



Communication, Collaboration and Coordinated Training to Mitigate Protocol Deviations

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Background

UAMS Clinical Trials Office has 10 Clinical Research Nurses, 20 Clinical Research Coordinators, and 4 Specimen Technicians. These teams support a growing portfolio of 280+ Interventional/Treatment trials that depend on supportive ancillary staff across the hospital and ambulatory clinics to perform many research duties. The 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 not communicated effectively to supportive clinical staff.

Metrics & Goals to be Achieved

- Piloted a program to reduce actionable deviations by 30% office wide.
- Raise awareness of Interventional/Treatment research across campus.
- Learn more about the functionality of the EMR and explore ways to increase efficiencies for research applications.

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.

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.
- **The number of deviations were reduced by over 50% from 2021 to 2023 when these methods were utilized for the pilot program.**

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 now often.
- Rollout across all disease teams.

Contact

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274863 A Phase 3 Randomized Study Comparing Talquetamab SC in Combination With Daratumumab SC and Pomalidomide (Tal-DP) or Talquetamab SC in Combination With Daratumumab SC (Tal-D) Versus Daratumumab SC

Enrolled | Status Effective Date: 7/10/2023 | Active Start Date: 5/4/2023 | Study Type: Interventional Only | Study Code: 274863 | IRB#: 274863

Tasks

Description

Next Study Visit
Cycle 11, Day 1 (5/15/2024)
CHEMOTHERAPY Visit - Canceled on 5/15/2024 | UAMS INFUSION CENTER B | Black, Natalie Nicole, APRN, CNP

Links
Study Information Sheet Outpatient IRB 274863
Study Information Sheet Inpatient IRB 274863

MonumenTAL-5 Cheat Sheet INFB

1. 3 arms: **A** is Tal Dara Pom, **B** is Dara Pom Dex, **C** is Tal Dara Dex.
2. OP starts on C1D22. This is a Dara only day.
3. Subcutaneous Talquetamab starts biweekly OP on C2D1 after priming as inpatient
4. (SC) Dara is weekly (days 1, 8, 15, 22) for C2 only, then goes biweekly on C3.
5. Order of administration on days with both Tal and Dara: Premeds, wait an hour, give dara, wait an hour, give talquetamab, observe 30 minutes.
6. Pre-meds are investigational and will come up with talquetamab and dara, not from the Pyxis.
7. SC dara is 15cc, given over 3-5 minutes. On MAR, document location and **start-stop time** after scanning medicine. Also, please document location of talquetamab injection on MAR, as well.

Warnings Report

New Warnings (2 unfiltered, 1 filtered) Show filtered (1)

Drug-Study: polyethylene glycol | polyethylene glycol (Glycolax) packet | Remove

IRB #: 274050
This medication is contraindicated based on the patient's participation in a study comparing TU-100 with placebo for enhanced bowel recovery following bowel resection. Ordering this medication will disqualify the patient from the study.

Very High | Details | Override reason