

## **Leveraging the Electronic Medical Record for Clinical Research Documentation: Concomitant Medication Log**

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### **1. Background**

A comprehensive medication and supplement list is required for all participants enrolled in therapeutic clinical trials to ensure patient safety, identify potential drug-drug interactions, and prevent confounding effects on study outcomes. The documentation, referred to as the concomitant medication log (Conmed log), is typically maintained in a study-specific electronic file accessible only to designated members of the study team. Simmons Comprehensive Cancer Center's Clinical Research Office (SCCC-CRO) has prioritized integration of Conmed log elements into the electronic medical record for visibility and review at required study visits.

### **2. Goals**

By August 1, 2025, implement and operationalize a standardized process within the electronic medical record (EMR) to capture 100 percent of required concomitant medication documentation for active therapeutic clinical trial participants, eliminating reliance on external logs and improving accessibility, compliance, and research data integrity.

### **3. Solutions and Methods**

A brainstorming session was conducted to identify factors contributing to issues with the current EMR. Feasible strategies for integrating concomitant medication documentation into the EMR were reviewed. The team proposed embedding a standardized Conmed log within the research note using the SmartPhrase functionality in the EMR. SmartPhrases allow users to create customizable documentation templates for frequently recorded data elements. The proposed template leveraged built-in formatting capabilities (e.g., editable tables, row, and column modification, bolding, font color changes, and strikethrough) to support structured, real-time documentation within the EMR.

### **4. Outcomes**

A team of research nurses and study coordinators within the SCCC-CRO offices piloted the Conmed log SmartPhrase and found the following:

- The SmartPhrase can be added to the notes within any study visit
- Version controlling is accomplished by adding a version number and date at the bottom of the Conmed log table
- All log lines appear on one page, and additional lines can be added at any time, eliminating the need for page numbers
- Improved readability with a typed document instead of a handwritten document
- Eliminated risk of lost documentation
- Strikethrough functionality to make corrections/updates like hand-written documentation
- Tables can be copied and pasted from prior research notes once created and updates made as needed
- Centrally accessible location for both internal and external study personnel

## **5. Lessons Learned and Future Directions**

Implementation of a SmartPhrase-based Conmed Log within Epic was well received by external research monitors, supporting its feasibility and audit readiness. Monitor feedback led to workflow refinements, including the addition of a standardized header identifying log line changes at each visit. Minor documentation challenges were mitigated through standardized formatting guidance. Elevating the SmartPhrase to an organizational tool improved accessibility across all areas. Based on positive feedback and improved standardization, the SCCC-CRO plans to adopt this as the required method for concomitant medication documentation.