CONFERENCE OVERVIEW & OBJECTIVES

Colin Baigent & John McMurray
Meeting objectives

**PROBLEM:** Inadequate evidence-base to manage patients with CKD effectively

- What RCTs have been completed in nephrology, and what have been the problems with such trials?
- What could we do to solve some of the problems to improve the quality and quantity of trials?
- What are the opportunities in the coming years for innovation in trial design and conduct?
- How can we work together effectively as a community to make trials efficient?
Meeting structure: DAY 1

• Plenary talks (strictly 30 minutes) then discussion, aiming to identify key issues for the breakouts:
  – Previous trials in nephrology – an overview
  – Important issues and challenges
    • Defining appropriate outcomes
    • Optimising trial design
    • Optimising trial execution
  – How do other stakeholders see things
    • Industry sponsor
    • Dialysis provider
    • Drug regulator
Meeting structure: DAYS 2 & 3

• Breakout groups
  – A: Renal outcomes including CKD progression
  – B: Non-renal outcomes in nephrology trials
  – C: Optimising trial design
  – D: Optimising trial conduct

• Lists of topics provided, but these are not exhaustive – discuss what seems germane

• 2 cycles of meetings & reporting to the whole conference, with subsequent discussion

• Breakout chairs responsible for note-keeping, reporting, and ensuring that the perspectives of all stakeholders are considered
SUMMARY

• This is a controversies conference – we will not agree on everything
• Instead, the aim is to discuss:
  – What is good practice in trials (design, conduct), and what are particular challenges in nephrology
  – From a practical view, how we might design trials to overcome these challenges in the future?
  – Can we embed trials efficiently (and at low cost) in routine nephrological care?