Top tips for developing and using progression criteria for internal pilot studies

Green (go), amber (amend) and red (stop) rather than a stop/go approach

Achieve a balance between being firm enough to promote ambition, yet flexible enough to remedy problems

Base criteria on rates per centre per unit time, rather than an absolute number

Explore screening logs to determine whether insufficient participants were approached, insufficient participants passed eligibility criteria or insufficient eligible participants agreed to randomisation

Explore the degree of missing data within key outcomes as well as the % of participants with missing data

Assessment of adherence, crossover & outcome event rates should account for the duration from randomisation to timing of outcomes if sufficient data are to be gleaned in time to inform progression

Pilot studies need to be reported fully. An extension to CONSORT guidelines for pilot and feasibility studies is now available