

Bhavya Soni, BS

Sylvester Comprehensive Cancer Center, University of Miami

1. BACKGROUND

- Theranostics SDG launched 4 early-phase oncology trials in 2025
- Rapid program growth created opportunities to standardize data management workflows
- Early sponsor monitoring reports identified significant query backlogs and prolonged query aging
- Need for centralized tracking, workflow accountability, and standardized onboarding resources

2. OPERATIONAL CHALLENGES

- Query Backlog**
 - High volume of unresolved sponsor queries
 - Delayed query resolution timelines
- Fragmented Documentation**
 - Protocol-specific calculations documented across multiple notes-to-file
 - Variable data retrieval workflows
- Communication Variability**
 - Action items tracked across emails and verbal communication
 - Increased risk of missed follow-up tasks
- Training Gaps**
 - Limited standardized onboarding resources for new data specialists

3. SOLUTIONS & METHODS: STANDARDIZED DATA MANAGEMENT FRAMEWORK

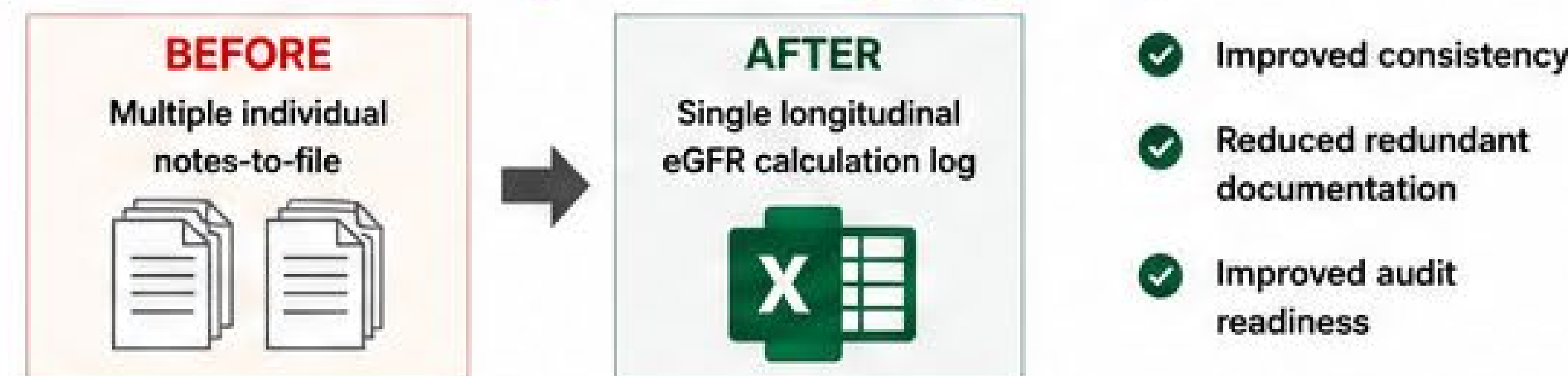
A. End-to-End Query Workflow



B. Centralized Query Tracker (Excel-Based)

Patient ID	Visit	Query Description	Action Item	Assigned To	Open Date	Resolution Date	Status	Days Open
1001-001	Cycle 1 Day 1	Please confirm exact time of drug administration.	Obtain drug administration log from nuclear medicine team	CRC	11/05/24	11/12/24	Closed	7
1001-002	Screening	eGFR calculation source not provided.	Provide eGFR calculation log	Data Mgr	11/08/24	11/15/24	Closed	7
1001-003	Cycle 2 Day 1	IP accountability log mismatch.	Verify IP dispensation record	CRC	11/12/24	11/20/24	Closed	8

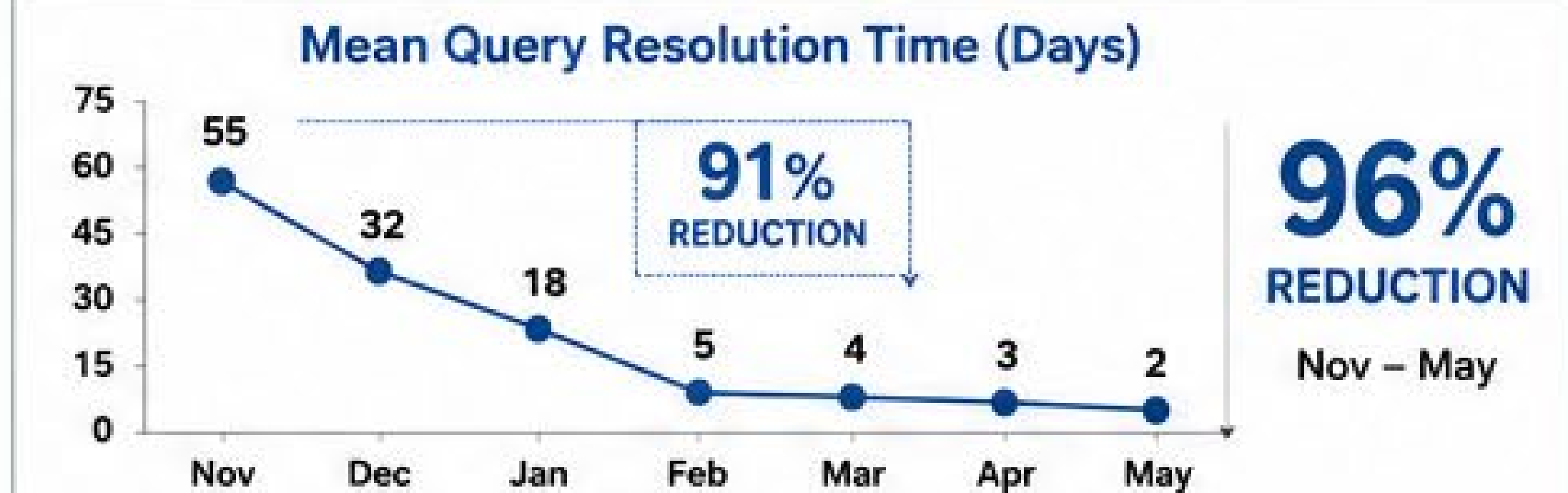
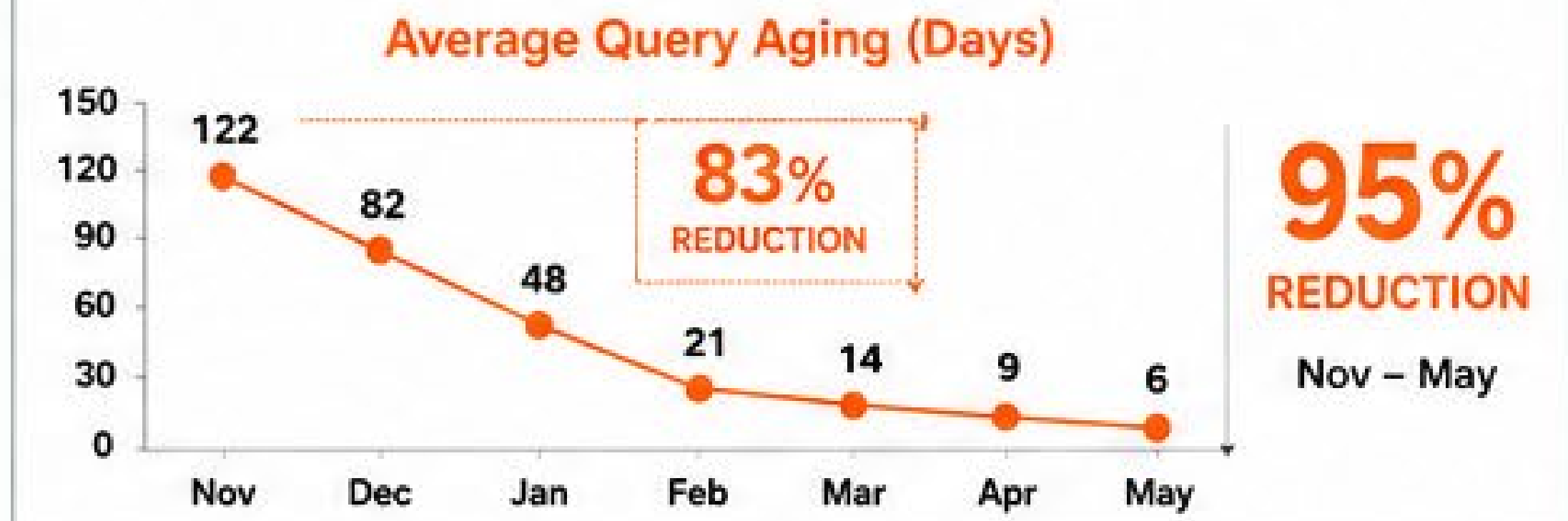
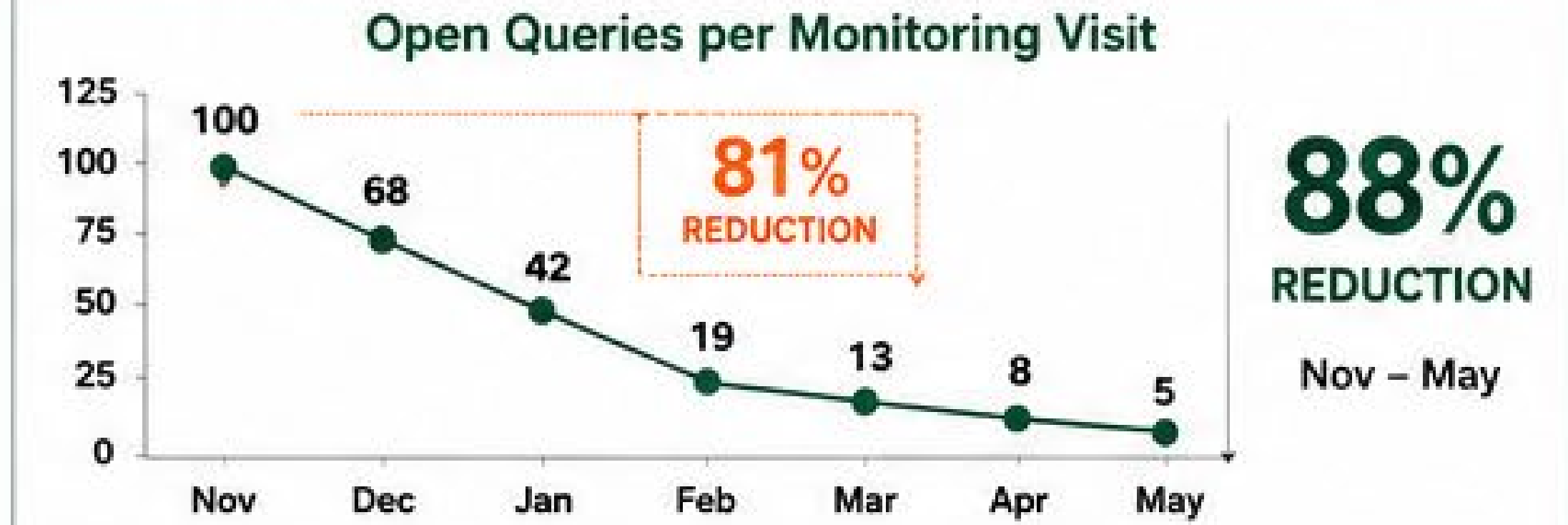
C. Centralized Laboratory Calculation Logs (e.g., eGFR)



D. Communication Workflow Integration



4. OUTCOMES



KEY OUTCOMES

- Positive sponsor feedback on data timeliness and organization
- Improved monitoring readiness
- Adopted by CRCs and SDG leadership
- Improved workflow transparency

5. LESSONS LEARNED & FUTURE DIRECTIONS

- LESSONS LEARNED**
 - Early-phase growth without standardized infrastructure leads to variability
 - Centralized tracking with timestamps improves accountability and visibility
 - Structured workflows reduce delays and improve efficiency
 - Standardization supports consistent training and scalability
- FUTURE DIRECTION**
Data Management Guide (In Development)
 - Common query categories
 - Data retrieval pathways
 - Key institutional contacts
 - Standardized onboarding resource
 - Expandable across site disease groups