

# 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 1<sup>o</sup> 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

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