

## ... about endpoints

- ◆ Studies should aim to have the smallest number of endpoints feasible. **Multiple endpoints** (more than one) can be used; however, all endpoints should be specified at the outset. Studies should be adequately powered for the specified endpoints and results for all endpoints should be reported.

- ◆ Endpoints with more than one component are **composite endpoints**. Using these increases event rates, thus reducing the number of subjects required for studies to be adequately powered. The separate components should not be reported as discrete endpoints.

For example, a composite cardiovascular endpoint could be defined as myocardial infarction, or stroke, or death occurring in a subject.

- ◆ The validity of a composite endpoint is dependent on the components being similar in the way they are affected by a treatment, the frequency with which they occur, and their importance to patients.

Consider the composite endpoint of hospitalisation or death from pneumonia. Do both components warrant equal weighting?

- ◆ A **surrogate endpoint** is an outcome, which is relatively easy to measure (such as a biological marker, laboratory finding, or physical sign) that is often used when observing important clinical events is expected to be impractical or expensive - frequently involving too long a follow-up.

For example, bone mineral density for vertebral fracture, endoscopy findings for gastrointestinal bleeding, and cholesterol concentrations for myocardial infarction.

- ◆ The validity of a surrogate endpoint depends on the extent to which it correlates with, or is indicative or predictive of, the relevant clinical outcome.