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:	2025-01-08
Visit Type:	On-Site
CRA:	CRA-001

SUMMARY OF MONITORING VISIT

This Remote Monitoring Visit (RMV) was conducted on 08-Jan-2025 to review the status of Site SITE-012 (Clearview Cancer Institute). The primary objectives of the visit were to perform Source Document Verification (SDV) for recent data entries, review the Investigator Site File (ISF) via the eRegulatory system, and assess the status of data entry and query resolution in preparation for the upcoming interim database lock. The Principal Investigator, Dr. Reynolds, and the Study Coordinator (SC), Ms. Davis, were available for the remote exit interview via teleconference.

Enrollment has reached 12 randomized subjects. While recruitment is steady, a significant concern regarding data quality has re-emerged. During the review of clinical data for Subjects 101-008, 101-009, 101-010, and 101-011, it was noted that the specific data entry error regarding laboratory result units--previously identified and reportedly resolved during Visit 4--has recurred. Despite retraining provided at that time, the SC continues to transcribe local lab units incorrectly into the eCRF standard unit fields without performing the necessary conversion. This has resulted in a new batch of discrepancies that mirror the previous findings.

Furthermore, overall responsiveness to EDC queries has declined. There are currently 8 queries aged greater than 14 days, specifically related to the Lab Results and Vital Signs domains. During the exit interview, this systemic error pattern was discussed with Dr. Reynolds, who acknowledged the oversight. A corrective action plan was discussed to implement a secondary check for lab data entry moving forward.

Overall Impression:

The site is enrolling well, but data quality control has regressed regarding laboratory data transcription; immediate PI oversight is required to correct systemic entry errors.

Exit Interview Comments:

Dr. Reynolds and Ms. Davis were present. The recurring nature of the lab unit transcription errors was the main topic. Ms. Davis admitted to auto-filling the fields based on previous templates without verifying the specific unit changes on the new lab reports. Dr. Reynolds committed to reviewing the source-to-CRF process for the next 3 subjects personally.

URGENT ISSUES

Yes

A. Recurrence of systemic data entry errors regarding Laboratory Result Units in 4 subjects.

B. Backlog of aged queries (>14 days) in EDC requiring immediate resolution.

PERSONS PRESENT

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

ENROLLMENT STATUS

Screened: 19

Consented: 12

Pre Randomization Failure: 7

Randomized: 12

Completed: 11

Ongoing: 1

Withdrawn: 0

Recruitment Plan Notes:

The site has randomized 12 subjects against a target of 28. Recruitment has slowed slightly over the holidays but remains on track with the projected timeline.

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 Subject 101-012.
3	Is the correct version of the ICF signed?	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 PI available for supervision?	Yes	PI attended exit interview.
6	Are Sub-Is qualified and delegated?	Yes	DOA log reviewed.
7	Is the Study Coordinator trained and familiar with the protocol?	No	Retraining on CRF Completion Guidelines required.
8	Are pharmacy facilities adequate?	Yes	Not physically inspected (Remote Visit), but logs indicate c
9	Is the laboratory certified/accredited?	Yes	CAP/CLIA current in ISF.
10	Is equipment calibrated and maintained?	Yes	ECG calibration certificates current.
11	Is the Delegation of Authority log current?	Yes	Updated to reflect new Phlebotomist.
12	Is the Training Log complete?	Yes	
13	Are CVs current for all staff?	Yes	

Investigator Site File / Monitoring Activities

14	Is the ISF complete and up to date?	Yes	eRegulatory binder reviewed.
15	Are essential documents current?	Yes	
16	Is the Monitoring Visit Log signed?	Yes	Electronic signature applied.
17	Are follow-up actions from prior visits complete?	Yes	Previous action items closed, though the issue itself has re

Research Ethics Board

18	Is IRB/EC approval current?	Yes	Continuing Review approval on file.
19	Are protocol amendments approved?	Yes	
20	Are safety reports submitted to IRB?	Yes	IND safety reports submitted per local requirements.
21	Is annual renewal current?	Yes	
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 Subject 101-011 reviewed against source notes.
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 deviation for out-of-window visit documented for 101-
28	Is the safety database reconciled with the CRF?	Yes	
29	Are SUSAR notifications timely?	Yes	
30	Are DSMB recommendations implemented?	N/A	
31	Is the risk-benefit assessment current?	Yes	

Compliance

32	Is protocol compliance acceptable?	Yes	Clinical compliance is good; data entry compliance needs ir
33	Is GCP compliance maintained?	Yes	
34	Is regulatory compliance current?	Yes	

Study Investigational Product

35	Is IP storage adequate?	Yes	Temperature logs reviewed remotely.
36	Is IP accountability current?	Yes	e-Accountability logs match IWRS.
37	Is IP dispensing correct?	Yes	Verified for Subject 101-012.
38	Are IP returns documented?	Yes	
39	Is temperature monitoring compliant?	Yes	No excursions noted.

Study Supplies/Vendors

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40	Are lab kits/supplies adequate?	Yes	Site has sufficient stock.
Source Document Verification & Review			
41	Are source documents available?	Yes	Uploaded to EMR portal for review.
42	Is SDV completed per plan?	Yes	100% SDV performed for new data.
43	Are data discrepancies identified?	Yes	See Item 45.
44	Does CRF data match source?	No	See Item 45.
45	Are data corrections documented?	Yes	SC to correct lab units for Subjects 101-008, 101-009, 101-
46	Is query resolution timely?	No	SC to resolve all aged queries within 5 business days.

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
101-008	Cycle 1 Day 1	Lab units entered as standard units but	Update CRF with converted values.
101-009	Cycle 1 Day 1	Lab units entered as standard units but	Update CRF with converted values.
101-010	Screening	Lab units entered as standard units but	Update CRF with converted values.
101-011	Screening	Lab units entered as standard units but	Update CRF with converted values.

FOLLOW-UP FROM PRIOR VISIT

Action: SC to correct lab units for Subjects 101-006 and 101-007 (Visit 4 finding) | Status: Resolved | Corrections were made for these specific subjects, but the error has recurred in subsequent subjects.

CRA ASSESSMENT

Site SITE-012 continues to demonstrate strong enrollment potential and good clinical care for subjects. However, the administrative aspect of the study, specifically data entry quality, is deteriorating. The recurrence of the lab unit transcription error--despite previous identification and resolution--suggests that the site staff are not utilizing the CRF Completion Guidelines effectively or are relying on auto-population features without verification. The backlog of aged queries further indicates that the Study Coordinator is falling behind on data management tasks. While no critical safety findings were noted, the systemic nature of the data entry errors poses a risk to data integrity if not arrested immediately. I will schedule a follow-up call in 2 weeks to verify that the aged queries have been addressed and the lab data corrections have been implemented.