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:	2025-05-11
Visit Type:	On-Site
CRA:	CRA-005

SUMMARY OF MONITORING VISIT

This Monitoring Visit Report (MVR) documents the seventh monitoring visit (Visit 7) conducted at CBCC Global Research Inc. (Site SITE-022) for Protocol M14-359 on 11-May-2025. The visit was conducted on-site by CRA-005. The primary objectives of this visit were to perform Source Document Verification (SDV) for the one (1) ongoing subject (SUBJ-012) and conduct a retrospective review of data for recently completed subjects (SUBJ-009 through SUBJ-011). A review of the Investigator Site File (ISF) and Investigational Product (IP) accountability was also performed.

During the visit, it was noted that a data entry backlog has accumulated since the CRA transition earlier this year. While the site staff remains cooperative, the timeliness of EDC entry has declined significantly. Specifically, batch corrections were noted in multiple eCRF pages; CRF data for 4 subjects appeared to be entered or corrected in bulk on a single date rather than contemporaneously with subject visits. Additionally, the query backlog is increasing, with several queries now aged greater than 14 days. These issues were discussed with the Study Coordinator, who cited staffing constraints.

Source Document Verification was completed for the ongoing subject. No significant safety issues or unreported SAEs were identified. IP accountability was verified with no discrepancies found. The site was reminded of the importance of timely data entry to facilitate ongoing safety review.

Overall Impression:

The site is generally compliant with the protocol, but data entry timeliness and query resolution have deteriorated and require immediate attention.

Exit Interview Comments:

Discussed the data entry backlog with the Study Coordinator and PI. The PI acknowledged the delay and stated that the site staff will dedicate time next week to clear the backlog. The batch entry issue was highlighted as a GCP concern.

URGENT ISSUES

Yes

A. Data entry backlog and batch corrections observed in EDC.

B. Query backlog exceeding 14 days.

PERSONS PRESENT

Name	Position/Title

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Dr. Arvin Patel	Principal Investigator
Sarah Jenkins	Study Coordinator

ENROLLMENT STATUS

Screened: 13

Consented: 12

Pre Randomization Failure: 1

Randomized: 12

Completed: 11

Ongoing: 1

Withdrawn: 0

Recruitment Plan Notes:

Enrollment is closed at this site. Focus is now on the follow-up of the remaining ongoing subject and data cleaning for completed subjects.

Recruitment Rate Adequate? Yes

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MONITORING CHECKLIST

Informed Consent

1	Is the current IRB/EC-approved ICF version being used?	Yes	
2	Was ICF signed prior to any study procedures?	Yes	
3	Is the correct version of the ICF signed and dated?	Yes	
4	Is re-consent required and obtained if applicable?	Yes	SUBJ-012 re-consented.

Site Staff/Facilities

5	Is the PI available for supervision?	Yes	Met with PI during exit interview.
6	Are Sub-Investigators qualified and delegated?	Yes	
7	Is the Study Coordinator trained and familiar with the protocol?	Yes	
8	Are pharmacy facilities adequate?	Yes	
9	Is the laboratory certified and ranges current?	Yes	CAP/CLIA current.
10	Is equipment calibrated and maintained?	Yes	
11	Is the Delegation of Authority Log current?	Yes	
12	Is the Training Log complete for all staff?	Yes	
13	Are CVs and Medical Licenses current?	Yes	

Investigator Site File / Monitoring Activities

14	Is the ISF complete and organized?	Yes	General review performed.
15	Are essential documents current?	Yes	
16	Is the Site Visit Log signed?	Yes	Signed by CRA-005.
17	Have prior visit follow-up items been addressed?	N/A	No open items from Visit 5.

Research Ethics Board

18	Is IRB/EC approval current?	Yes	Continuing Review approved 15-Apr-2025.
19	Are protocol amendments approved?	Yes	
20	Are safety reports submitted to IRB?	Yes	
21	Is annual renewal current?	Yes	
22	Is site-specific consent approved?	Yes	
23	Is SAE reporting to IRB compliant?	Yes	

Safety

24	Is AE reporting timely and accurate?	Yes	Source matches EDC for reported AEs.
25	Are SAEs followed to resolution?	Yes	
26	Is pregnancy reporting compliant?	N/A	No pregnancies reported.
27	Are protocol deviations documented?	Yes	Minor deviations noted in logs.
28	Is the safety database reconciled with EDC?	Yes	
29	Are SUSAR notifications timely?	Yes	
30	Are DSMB recommendations implemented?	Yes	
31	Is the risk-benefit assessment current?	Yes	

Compliance

32	Is protocol compliance acceptable?	Yes	
33	Is GCP compliance maintained?	Yes	See findings regarding data entry timeliness.
34	Is regulatory compliance current?	Yes	

Study Investigational Product

35	Is IP storage adequate and secure?	Yes	Ambient storage, restricted access.
36	Is IP accountability current?	Yes	Logs reviewed for SUBJ-012.
37	Is IP dispensing correct per protocol?	Yes	
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 and supplies adequate?	Yes	Inventory sufficient for remaining subject.
Source Document Verification & Review			
41	Are source documents available?	Yes	EMR access provided.
42	Was SDV completed per the monitoring plan?	Yes	100% SDV for ongoing subject.
43	Were data discrepancies identified?	Yes	Site to correct.
44	Does CRF data match source?	No	Site to update EDC.
45	Is query resolution timely?	No	Site to answer outstanding queries.
46	Are data corrections documented appropriately?	No	Site to explain bulk entry process and ensure contemporan

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
SUBJ-012	Cycle 12 Day 1	Data verified. Entry was delayed by 3 we	Site to ensure timely entry.
SUBJ-009	End of Treatment	Batch entry observed. Data entered on sa	Site cautioned on batch entry.

CRA ASSESSMENT

The site continues to enroll and treat subjects according to the protocol. However, since the previous monitoring visit, there has been a noticeable decline in the timeliness of data entry. The observation of batch data corrections suggests that the site staff may be saving data entry for specific days rather than entering it as visits occur, which raises concerns about data accuracy and recall. The query backlog is also growing. While the site is cooperative, these administrative aspects of the study need to be tightened up to ensure the database can be locked on time. I will continue to monitor the data entry rates remotely before the next visit.