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:	2025-07-04
Visit Type:	On-Site
CRA:	CRA-005

SUMMARY OF MONITORING VISIT

This Monitoring Visit Report (MVR) documents the eighth monitoring visit (Visit 8) conducted at CBCC Global Research Inc. (Site SITE-022) for Protocol M14-359. The visit was conducted remotely on 04-Jul-2025 by CRA-005. The primary objectives of this visit were to review the status of the two (2) ongoing subjects, perform remote Source Document Verification (SDV) for recent data entries, and follow up on outstanding action items from the previous monitoring visit. The site has currently randomized 15 subjects, with 13 subjects having completed the study and 2 subjects remaining in the treatment/follow-up phase.

During the remote review, it was noted that the site is experiencing significant delays in data entry. Despite previous discussions regarding the importance of timely data transcription, a review of the EDC audit trails indicates a 'batch entry' pattern, where data for multiple visits is entered in a single session weeks after the actual patient visits occurred. This practice impedes the CRA's ability to perform timely safety reviews and query generation. Specifically, data entry lag now exceeds 7 days for 6 subjects (including retrospective data for recently completed subjects). Consequently, SDV was only partially completed due to the unavailability of up-to-date EDC entries for the most recent visits of the ongoing subjects.

Furthermore, the action items generated during Visit 7 regarding these batch corrections remain unresolved. The site coordinator cited staffing shortages as the primary reason for the delay; however, no concrete plan has been provided to rectify the backlog. Five (5) new queries were generated during this review related to missing concomitant medication start dates and inconsistent adverse event causality assessments. The Principal Investigator was briefed on these issues during the exit interview and acknowledged the need for immediate improvement in data currency.

Overall Impression:

The site's enrollment remains static as target enrollment is near completion, but operational quality has degraded. Significant attention is required to address the data entry backlog and resolve aged queries.

Exit Interview Comments:

Dr. Miller (PI) and Mr. Davis (SC) were present for the remote exit interview. The PI acknowledged the data entry lag and stated that the site is currently interviewing for a backup data entry specialist. The SC committed to clearing the current backlog of 6 subjects by 18-Jul-2025.

URGENT ISSUES

Yes

A. Data entry lag exceeds 7 days for 6 subjects, preventing timely safety review.

B. Batch data entry pattern persists despite prior warnings.

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PERSONS PRESENT

Name	Position/Title
Dr. Sarah Miller	Principal Investigator
John Davis	Study Coordinator

ENROLLMENT STATUS

Screened: 17

Consented: 16

Pre Randomization Failure: 1

Randomized: 15

Completed: 13

Ongoing: 2

Withdrawn: 0

Recruitment Plan Notes:

Recruitment is effectively closed for this site as they are nearing the global enrollment cap. Focus has shifted entirely to retention and data cleaning.

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 prior to any study procedures?	Yes	No
3	Is the correct version of the ICF signed?	Yes	No
4	Was re-consent obtained if applicable?	N/A	No

Site Staff/Facilities

5	Is the PI available for supervision?	Yes	No
6	Are Sub-Investigators qualified and delegated?	Yes	No
7	Is the Study Coordinator trained and familiar with the protocol?	Yes	No
8	Are pharmacy facilities adequate?	Yes	No
9	Is the laboratory certified and adequate?	Yes	No
10	Is equipment calibrated and maintained?	Yes	No
11	Is the Delegation of Authority Log current?	Yes	No
12	Is the Training Log complete for all staff?	Yes	No
13	Are CVs current for all staff?	Yes	No

Investigator Site File / Monitoring Activities

14	Is the ISF complete and up to date?	Yes	No
15	Are essential documents current?	Yes	No
16	Is the Monitoring Visit Log signed?	Yes	No
17	Are follow-up actions from the prior visit complete?	No	Yes

Research Ethics Board

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

Safety

24	Is AE reporting timely?	No	Yes
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 the safety database reconciled with EDC?	Yes	No
29	Are SUSAR notifications timely?	Yes	No
30	Are DSMB recommendations implemented?	Yes	No
31	Is the risk-benefit assessment current?	Yes	No

Compliance

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

Study Investigational Product

35	Is IP storage adequate?	Yes	No
36	Is IP accountability current?	Yes	No
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 & Review			
41	Are source documents available?	Yes	No
42	Is SDV completed per plan?	No	Yes
43	Are data discrepancies identified?	Yes	No
44	Does CRF data match source?	Yes	No
45	Is data entry timely?	No	Yes
46	Is query resolution timely?	No	Yes

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
SUBJ-014	Cycle 12 Day 1	Source uploaded but EDC not populated fo	Site to enter data by 18-Jul-2025.
SUBJ-015	Cycle 10 Day 1	Discrepancy in AE start date vs Nursing	Site to answer query.

FOLLOW-UP FROM PRIOR VISIT

Action: Site to explain batch data entry pattern and implement real-time entry. | Status: Open | Prior visit action items regarding batch corrections -- Status: Open -- Site has not provided explanation for batch data entry pattern.
Action: Resolve queries for SUBJ-009 and SUBJ-011. | Status: Open | Queries remain unanswered in EDC.

CRA ASSESSMENT

Ongoing data entry quality issues. Prior visit action items remain open. Entry lag elevated compared to historical site performance. While the site has historically been a high performer, the recent turnover in data management staff has created a bottleneck that is now affecting clinical monitoring activities. The site is urged to prioritize the retrospective data entry for the 6 identified subjects to allow for full SDV and safety reconciliation. Failure to resolve the backlog by the next visit may trigger a formal escalation to the Study Manager.