

Sample size calculation for estimands and the impact of intercurrent events on power.

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Please provide a brief biography for the Presenting author(s)

Thomas Drury has worked in the pharmaceutical industry for 20 years and has worked as a project programmer, project statistician and in the last six years a methodology statistician. He has worked at Astra Zeneca, Takeda, Eli Lilly, Mitsubishi-Tanabe and GSK.

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Sample size calculation for different estimands and the impact of intercurrent events (IEs) on power are important considerations at the design stage of clinical trials. Until recently this has been given little attention in the literature and has the potential to be overlooked. We show how mixture theory and simple "conservative" assumptions can be used to investigate the impact of IEs on power. We present some formulae that can act as "rules of thumb" for power calculations that we have validated through simulation and then discuss how the problem becomes more complex with multiple IEs. Finally we showcase some simulation tools built to validate the simple analytical formulae.