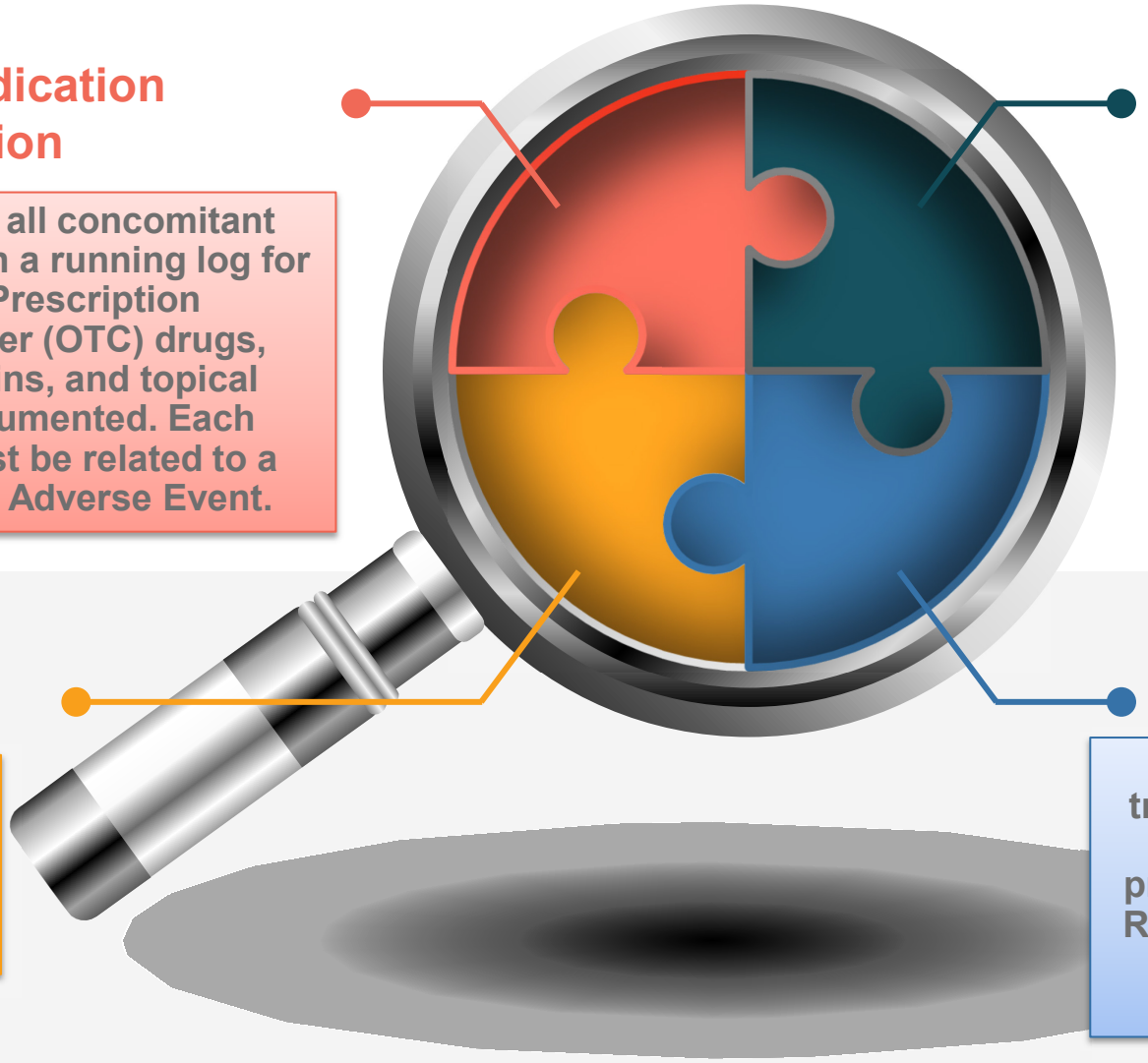
Prior & Concomitant Medication Documentation

Current and prior medications should be documented and reviewed by the Principal Investigator (PI) or delegated Sub-Investigator (Sub-I) prior to enrollment/administration of study intervention and maintained for the duration of the study to prevent potential interactions with study intervention and help identify eligibility exclusion medications or required medication washout periods.

Concomitant Medication Documentation

It is recommended to record all concomitant medications and treatments on a running log for each study participant. Prescription medications, over the counter (OTC) drugs, dietary supplements, vitamins, and topical medications should be documented. Each concomitant medication must be related to a Medical History condition or Adverse Event.



Protocol Review

Review the current, approved IRB study protocol within ERICA for specific defined time windows required to collect/document prior & concomitant medications.

Tracking Specifications

Multiple entries may occur for the same medication if there are changes in dosage or the study participants stops and restarts the medication.

Source Documentation

Concomitant medications and treatments may be identified through medical records, patient report, procedure notes, and Adverse Events Reports (medications/treatment given for AE's and procedures should be documented).