



JOHNS HOPKINS
BLOOMBERG
SCHOOL of PUBLIC HEALTH

Department of Epidemiology
Johns Hopkins Bloomberg School of Public Health
415 N. Washington Street, 2nd Floor
Baltimore, Maryland 21231

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Memorandum

To: Trialists

Fr: Curtis Meinert

Re: Start and end dates for trials

If you are at the Daytona 500 you know when the race starts and ends, but starts and ends are matters of judgment in trials.

There are 18 registries for trials; ClinicalTrials.gov plus 17 comprising the WHO registration platform.

Since there are now requirements for trials to be registered before starting and for results to be posted within one year of completion, one would expect a common glossary to allow users to combine registries to provide an overview of all registered trials. But a look at a few websites for start and end dates says we are far from a common vocabulary.

CT.gov (US National Library of Medicine)

Start date

The day on which first participant is enrolled

End date

The date on which last participant examined or received treatment to collect final data for the primary outcome, secondary outcome, and adverse events.

ISCRTN (United Kingdom)

Start date

Study starts when investigators begin planning the design and developing the protocol.

End date

Stated in study protocol; expected to be the last date data collected.

EudraCT (European Union Drug Registry Authority)

Start date

Date on which study was authorised to proceed. For trials marked as "outside of EU/EEA", the date in which the study was uploaded in EudraCT by third country data provider".

End date

Date on which trial ended in all countries.

ANZCTR (Australians New Zealand CT registry)

Start date

Date of randomisation of first participant. For non-randomised studies, date first participant commences treatment/intervention/ exposure.

End date

The anticipated date that recruitment will cease. The actual date the final participant was enrolled into the study.

Section 801 of the Food and Drug Administration Amendments Act (FDAAA) of 2007 requires trialists post results within one year of end. From the definitions above do you know when trials end?