# 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 #:** | Clearview Cancer Institute / SITE-012 |
| **Site Address:** | Huntsville, USA |
| **Site Activation Date:** | 2024-03-09 |
| **Monitoring Visit Date:** | 2025-03-05 |
| **Visit Type:** | On-Site |
| **CRA:** | CRA-001 |

## SUMMARY OF MONITORING VISIT

This On-Site Monitoring Visit (Visit 7) was conducted at Clearview Cancer Institute on 05-Mar-2025. The primary objectives were to perform Source Document Verification (SDV) for ongoing subjects, review Investigational Product (IP) accountability, and assess the status of data entry and query resolution following the recent interim database lock. The Principal Investigator, Dr. Reynolds, and the Study Coordinator (SC), Ms. Davis, were available to facilitate the visit. The site has successfully randomized 17 subjects to date, with 15 completed and 2 ongoing. Recruitment is currently paused as the site nears its target, allowing focus to shift toward data cleaning and maintenance.

During the visit, a comprehensive review of the Investigator Site File (ISF) and regulatory binders confirmed that essential documents remain current. However, significant data quality issues were identified during the review of source data against the CRF. Specifically, a recurring pattern of discrepancies was noted in the Drug Accountability logs and the Lab Results domain. Despite prior corrective actions discussed during Visit 6 regarding data entry accuracy, similar errors have resurfaced. Discrepancies between the pharmacy dispensing records and the CRF entries were noted for two subjects, and previously flagged query types regarding Lab Results remain unresolved. These findings were discussed in detail during the exit interview, and a corrective action plan was reinforced to prevent further data integrity issues.

**Overall Impression:**

The site demonstrates strong subject retention and protocol adherence; however, recurring data entry errors in specific domains (IP and Labs) indicate a need for increased attention to detail by the study coordinator.

**Exit Interview Comments:**

Dr. Reynolds acknowledged the findings regarding the IP accountability discrepancies. Ms. Davis explained that the IP date errors were likely due to a transcription delay between the pharmacy software and the paper logs. Both agreed to implement a 'double-check' process for all future data entry. Regarding the open lab queries, the SC committed to resolving the 6 outstanding items by 12-Mar-2025.

## URGENT ISSUES

**Yes**

A. Drug Accountability Discrepancies: IP dispensing dates in the CRF/Logs do not match source pharmacy records for Subjects 101-016 and 101-017.

B. Recurring Data Quality/Query Resolution: 6 queries remain open on Lab Results pages, representing a recurring issue despite prior training.

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## PERSONS PRESENT

| Name | Position/Title |
|---|---|
| Dr. Reynolds | Principal Investigator |
| Ms. Davis | Study Coordinator |

## ENROLLMENT STATUS

**Screened:** 26

**Consented:** 18

**Pre Randomization Failure:** 8

**Randomized:** 17

**Completed:** 15

**Ongoing:** 2

**Withdrawn:** 0

**Recruitment Plan Notes:**

Recruitment is currently on hold as the study-wide enrollment cap approaches. The site has met 60% of their specific target (17/28). Retention is excellent with 0 withdrawals.

**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 | Is re-consent required and completed if applicable? | N/A | No |

### Site Staff/Facilities

| | | | |
|---|---|---|---|
| 5 | Is the PI available for supervision? | Yes | No |
| 6 | Are Sub-Is 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/accredited? | 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? | Yes | No |
| 13 | Are CVs current for all staff? | Yes | No |

### Investigator Site File / Monitoring Activities

| | | | |
|---|---|---|---|
| 14 | Is the ISF complete and organized? | Yes | No |
| 15 | Are essential documents current? | Yes | No |
| 16 | Is the Site Visit Log signed? | Yes | No |
| 17 | Are follow-up actions from prior visits complete? | Yes | No |

### 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? | Yes | No |
| 21 | Is annual renewal current? | Yes | No |
| 22 | Is site-specific consent approved? | Yes | No |
| 23 | Is SAE reporting compliant with IRB requirements? | Yes | No |

### Safety

| | | | |
|---|---|---|---|
| 24 | Is AE reporting timely and accurate? | Yes | No |
| 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 the CRF? | 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? | Yes | No |
| 34 | Is regulatory compliance current? | Yes | No |

### Study Investigational Product

| | | | |
|---|---|---|---|
| 35 | Is IP storage adequate? | Yes | No |
| 36 | Is IP dispensing correct? | Yes | No |
| 37 | Are IP returns documented? | Yes | No |
| 38 | Is temperature monitoring compliant? | Yes | No |
| 39 | Is IP accountability current? | No | Yes |

### Study Supplies/Vendors

# MONITORING VISIT REPORT

| | | | |
|---|---|---|---|
| 40 | Are lab kits/supplies adequate? | Yes | No |
| **Source Document Verification & Review** | | | |
| 41 | Are source documents available? | Yes | No |
| 42 | Was SDV completed per the monitoring plan? | Yes | No |
| 43 | Does CRF data match source? | No | Yes |
| 44 | Are data corrections documented? | Yes | No |
| 45 | Were data discrepancies identified? | Yes | Yes |
| 46 | Is query resolution timely? | No | Yes |

# MONITORING VISIT REPORT

## SOURCE DOCUMENT VERIFICATION & CHART REVIEW

| Subject | Visits Reviewed | Comments | Action Required |
|---|---|---|---|
| 101-016 | Cycle 4 Day 1 | Discrepancy: CRF IP Dispensing Date ente | Site to correct CRF. |
| 101-017 | Cycle 3 Day 1 | Discrepancy: CRF IP Dispensing Date ente | Site to correct CRF. |
| 101-017 | Cycle 3 Day 1 | Queries regarding hematology units remai | Site to answer queries. |

## CRA ASSESSMENT

Site SITE-012 continues to be a high-performing site regarding enrollment and subject retention. The staff are cooperative and the facilities remain adequate for the study. However, the quality of data entry has shown a concerning trend of regression. Two separate CRF domains (Drug Accountability and Lab Results) now show recurring data quality issues despite prior corrective actions and training provided at Visit 6. The 'Zombie Cycle' of corrected errors reappearing in new data entries suggests a systemic issue with the site's transcription process or a lack of QC before entry. I have emphasized to the SC that while recruitment is successful, data integrity is paramount. A follow-up call is scheduled for 12-Mar-2025 to verify the resolution of the open lab queries and the correction of the IP dates. If these issues persist at the next visit, escalation to the CTM may be necessary.