



# 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?