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: 2025-02-10

Visit Type: On-Site

CRA: CRA-005

SUMMARY OF MONITORING VISIT

This Monitoring Visit Report documents the fifth monitoring visit conducted at CBCC Global Research Inc. for Protocol M14-359. The visit was conducted remotely on 10-Feb-2025 by CRA-005. The primary objective of the visit was to review the progress of the study and verify source data for the recently enrolled subjects. The site appears cooperative and willing to comply with study requirements.

During the visit, source document verification was performed for the new subjects. The Investigator Site File was reviewed for essential documents. The site staff was available to answer questions during the remote visit. Overall, the study is progressing according to the protocol. There were no significant issues identified during the review of the data or the regulatory binder.

Overall Impression:

Site is performing adequately. No major concerns.

Exit Interview Comments:

The CRA discussed the visit outcome with the Study Coordinator. The Principal Investigator was available for a brief discussion. The site acknowledged the minor finding regarding the delegation log.

URGENT ISSUES

No

PERSONS PRESENT

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

ENROLLMENT STATUS

Screened: 9

Consented: 8

Pre Randomization Failure: 1

Randomized: 7

Completed: 6

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Ongoing:	1
Withdrawn:	0

Recruitment Plan Notes:

Recruitment is on track. The site has enrolled 7 subjects against the target of 24.

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 the ICF signed prior to any study-related procedures?	Yes	
3	Is the correct version of the ICF signed and dated by the subject and person obt	Yes	
4	Is re-consent required for any subjects?	No	

Site Staff/Facilities

5	Is the Principal Investigator available for supervision?	Yes	
6	Are Sub-Investigators qualified and listed on the 1572?	Yes	
7	Is the Study Coordinator trained and familiar with the protocol?	Yes	
8	Are pharmacy facilities adequate and secure?	Yes	
9	Is the laboratory certified and are normal ranges current?	Yes	
10	Is equipment calibrated and maintained?	Yes	
11	Is the Site Delegation Log current and signed?	No	Update delegation log.
12	Is the Training Log complete for all staff?	Yes	
13	Are CVs and medical licenses current for all staff?	Yes	

Investigator Site File / Monitoring Activities

14	Is the Investigator Site File (ISF) complete and organized?	Yes	
15	Are all essential documents current and filed?	Yes	
16	Is the Site Visit Log signed by the monitor?	Yes	Remote visit.
17	Have action items from the prior visit been resolved?	Yes	

Research Ethics Board

18	Is IRB/EC approval current for the protocol and ICF?	Yes	
19	Have all protocol amendments been approved?	Yes	
20	Have safety reports been submitted to the IRB/EC?	Yes	
21	Is the annual renewal current?	Yes	
22	Has site-specific consent been approved?	Yes	
23	Is SAE reporting to the IRB compliant?	Yes	

Safety

24	Are Adverse Events (AEs) reported in a timely manner?	Yes	
25	Are SAEs followed to resolution?	Yes	
26	Is pregnancy reporting compliant with the protocol?	N/A	
27	Are protocol deviations documented and reported?	Yes	
28	Is the safety database reconciled with the CRF?	Yes	
29	Are SUSAR notifications filed in a timely manner?	Yes	
30	Have DSMB recommendations been implemented?	Yes	
31	Is the risk-benefit assessment current?	Yes	

Compliance

32	Is protocol compliance acceptable?	Yes	
33	Is GCP compliance maintained?	Yes	
34	Is regulatory compliance current?	Yes	

Study Investigational Product

35	Is IP storage adequate and secure?	Yes	
36	Is IP accountability current and accurate?	Yes	
37	Is IP dispensing correct per protocol?	Yes	
38	Are IP returns documented?	Yes	
39	Is temperature monitoring compliant?	Yes	

Study Supplies/Vendors

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40	Are lab kits and supplies adequate?	Yes	
Source Document Verification & Review			
41	Are source documents available for all subjects?	Yes	
42	Was SDV completed per the monitoring plan?	Yes	
43	Were data discrepancies identified?	No	All data reviewed.
44	Does CRF data match source documents?	Yes	
45	Is query resolution timely?	Yes	
46	Are data corrections documented properly?	Yes	

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
SUBJ-006	Visit 1-4	Data reviewed. No issues.	
SUBJ-007	Visit 1-2	Data reviewed. No issues.	

CRA ASSESSMENT

The site is performing adequately. The staff is helpful and the documents are in order. Recruitment is proceeding. No major concerns were noted during this visit. The site should continue to enroll subjects and maintain compliance.