

### **INTERNAL VALIDITY QUESTIONS**

- **Was the assignment of patients to treatment randomized?**
- **Were all patients who entered the trial properly accounted for and attributed at its conclusion?**
- **Was follow-up complete?**
- **Were patients analyzed in the groups to which they were randomized?**
- **Were patients, their clinicians, and study personnel 'blind' to treatment?**
- **Were the groups similar at the start of the trial?**
- **Aside from the experimental intervention, were the groups treated equally?**

### **EXTERNAL VALIDITY QUESTIONS**

- **Can the results be applied to my patient care?**
- **Compelling reason why the results should not be applied?**
- **Were all clinically important outcomes considered?**
- **Are substitute endpoints valid?**
- **Are the likely treatment benefits worth the potential harms and costs?**
- **Number needed to treat ?**