

Communication, Collaboration and Coordinated Training to Mitigate Protocol Deviations

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1. Background

UAMS Clinical Trials Office has 15 clinical research nurses, 28 clinical research coordinators, and specimen technicians. Interventional/Treatment trials depend on supportive ancillary staff across the hospital and ambulatory clinics to perform many research duties. The Clinical Trials Office (CTO) staff work to educate various departments on the requirements and timepoints of each study and act as a resource to accomplish study tasks. Deviations occur when critical information is poorly communicated to supportive clinical staff.

2. Goals

- Pilot a program to reduce actionable deviations by 30 percent office-wide
- Raise awareness of Interventional/Treatment research across campus
- Learn more about the functionality of the electronic medical record (EMR) and explore ways to increase efficiencies for research applications

3. Solutions and Methods

- Leveraged EMR to:
 - Provide basic protocol details by adding Clinical Information Sheets to the Research Banner in the EMR that is visible to all EMR users
 - Utilize Prohibitive Medication Groupers to prevent contraindicated medication administration
 - Maximizing provider and nursing communication in the Treatment Plan Orders
- Collaboration and Coordinated Training:
 - Support Staff Huddles – meet monthly with critical areas such as inpatient, infusion centers, clinics, pharmacy, procedure departments, lab, etc.
 - Research Staff Education – monthly topical discussions such as handling oral chemotherapy drugs, language translation services, deviation prevention
- Communication:
 - Real-Time Communication – available by secure chat or at the elbow for first participant, first administration, and providing in-room task reminders for infusion staff

4. Outcomes

- Research awareness has increased across campus
- Huddles have opened communication and provided a more collaborative work environment
- Ability to implement corrective action plans quickly to prevent major compliance issues
- Decrease in repetitive protocol deviations
- Deviations were reduced by over 50 percent from 2021 to 2023, when these methods were utilized for the pilot program

5. Lessons Learned and Future Directions

Lessons Learned:

- There is no such thing as over-communication
- Feedback from the bedside provider is key to clearly communicating the needs of the study
- Regular reinforcement and reeducation is crucial

Future Directions:

- Perform EMR analytics to see which teams are using the clinical information sheets and how often
- Rollout across all disease teams