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 #:	CRU Hungary Egeszsegugyi Kft. / SITE-074
Site Address:	Miskolc, HUN
Site Activation Date:	2024-09-23
Monitoring Visit Date:	2025-03-31
Visit Type:	On-Site
CRA:	CRA-117

SUMMARY OF MONITORING VISIT

This Interim Monitoring Visit (IMV) was conducted at CRU Hungary Egeszsegugyi Kft. (SITE-074) on 31-Mar-2025 to review study progress, verify source data, check investigational product (IP) accountability, and ensure compliance with Protocol M14-359, GCP, and local regulations. The monitor met with the Principal Investigator, Dr. Laszlo Kovacs, and the Study Coordinator, Eva Nagy, to discuss the study status. The site has shown remarkable recruitment performance, having already met the target enrollment. No concerns noted during this monitoring visit. Site performing well.

Overall Impression:

Site performing well.

Exit Interview Comments:

PI available and cooperative. No issues to discuss.

URGENT ISSUES

No

PERSONS PRESENT

Name	Position/Title
Dr. Laszlo Kovacs	Principal Investigator
Eva Nagy	Study Coordinator

ENROLLMENT STATUS

Screened:	29
Consented:	22
Pre Randomization Failure:	7
Randomized:	20
Completed:	17
Ongoing:	3
Withdrawn:	0

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Recruitment Plan Notes:

Recruitment target met. No concerns.

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 used?	Yes	
4	Is re-consent required and completed if applicable?	Yes	

Site Staff/Facilities

5	Is the Principal Investigator available?	Yes	
6	Are Sub-Investigators qualified?	Yes	
7	Is the Study Coordinator trained?	Yes	
8	Is the Pharmacy adequate?	Yes	
9	Is the Laboratory certified?	Yes	
10	Is equipment calibrated?	Yes	
11	Is the Delegation Log current?	Yes	
12	Is the Training Log complete?	Yes	
13	Are CVs current?	Yes	

Investigator Site File / Monitoring Activities

14	Is the ISF complete?	Yes	
15	Are Essential Documents current?	Yes	
16	Is the Monitoring Log signed?	Yes	
17	Is prior visit follow-up complete?	Yes	

Research Ethics Board

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

Safety

24	Is AE reporting timely?	Yes	
25	Are SAEs followed to resolution?	Yes	
26	Is pregnancy reporting compliant?	Yes	
27	Are protocol deviations documented?	Yes	
28	Is the safety database reconciled?	Yes	
29	Are SUSAR notifications timely?	Yes	
30	Are DSMB recommendations implemented?	Yes	
31	Is 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?	Yes	
36	Is IP accountability current?	Yes	
37	Is IP dispensing correct?	Yes	
38	Are IP returns documented?	Yes	
39	Is temperature monitoring compliant?	Yes	

Study Supplies/Vendors

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40	Are lab kits/supplies adequate?	Yes	
Source Document Verification & Review			
41	Are source documents available?	Yes	
42	Is SDV completed per plan?	Yes	
43	Are data discrepancies identified?	Yes	
44	Does CRF data match source?	Yes	
45	Is query resolution timely?	Yes	
46	Are data corrections documented?	Yes	

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SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
SUBJ-020	Visit 4	All source data verified, no discrepanci	
SUBJ-021	Visit 3	All source data verified, no discrepanci	
SUBJ-022	Visit 2	All source data verified, no discrepanci	

CRA ASSESSMENT

The site continues to perform well. All source documents were verified against the CRFs with no discrepancies noted. The Investigator Site File is up to date and complete. IP accountability was reviewed and found to be accurate. The site staff are well trained and following the protocol. No concerns noted during this monitoring visit.