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:	2024-04-19
Visit Type:	On-Site
CRA:	CRA-001

SUMMARY OF MONITORING VISIT

This was the first Interim Monitoring Visit (IMV) conducted at Clearview Cancer Institute following site activation on 09-Mar-2024. The primary purpose of this visit was to review the Investigator Site File (ISF), verify the qualifications and delegation of site staff, and perform Source Document Verification (SDV) for the first subject screened (Subject 101-001). The Principal Investigator, Dr. Reynolds, and the Study Coordinator (SC), Ms. Davis, were available to facilitate the visit. The site has screened and consented one subject to date, who is currently in the screening phase pending central lab results.

Overall, the site initiation processes have been executed well, though one Critical finding was identified regarding the Delegation of Authority Log. It was noted that Sub-Investigator Dr. Patel performed a physical examination on Subject 101-001 prior to signing the delegation log. This was discussed with the PI, and a Note to File (NTF) has been generated to document the discrepancy. Additionally, two minor findings were noted: missing normal ranges for the local laboratory in the ISF and a backlog of queries in the EDC system related to concomitant medications.

Investigational Product (IP) accountability was reviewed; the initial shipment has been received and stored correctly with temperature excursions. The site staff demonstrated a good understanding of the protocol, specifically the complex randomization stratification factors. The focus for the next visit will be ensuring the timely resolution of EDC queries and confirming the eligibility of Subject 101-001 prior to randomization.

Overall Impression:

The site is off to a satisfactory start with adequate facilities and engaged staff, though immediate attention is required to correct the delegation documentation and improve EDC query response times.

Exit Interview Comments:

Dr. Reynolds acknowledged the finding regarding the Sub-I delegation and committed to signing off on the updated log immediately. Ms. Davis agreed to dedicate time this Friday to clear the pending EDC queries.

URGENT ISSUES

Yes

A. CRITICAL: Sub-Investigator Dr. Patel performed protocol-mandated physical exam on Subject 101-001 on 12-Apr-2024, but was not delegated this duty on the DOA log until 19-Apr-2024. This is a GCP non-compliance regarding unauthorized study activities.

PERSONS PRESENT

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Name	Position/Title
Dr. Alan Reynolds	Principal Investigator
Sarah Davis	Study Coordinator
Dr. Ravi Patel	Sub-Investigator

ENROLLMENT STATUS

Screened: 1

Consented: 1

Pre Randomization Failure: 0

Randomized: 0

Completed: 0

Ongoing: 0

Withdrawn: 0

Recruitment Plan Notes:

Site has screened 1 subject against a target of 28. This is consistent with the projected start-up curve. The site has identified 3 potential candidates from their database for pre-screening next week.

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 1.0 approved 01-Mar-2024.
2	Was ICF signed prior to any study procedures?	Yes	Subject 101-001 signed prior to vitals/labs.
3	Is the correct version of the ICF used?	Yes	
4	Is re-consent required and completed if applicable?	N/A	No amendments requiring re-consent yet.

Site Staff/Facilities

5	Is the PI available for supervision?	Yes	Met with PI during visit.
6	Are Sub-Is qualified and trained?	Yes	CVs and GCP certs on file.
7	Is the Study Coordinator trained on the protocol?	Yes	SIV training log signed.
8	Is the Pharmacy/IP storage adequate?	Yes	Restricted access, temp monitored.
9	Is the Laboratory certified (CLIA/CAP)?	Yes	Current certifications in ISF.
10	Is equipment calibrated and maintained?	Yes	ECG and Scale calibration records current.
11	Is the Delegation of Authority log current and signed?	No	PI to update log; NTF to be filed explaining discrepancy.
12	Is the Training Log complete for all staff?	Yes	
13	Are CVs current and signed/dated?	Yes	All CVs within 2 years.

Investigator Site File / Monitoring Activities

14	Is the ISF complete and organized?	No	SC to obtain current ranges from Lab Director.
15	Are essential documents current?	Yes	FDA 1572, FDFs present.
16	Is the Site Visit Log signed by the monitor?	Yes	Signed for today's visit.
17	Are prior visit follow-up items complete?	N/A	First monitoring visit.

Research Ethics Board

18	Is IRB/EC approval current?	Yes	Initial approval valid until Mar-2025.
19	Are protocol amendments approved?	N/A	No amendments yet.
20	Are safety reports submitted to IRB?	Yes	IND safety report submitted 05-Apr-2024.
21	Is annual renewal current?	N/A	Not due yet.
22	Is site-specific consent approved?	Yes	
23	Is SAE reporting compliant with IRB requirements?	N/A	No SAEs to date.

Safety

24	Is AE reporting timely in source and EDC?	Yes	Minor AEs (nausea) recorded in source.
25	Are SAEs followed to resolution?	N/A	
26	Is pregnancy reporting compliant?	N/A	
27	Are protocol deviations documented?	Yes	One deviation noted regarding DOA log (see Urgent Issues)
28	Is the safety database reconciled with EDC?	N/A	No SAEs.
29	Are SUSAR notifications timely?	Yes	Filed in ISF.
30	Are DSMB recommendations implemented?	N/A	No DSMB meetings yet.
31	Is the risk-benefit assessment current?	Yes	IB v4.0 on file.

Compliance

32	Is protocol compliance acceptable?	Yes	Screening procedures followed correctly.
33	Is GCP compliance maintained?	No	See Item 11.
34	Is regulatory compliance current?	Yes	

Study Investigational Product

35	Is IP storage adequate?	Yes	Ambient storage 15-25C verified.
36	Is IP accountability current?	Yes	Receipt of Shipment 1 logged in IWRS and paper log.
37	Is IP dispensing correct?	N/A	No subjects randomized yet.
38	Are IP returns documented?	N/A	
39	Is temperature monitoring compliant?	Yes	Temp logs reviewed, no excursions.

Study Supplies/Vendors

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40	Are lab kits/supplies adequate?	Yes	Sufficient kits for 5 subjects.
Source Document Verification & Review			
41	Are source documents available?	Yes	EMR access granted.
42	Is SDV completed per plan?	Yes	100% SDV for Subject 101-001.
43	Are data discrepancies identified?	Yes	Minor transcription errors in ConMeds.
44	Does CRF data match source?	Yes	After corrections made during visit.
45	Is query resolution timely?	No	SC to answer queries by 26-Apr-2024.
46	Are data corrections documented?	Yes	Audit trail visible in EDC.

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
101-001	Screening (Visit 1)	Subject consented 10-Apr-2024. All inclu	Monitor for lab results and randomi

CRA ASSESSMENT

Clearview Cancer Institute has successfully activated the study and screened their first patient. The site staff are experienced and cooperative. The critical finding regarding the Delegation of Authority log appears to be an administrative oversight rather than a systemic lack of supervision, as the Sub-Investigator is fully qualified and trained, merely missing a signature on the log at the time of the procedure. This was rectified immediately. However, the site is showing early signs of data entry delays, specifically with responding to EDC queries. I have emphasized to the Study Coordinator that maintaining a low query burden is essential for this phase 3 trial. I will continue to monitor the query aging report closely before the next visit. The site is suitable to continue enrollment.