

Many times studies include a mortality endpoint and could remain open for several years following the completion of the intervention under investigation. Should we wait until study is closed to enter results?

If the applicable clinical trial has reached the primary completion date, then results must be submitted by the Responsible Party no later than 12 months after the primary completion date. If the ACT is investigating mortality over a long period of time (e.g., 10 years) and the investigator chooses to analyze mortality trends over time during the course of the study, the outcome measures may be revised in the PRS according to the desired analysis timeframe while the study is still ongoing. If, in this example, the only primary outcome measure is mortality at 10 years and the investigator does not choose to analyze the data prior to the primary completion date, the study will still be considered ongoing. The record, however, should be updated regularly to accommodate for enrollment status and protocol/amendment verification.

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Source

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