What is the best way to evaluate CV safety in diabetes?

- Clinical trials
- Outcome studies with every diabetes drug
  - Only look at the primary endpoint?
- How supportive are other data from clinical trials ?
- How reliable is observational data?
- How good is pharmacovigilance?
- Are Registries worthwhile ?

What is the best CV outcome study in diabetes?

- Double blind preferred
  - Open label – when using insulin as strategy
- Superiority preferred
  - But regulatory guidelines support non-inferiority
- Placebo or active
  - Placebo preferred by reg – active by clinicians
- Primary end point
  - MACE – but may depend on safety issues
- Ask and answer one clear question
- Entry criteria should be considered carefully
  - Balance between high risk cohorts and broad type 2 diabetes population

Who should conduct clinical trials? Academia, Pharma, CRO's

- All partners have valuable experience and skill sets which should be respected
- Any of the above combination could and does run outcome studies.
- Depending on the question may determine the partners
- Goals are very similar – to do robust clinical science to answer key questions to advance management of patients with CV disease

How good are we at conducting clinical trials ?

- Are committee's independent?
- Are investigators of high quality across the world?
- What is the quality of the data
  - Collecting data – SAE's endpoints CRF's
  - Transfer of data – what goes to the CEC
  - Missing data
  - Follow up – are phone calls adequate

Summary of industry involvement in CV safety in diabetes

- Industry develop drugs to benefit patients
- Industry wants to ensure safety of their products and therefore welcome CV safety assessment
- Industry can and do run large outcome studies, observational studies and undertakes pharmacovigilance
- Industry has experience and wants to be key participants in developing better outcome studies for patients with type 2 diabetes mellitus