



# EPOCH in Reverse



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**Earliest date from informed consent, and all visits (including screening)**

**Minimum date/time of first study drug, logical/robust first study drug date, date of randomisation**

**Latest date/time of last on-treatment visit, death (if last visit not attended), last known treatment**

**Latest date of follow-up visit, start or end of adverse event date/time, laboratory assessments**



**Patient diary first treatment date**

**Visit subject should be randomised**

**Date/time of randomisation after first dose**

**Alternative treatment end date**

**Patient diary last treatment date**

**Date medication returned**

Data from comments on the CRF or deviations reported by the study team are good for investigating

Studies where first dose is administered by the investigator (the date based on subject visit) may conflict with Interactive Voice Response System/ Interactive Web Response System (IVRS/IWRS)

Treatment diaries can conflict with the CRF information as subject reported data cannot be subjected to the same data management queries as the rest of the CRF data

## Complex Study Designs

Cross-over designs and studies which mix models of blinded, open-label, and cross-over study types need careful thought of how the data will fit

Deriving EPOCH in a completed study - ensure that tabular results and any assumptions, created as part of the study results, are involved in the derivation

**Adding EPOCH to SDTMs of a completed study should not change the results**