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:	2025-05-26
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 26-May-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.

Overall Impression:

Site performing well. No issues identified.

Exit Interview Comments:

The monitor met with the Principal Investigator and Study Coordinator at the conclusion of the visit. PI available and cooperative. No findings to report.

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Withdrawn:	0

MONITORING VISIT REPORT

Recruitment Plan Notes:

Target enrollment met. Recruitment is closed.

Recruitment Rate Adequate? Yes

MONITORING VISIT REPORT

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	Was re-consent obtained if applicable?	N/A	

Site Staff/Facilities

5	Is the PI available for supervision?	Yes	PI available and cooperative.
6	Are Sub-Investigators qualified and delegated?	Yes	
7	Is the Study Coordinator trained on the protocol?	Yes	
8	Are pharmacy facilities adequate?	Yes	
9	Is the laboratory certified/accredited?	Yes	
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 current for all staff?	Yes	

Investigator Site File / Monitoring Activities

14	Is the Investigator Site File (ISF) complete?	Yes	ISF reviewed and complete.
15	Are essential documents current?	Yes	
16	Is the Site Visit Log signed?	Yes	
17	Have prior visit follow-up items been completed?	Yes	No prior actions pending.

Research Ethics Board

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

Safety

24	Is AE reporting timely and accurate?	Yes	No issues.
25	Are SAEs followed to resolution?	Yes	
26	Is pregnancy reporting compliant?	N/A	No pregnancies reported.
27	Are protocol deviations documented?	Yes	No deviations noted.
28	Is the safety database reconciled with source?	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	Site performing well.
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?	Yes	100% accountability verified.
37	Is IP dispensing correct?	Yes	
38	Are IP returns documented?	Yes	
39	Is temperature monitoring compliant?	Yes	No excursions.

Study Supplies/Vendors

MONITORING VISIT REPORT

40	Are lab kits and supplies adequate?	Yes	
Source Document Verification & Review			
41	Are source documents available?	Yes	
42	Was SDV completed per plan?	Yes	100% SDV completed.
43	Were data discrepancies identified?	N/A	No discrepancies identified.
44	Does CRF data match source?	Yes	
45	Is query resolution timely?	Yes	No open queries.
46	Are data corrections documented?	Yes	

MONITORING VISIT REPORT

SOURCE DOCUMENT VERIFICATION & CHART REVIEW

Subject	Visits Reviewed	Comments	Action Required
SUBJ-018	Visit 10-12	No concerns noted.	
SUBJ-019	Visit 8-10	No concerns noted.	
SUBJ-020	Visit 6-8	No concerns noted.	

CRA ASSESSMENT

The site continues to perform excellently. All source data was verified against the CRFs with no discrepancies found. The Investigator Site File is up to date. IP accountability is accurate. No protocol deviations were noted. The PI and staff are very cooperative. No concerns noted during this monitoring visit.