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:	2025-06-11
Visit Type:	On-Site
CRA:	CRA-001

SUMMARY OF MONITORING VISIT

This Remote Monitoring Visit (RMV) was conducted on 11-Jun-2025 to review the ongoing data quality and regulatory compliance at Clearview Cancer Institute (Site SITE-012). With the study enrollment phase complete and 20 subjects having completed the protocol, the site is currently managing 3 ongoing subjects in the maintenance phase. The primary objectives of this visit were to perform remote Source Document Verification (SDV) for recent laboratory data, review the resolution status of previously identified Drug Accountability discrepancies, and verify the training documentation for new site staff. The Principal Investigator, Dr. Reynolds, and Study Coordinator, Ms. Davis, were available for the remote exit interview via teleconference.

While the site has successfully met enrollment targets, this visit identified scattered compliance issues suggesting a systemic difficulty in maintaining data entry quality during the maintenance phase. Specifically, Source Document Verification (SDV) revealed persistent discrepancies in Lab Results data entry for 5 subjects, primarily involving unit transcription errors that have not been corrected despite previous guidance. Additionally, a review of the eRegulatory binder indicated that training records (GCP certificates and Delegation of Authority Log signatures) were missing for two new staff members recently assigned to data entry tasks.

Furthermore, the site is carrying a backlog of 11 open queries across Lab Results, Drug Accountability, and AE Log domains, several of which have been open for >30 days. The Drug Accountability discrepancies noted during the previous visit have only been partially resolved; while one kit variance was explained, a second remains outstanding. The site staff have been instructed to prioritize query resolution and update the ISF with the missing training documents immediately to ensure inspection readiness.

Overall Impression:

The site has met enrollment goals, but data hygiene is deteriorating with multiple open queries and recurrent transcription errors requiring immediate remediation.

Exit Interview Comments:

Dr. Reynolds acknowledged the data entry backlog, attributing it to the recent turnover of the data entry assistant. Ms. Davis committed to dedicating two full days next week to clearing the 11 open queries and correcting the lab unit errors. They agreed to upload the missing training documents for the new staff by 18-Jun-2025.

URGENT ISSUES

Yes

A. Training records (GCP/DOAL) missing for 2 new staff members performing data entry.

B. 11 open queries >30 days across multiple domains (Labs, IP, AE).

C. Systemic data entry errors in Lab Results for 5 subjects.

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PERSONS PRESENT

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

ENROLLMENT STATUS

Screened: 33

Consented: 23

Pre Randomization Failure: 10

Randomized: 23

Completed: 20

Ongoing: 3

Withdrawn: 0

Recruitment Plan Notes:

Enrollment is closed. Site met 82% of original target (23/28) but recruitment is now complete. Focus is on retention of the 3 ongoing subjects.

Recruitment Rate Adequate? Yes

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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 randomized subjects.
3	Are all pages of the ICF present and signed/dated correctly?	Yes	
4	Is re-consent required and has it been performed?	N/A	No new ICF amendments requiring re-consent since last vis

Site Staff/Facilities

5	Is the Principal Investigator available and involved?	Yes	Dr. Reynolds attended 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 but struggling with data entry v
8	Are pharmacy facilities adequate and secure?	Yes	Remote verification of temp logs confirms compliance.
9	Is the laboratory certified and are normal ranges current?	Yes	CAP/CLIA current.
10	Is equipment calibrated and maintained?	Yes	Centrifuge calibration logs up to date.
11	Is the Delegation of Authority Log (DOAL) current?	No	Update DOAL and obtain PI signature.
12	Is the Training Log complete for all staff?	No	Upload GCP certs to eReg.
13	Are CVs current and signed for all staff?	Yes	CVs were present, just training logs missing.

Investigator Site File / Monitoring Activities

14	Is the Investigator Site File (ISF) complete and organized?	Yes	eRegulatory binder is generally well maintained aside from
15	Are essential documents current (FDA 1572, FDF, etc.)?	Yes	
16	Is the Site Visit Log signed by the monitor?	Yes	Electronic signature applied.
17	Have actions from prior visits been resolved?	No	Resolve remaining IP discrepancy.

Research Ethics Board

18	Is IRB/EC approval current for protocol and ICF?	Yes	Continuing Review approval on file.
19	Are protocol amendments approved and implemented?	Yes	
20	Are safety reports (IND Safety Reports) submitted to IRB?	Yes	Acknowledged via portal.
21	Is annual renewal/continuing review current?	Yes	Next due date: 15-Feb-2026.
22	Is site-specific consent approved (if applicable)?	N/A	
23	Is SAE reporting compliant with IRB requirements?	Yes	

Safety

24	Are Adverse Events (AEs) reported in a timely manner?	Yes	Generally yes, though some start dates required query clari
25	Are SAEs followed to resolution?	Yes	No open SAEs at this time.
26	Is pregnancy reporting compliant?	N/A	No pregnancies reported.
27	Are protocol deviations documented?	Yes	Minor deviations regarding visit windows documented.
28	Is the safety database reconciled with the CRF?	Yes	
29	Are SUSAR notifications processed timely?	Yes	
30	Are DSMB recommendations implemented?	Yes	
31	Is the risk-benefit assessment current?	Yes	

Compliance

32	Is protocol compliance acceptable?	Yes	Acceptable overall, though minor deviations in visit windows
33	Is GCP compliance maintained?	Yes	Generally yes, but documentation practices regarding data
34	Is regulatory compliance current?	No	Obtain and file missing training records.

Study Investigational Product

35	Is IP storage adequate and secure?	Yes	Ambient temperature logs reviewed; no excursions.
36	Is IP accountability current?	No	Reconcile Kit #20991 status.
37	Is IP dispensing correct per protocol?	Yes	IWRS confirmations match source.
38	Are IP returns documented?	Yes	Subject returns logged correctly.
39	Is temperature monitoring compliant?	Yes	

Study Supplies/Vendors

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40	Are lab kits and supplies adequate?	Yes	Inventory sufficient for remaining 3 subjects.
Source Document Verification & Review			
41	Are source documents available?	Yes	EMR access provided remotely.
42	Is SDV completed per the monitoring plan?	Yes	100% SDV performed for ongoing subjects.
43	Are data discrepancies identified?	Yes	Multiple discrepancies in lab units.
44	Does CRF data match source documents?	No	Correct CRF entries for Subjects 101-019 through 101-023.
45	Is query resolution timely?	No	Resolve all queries >30 days.
46	Are data corrections documented?	Yes	Audit trails are visible in EDC.

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
101-021	Cycle 12	Neutrophil count entered as 2.1 (10^9/L)	Update EDC to match source units.
101-022	Cycle 10	Creatinine value missing from EDC; prese	Enter missing data.
101-023	Cycle 8	Stop date for Ondansetron incorrect in E	Correct stop date.
101-019	Cycle 14	Unit discrepancy in Platelet count. Recu	Correct unit error.
101-020	Cycle 14	Unit discrepancy in WBC count. Recurring	Correct unit error.

FOLLOW-UP FROM PRIOR VISIT

Action: Resolve Drug Accountability discrepancies for Kit #20990 and #20991 | Status: Partially Resolved | Kit #20990 resolved (lost by subject). Kit #20991 still unaccounted for in logs vs EDC.

CRA ASSESSMENT

Site SITE-012 has successfully completed enrollment and is managing the remaining subjects adequately from a clinical perspective. However, administrative compliance and data quality have degraded over the last monitoring interval. The site demonstrates difficulty maintaining consistent data entry quality despite repeated corrective actions, evidenced by the 11 open queries and recurrent lab unit transcription errors across 5 subjects. The failure to update training records for new staff members represents a GCP compliance gap that must be addressed immediately. While the SC is cooperative, the workload appears to be impacting the timeliness of data entry and query resolution. Close monitoring will continue to ensure the site cleans the data in preparation for the final database lock.