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:	2024-08-13
Visit Type:	On-Site
CRA:	CRA-001

SUMMARY OF MONITORING VISIT

This Remote Monitoring Visit (RMV) was conducted to review subject data, essential documents, and study progress at Clearview Cancer Institute. The visit focused on Source Document Verification (SDV) for Subjects 101-003, 101-004, and 101-005, as well as a review of the Investigator Site File (ISF) via the site's eRegulatory binder system. The Principal Investigator, Dr. Reynolds, and Study Coordinator, Ms. Davis, were available for the remote exit interview. Recruitment is progressing well, with 5 subjects randomized to date.

During the review of electronic Case Report Forms (eCRFs) against uploaded source documents, a trend of transcription errors was identified specifically regarding Laboratory Results. Discrepancies were noted in hematology and chemistry values for three subjects. Additionally, Data management queries have increased since last visit; there are currently 5 open queries regarding Lab Results and Vital Signs that require immediate attention. The Study Coordinator attributed these issues to a new data entry assistant who requires additional training. A plan was discussed to correct the current data and retrain the staff member.

Overall Impression:

The site remains engaged and recruitment is on target, but data entry quality has declined since the previous visit requiring immediate retraining of delegated staff.

Exit Interview Comments:

Discussed the specific lab value discrepancies with Ms. Davis and Dr. Reynolds. Dr. Reynolds acknowledged the oversight and confirmed that the new data entry assistant will undergo re-training on the EDC completion guidelines before entering further data. The site committed to answering the 5 outstanding queries by 20-Aug-2024.

URGENT ISSUES

No

PERSONS PRESENT

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

ENROLLMENT STATUS

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Screened:	8
Consented:	5
Pre Randomization Failure:	3
Randomized:	5
Completed:	5
Ongoing:	0
Withdrawn:	0

Recruitment Plan Notes:

Site has randomized 5 subjects against a target of 28. Recruitment rate is consistent with the projected timeline. No new recruitment barriers identified.

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 before any study procedures?	Yes	Verified for all randomized subjects.
3	Is the correct version used?	Yes	
4	Is re-consent needed/completed?	N/A	No new ICF amendments since last visit.

Site Staff/Facilities

5	Is the PI available and involved?	Yes	Dr. Reynolds attended the exit interview.
6	Are Sub-Is qualified and delegated?	Yes	CVs and medical licenses current in ISF.
7	Is the Study Coordinator trained?	Yes	GCP training is current.
8	Is Pharmacy adequate?	Yes	Temperature logs reviewed remotely; no excursions.
9	Is the Lab certified?	Yes	CLIA/CAP current.
10	Is equipment calibrated?	Yes	Centrifuge and ECG calibration records up to date.
11	Is the Delegation log current?	Yes	New data entry assistant added 01-Aug-2024.
12	Is the Training log complete?	Yes	
13	Are CVs current?	Yes	

Investigator Site File / Monitoring Activities

14	Is the ISF complete?	Yes	eISF reviewed.
15	Are essential documents current?	Yes	
16	Is the Monitoring log signed?	Yes	Electronic signature applied.
17	Is prior visit follow-up complete?	Yes	No open actions from Visit 2.

Research Ethics Board

18	Is IRB/EC approval current?	Yes	Approval valid through Mar-2025.
19	Are protocol amendments approved?	Yes	
20	Are safety reports submitted?	Yes	IND safety reports submitted to IRB as per local requiremen
21	Is annual renewal current?	N/A	Not yet due.
22	Is site-specific consent approved?	Yes	
23	Is SAE reporting compliant?	Yes	No SAEs reported this period.

Safety

24	Is AE reporting timely?	Yes	AEs entered in EDC within 5 days of visit.
25	Are SAEs followed to resolution?	N/A	No SAEs.
26	Is pregnancy reporting compliant?	N/A	No pregnancies reported.
27	Are protocol deviations documented?	Yes	Minor deviation log reviewed.
28	Is the safety database reconciled?	Yes	
29	Are SUSAR notifications timely?	Yes	
30	Are DSMB recommendations implemented?	N/A	No new DSMB letters.
31	Is risk-benefit assessment current?	Yes	

Compliance

32	Is protocol compliance acceptable?	Yes	Generally compliant, aside from data entry issues noted.
33	Is GCP compliance maintained?	Yes	
34	Is regulatory compliance current?	Yes	1572 updated with new sub-I.

Study Investigational Product

35	Is IP storage adequate?	Yes	Controlled access, temp monitored.
36	Is IP accountability current?	Yes	Logs match IWRS.
37	Is IP dispensing correct?	Yes	Verified for randomized subjects.
38	Are IP returns documented?	Yes	
39	Is temperature monitoring compliant?	Yes	No excursions.

Study Supplies/Vendors

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40	Are lab kits/supplies adequate?	Yes	Inventory sufficient for next 3 months.
Source Document Verification & Review			
41	Are source documents available?	Yes	Uploaded to secure portal.
42	Is SDV completed per plan?	Yes	100% SDV for randomized subjects.
43	Is query resolution timely?	No	Site to resolve pending queries.
44	Are data corrections documented?	Yes	Audit trails visible in EDC.
45	Does CRF data match source?	No	Site to correct Lab Results CRF entries.
46	Are data corrections documented?	Yes	

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
101-003	Visit 2	Hemoglobin value entered as 10.2 g/dL; s	Site to correct eCRF.
101-004	Visit 2	Creatinine unit entered as µmol/L; sourc	Site to correct eCRF.
101-005	Visit 1	Collection date entered as 10-Aug; sourc	Site to correct eCRF.

CRA ASSESSMENT

Clearview Cancer Institute continues to demonstrate strong recruitment potential and PI oversight. However, the data quality issues identified during this visit regarding Laboratory Results transcription are a concern that requires immediate remediation. The recent increase in open queries suggests that the new data entry support staff may not be fully proficient with the EDC specifications or the source document workflow. The PI and SC were receptive to feedback and have agreed to a retraining plan. I will perform a targeted review of data entry at the next visit to ensure these corrective actions have been effective. The site remains in good standing overall.