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 #:	CBCC Global Research Inc. / SITE-022
Site Address:	Bakersfield, USA
Site Activation Date:	2024-05-16
Monitoring Visit Date:	2024-12-29
Visit Type:	On-Site
CRA:	CRA-005

SUMMARY OF MONITORING VISIT

This Monitoring Visit Report (MVR) documents the fourth Interim Monitoring Visit (IMV) conducted at CBCC Global Research Inc. (Site SITE-022) for Protocol M14-359 on 29-Dec-2024. The visit was conducted by CRA-005. The primary objectives of this visit were to perform 100% Source Document Verification (SDV) for all five (5) randomized subjects (SUBJ-001 through SUBJ-005), all of whom have now completed the study treatment phase. Additionally, a comprehensive review of the Investigator Site File (ISF), Investigational Product (IP) accountability, and regulatory compliance was performed. The Principal Investigator, Dr. Patel, and the Study Coordinator, Sarah Jenkins, were available throughout the visit to facilitate document access and discuss queries.

During the visit, 100% SDV was completed for all enrolled subjects up to the End of Treatment (EOT) visit. Overall, the data quality is high; however, specific discrepancies were noted regarding Concomitant Medication start dates for SUBJ-004 and AE grading for SUBJ-003, which require query resolution. A review of the ISF confirmed that most essential documents are current and filed according to ALCOA+ principles. One administrative finding was identified regarding the Site Delegation of Authority Log (DOAL), where the end date for a departing sub-investigator was not entered. IP accountability was reconciled for all returned kits, with one minor calculation error noted on the dispensing log for Kit #2004.

Three (3) new action items were generated during this visit. The site staff has been instructed to address the data queries within the EDC system within 5 business days and to update the DOAL immediately. Follow-up on action items from the previous visit (Visit 2/3) confirmed that all prior issues, including the calibration certificate filing, have been satisfactorily resolved. The site remains in good standing, and the next visit is tentatively scheduled for Q1 2025 to focus on database lock preparation.

Overall Impression:

The site continues to demonstrate a high level of engagement and protocol compliance, with all five subjects successfully completing the study; minor data entry errors and one administrative documentation omission were the only issues noted.

Exit Interview Comments:

An exit interview was conducted with Dr. Patel (PI) and Ms. Jenkins (SC) at 15:30. We discussed the three new findings. Dr. Patel acknowledged the discrepancy in the AE grading for SUBJ-003 and agreed to review the source notes against the CTCAE criteria. Ms. Jenkins corrected the IP accountability math error on the spot (initialed and dated). The missing end date on the Delegation Log will be entered by Dr. Patel tomorrow. We also discussed the timeline for data freeze.

URGENT ISSUES

No

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PERSONS PRESENT

Name	Position/Title
Dr. Ravi Patel	Principal Investigator
Sarah Jenkins	Study Coordinator

ENROLLMENT STATUS

Screened: 5

Consented: 5

Pre Randomization Failure: 0

Randomized: 5

Completed: 5

Ongoing: 0

Withdrawn: 0

Recruitment Plan Notes:

The site has met its initial recruitment target for this cohort. All 5 randomized subjects have completed the study. No further recruitment is currently planned unless the sponsor expands the cohort allocation. The site has effectively managed retention with 0% withdrawal rate.

Recruitment Rate Adequate? Yes

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MONITORING CHECKLIST

Informed Consent

1	Is the current IRB/EC-approved ICF version being used?	Yes	No
2	Was ICF signed before any study-specific procedures?	Yes	No
3	Is the correct version used?	Yes	No
4	Is re-consent needed?	N/A	No

Site Staff/Facilities

5	Is the PI available?	Yes	No
6	Is the Sub-I qualified?	Yes	No
7	Is the study coordinator trained?	Yes	No
8	Is the pharmacy adequate?	Yes	No
9	Is the lab certified?	Yes	No
10	Is equipment calibrated?	Yes	No
11	Is the Delegation log current?	No	Yes
12	Is the Training log complete?	Yes	No
13	Is the CV current?	Yes	No

Investigator Site File

14	Is the ISF complete?	Yes	No
15	Are essential documents current?	Yes	No
16	Is the monitoring log signed?	Yes	No
17	Is prior visit follow-up complete?	Yes	No

Research Ethics Board

18	Is IRB/EC approval current?	Yes	No
19	Are protocol amendments approved?	Yes	No
20	Are safety reports submitted?	Yes	No
21	Is annual renewal current?	Yes	No
22	Is site-specific consent approved?	Yes	No
23	Is SAE reporting compliant?	Yes	No

Safety

24	Is AE reporting timely?	Yes	No
25	Are SAEs followed to resolution?	Yes	No
26	Is pregnancy reporting compliant?	N/A	No
27	Are protocol deviations documented?	Yes	No
28	Is safety database reconciled?	Yes	No
29	Are SUSAR notifications timely?	Yes	No
30	Are DSMB recommendations implemented?	N/A	No
31	Is risk-benefit assessment current?	Yes	No

Compliance

32	Is protocol compliance acceptable?	Yes	No
33	Is GCP compliance maintained?	Yes	No
34	Is regulatory compliance current?	Yes	No

Study Investigational Product

35	Is IP storage adequate?	Yes	No
36	Is IP accountability current?	No	Yes
37	Is IP dispensing correct?	Yes	No
38	Are IP returns documented?	Yes	No
39	Is temperature monitoring compliant?	Yes	No

Study Supplies/Vendors

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40	Are lab kits/supplies adequate?	Yes	No
Source Document Verification			
41	Are source documents available?	Yes	No
42	Is SDV completed per plan?	Yes	No
43	Are data discrepancies identified?	Yes	Yes
44	Does CRF data match source?	No	Yes
45	Is query resolution timely?	Yes	No
46	Are data corrections documented?	Yes	No

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
SUBJ-003	Visit 4 (End of Treatment	Discrepancy noted in AE grading. Source	Site to update EDC or provide clari
SUBJ-004	Concomitant Medications	Discrepancy in start date for ConMed 'Li	Site to verify source and correct E
SUBJ-005	Visit 3	100% SDV completed. Lab values match sou	None

FOLLOW-UP FROM PRIOR VISIT

Action: Upload Centrifuge Calibration Certificate to ISF | Status: Resolved | Certificate dated 15-Aug-2024 was located and filed in ISF Section 10 on 29-Dec-2024.

Action: Resolve Query on SAE #002 Start Date | Status: Resolved | Query answered by SC on 15-Nov-2024. Data now matches source (hospital admission record).

Action: File Normal Ranges for Local Lab (Hematology) | Status: Resolved | Updated reference ranges effective 01-Jul-2024 were filed in ISF Section 5.

CRA ASSESSMENT

Site SITE-022 continues to perform at a high level. The study coordinator, Sarah Jenkins, is well-organized and maintains the ISF in near-audit-ready condition. The 100% SDV performed today confirms that the data entered for the five completed subjects is reliable, with only minor transcription errors identified in AE grading and ConMed dates. The PI, Dr. Patel, maintains excellent oversight, evidenced by his familiarity with the specific adverse events of the subjects. The only administrative gap noted was the failure to close out a sub-investigator on the delegation log, which is being addressed. IP accountability is acceptable despite a minor calculation error which was corrected on-site. I recommend this site for future studies based on their rapid enrollment and high-quality data management.