site has randomized 7 subjects against a target of 28. The recruitment rate is approximately 1 subject per month, which aligns with the projected timeline. No new recruitment strategies are required at this time.

Recruitment Rate Adequate? Yes

MONITORING VISIT REPORT

MONITORING CHECKLIST

Informed Consent

1	Is the current IRB/EC-approved ICF version being used?	Yes	
2	Was ICF signed prior to any study-specific procedures?	Yes	
3	Is the correct version of the ICF used?	Yes	Version 3.0 is current.
4	Is re-consent required and if so, has it been performed?	N/A	No new amendments requiring re-consent since last visit.

Site Staff/Facilities

5	Is the Principal Investigator available for supervision?	Yes	Dr. Reynolds was present for the exit interview.
6	Are Sub-Investigators qualified and delegated appropriately?	Yes	
7	Is the Study Coordinator trained and familiar with the protocol?	Yes	Ms. Davis is knowledgeable, though re-training on Lab Data
8	Are pharmacy facilities adequate?	Yes	Temperature logs reviewed; no excursions.
9	Is the laboratory certified and accreditation current?	Yes	CAP/CLIA certifications valid through 2025.
10	Is equipment calibrated and maintained?	Yes	
11	Is the Delegation of Authority Log current?	Yes	
12	Is the Training Log complete for all staff?	Yes	
13	Are CVs current for all staff?	Yes	

Investigator Site File / Monitoring Activities

14	Is the ISF complete and organized?	Yes	eRegulatory binder is up to date.
15	Are essential documents current?	Yes	
16	Is the Site Visit Log signed?	Yes	Signed electronically.
17	Are follow-up actions from prior visits complete?	Yes	Prior lab queries resolved, though new similar issues identi

Research Ethics Board

18	Is IRB/EC approval current?	Yes	
19	Are protocol amendments approved?	Yes	
20	Are safety reports submitted to IRB/EC?	Yes	
21	Is annual renewal current?	Yes	Next renewal due Feb 2025.
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 101-006 reviewed against source.
25	Are SAEs followed to resolution?	N/A	No active SAEs at this time.
26	Is pregnancy reporting compliant?	N/A	No pregnancies reported.
27	Are protocol deviations documented?	Yes	Minor deviation for window visit 101-004 documented.
28	Is the safety database reconciled with the EDC?	Yes	
29	Are SUSAR notifications timely?	Yes	Filed in ISF.
30	Are DSMB recommendations implemented?	Yes	
31	Is the risk-benefit assessment current?	Yes	

Compliance

32	Is protocol compliance acceptable?	Yes	Generally compliant, barring minor data entry issues.
33	Is GCP compliance maintained?	Yes	
34	Is regulatory compliance current?	Yes	

Study Investigational Product

35	Is IP storage adequate?	Yes	Secure, limited access, temp controlled.
36	Is IP accountability current?	Yes	Logs matched physical inventory.
37	Is IP dispensing correct?	Yes	Verified for 101-006 and 101-007.
38	Are IP returns documented?	Yes	
39	Is temperature monitoring compliant?	Yes	

Study Supplies/Vendors

MONITORING VISIT REPORT

40	Are lab kits/supplies adequate?	Yes	Inventory sufficient for next 3 months.
Source Document Verification & Review			
41	Are source documents available?	Yes	EMR access provided.
42	Was SDV completed per plan?	Yes	100% SDV for new subjects.
43	Were data discrepancies identified?	Yes	Site to answer queries and retrain on lab module.
44	Does CRF data match source?	No	Queries issued.
45	Is query resolution timely?	Yes	Previous queries resolved, but new ones opened.
46	Are data corrections documented?	Yes	Audit trails confirm corrections.

MONITORING VISIT REPORT

SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
101-006	Visit 1 (Screening), Visi	Lab results for Cycle 1 Day 1 entered wi	Site to correct unit entry.
101-007	Visit 1 (Screening)	Chemistry panel data missing for screeni	Site to enter missing data.

FOLLOW-UP FROM PRIOR VISIT

Action: Correct Lab Results CRF entries | Status: Resolved | Site corrected 3 CRF entries. However, similar errors were noted in new subjects during this visit.

CRA ASSESSMENT

Overall, Clearview Cancer Institute is performing well regarding recruitment and general regulatory compliance. The site staff is responsive and cooperative. However, the data quality regarding laboratory results remains a concern. Although the site successfully resolved the specific queries from Visit 3 (correcting the 3 flagged entries), the identification of two new queries for similar lab data discrepancies in subjects 101-006 and 101-007 indicates that the root cause has not been addressed. It appears the SC is struggling with the unit conversion requirements of the EDC lab module. This creates a risk of 'whack-a-mole' monitoring where individual errors are fixed, but the systemic error persists. I have flagged this as a critical training need. I will conduct a specific training session on the Lab Module via WebEx before the next visit to ensure this does not affect safety signal detection.