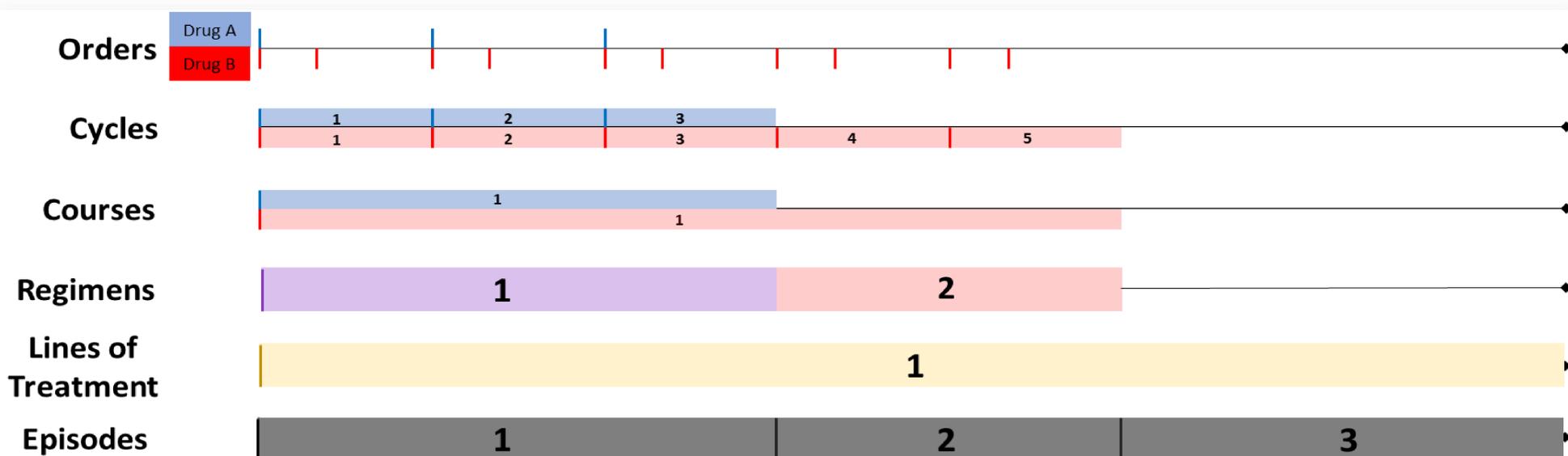


# Expanding the Episode concept in the Observational Medical Outcomes Partnership Common Data Model (OMOP CDM) Oncology Module: drug Order, Cycle, Course, Regimen and Line of Treatment.

**Background:** In the OMOP CDM Oncology Module extension, Treatment Episodes distinguish various treatment strategies as recorded in the HemOnc database. Such temporal delimitation is necessary when utilizing electronic health record (EHR) data for real-world evidence generation, since the EHR is build for clinical rather than research purposes. Clear data concept definitions can also facilitate a broader academic “standardization” when it comes to defining oncology treatment lines.

Here, we propose an extension of the data model building on the Treatment Episode concept:

Treatment Episode = period of time demarcated by any clinically significant change in antineoplastic treatment.



## Individual drug perspective: Order, Cycle & Course

**Drug order:** Date of administration of medication.

**Drug cycle:** Time period after Drug Order in which medication is biologically active, for example 21 days for chemotherapy.

**Drug course:** Repeating and consecutive cycles of same drug. Starts with first Drug Cycle and ends with last Drug Cycle.

Drug Orders, Cycles and Courses are unique for each drug and directly describes the active drug period with respect to both anti-neoplastic effect and toxic side-effects, i.e., the time in which the drug is believed to be biologically active with regards to acute effects (Cycles) and late or accumulated effects (Courses).

## Multiple drug perspective: Regimen & Line of Treatment

**Drug regimen:** Combination of drug courses that are overlapping in time. The addition or discontinuation of a Drug Course denotes a new regimen.

**Line of treatment (LoT):** expands the Regimen concept by considering the cancer diagnosis and treatment intent. LoT operates with a single diagnosis, which correspond to the overarching Disease Episode in the OMOP CDM. A patient with syn/meta-chronous cancers may receive 1<sup>st</sup> LoT for both. By incorporating treatment intent, LoT can be coupled with the dynamic and extent Disease Episodes in the OMOP CDM. The line of treatment increases whenever a regimen with a new drug is initiated. The line of treatment continues until next line of treatment, death, or censoring.

**Conclusion:** In our proposed definition, Treatment Episodes correspond to Drug Regimen changes as depicted above. Clarifications and further definitions are still needed.

Clear concept definitions are necessary but can enable both studies of classic oncology treatments while simultaneously enabling novel and granular real-world data analyses.

Next, we aim at integrating surgical and radiotherapeutic procedures and supportive drug treatment in the concepts, in addition to defining criteria for dose alterations. We will publish all code as open source when it has been validated.

