

The context under which the medication is being studied

- Describe how the medication will be incorporated into the analysis (e.g., exposure, covariate, confounder, outcome)
- Specify the preferred measure of use (e.g., prescriptions, dispensing, reimbursements, administrations)

The research concept of interest

- Specify the aspect of the medication that is the focus (e.g., an ingredient, a specific drug, or a class of drugs)

The route(s) of administration

- Describe the routes of medication administration that are of interest and/or should be excluded

The medication dose of interest

- Describe the medication dose for each administration, daily dose, and/or estimated cumulative dose, if applicable for the study
- Describe how different dosage forms will be incorporated into the dose calculation

The timing and duration of medication use

- Describe whether aspects of timing (including date of initiation, duration of use, timing of use relative to other medication or health events of interest, continuous or cumulative exposure, discontinuation, or changes in medications) are important for the research question
- Describe whether gaps in treatment should be considered
- Describe whether the drug effect is expected to persist after treatment discontinuation