

## Session 4: Clinical Endpoints

Chair: Andrew Blight

Two primary issues will be addressed in this session:

1. Clinically meaningful improvements in SCI can come from a range of domains other than the motor improvements, particularly lower extremity function, that have been the main focus of attention.
2. The definition of clinical meaningfulness in outcome measures is important, both in terms of matching academic scientific research to outcomes of real interest to patients and also with respect to the regulatory goal of approving treatments that are truly beneficial in the lives of the consumer. Among a number of questions embedded in consideration of this issue are:
  - a. How do we define changes as at least minimally important (see attached documents – Beckerman et al., 2001; Beaton et al., 2001)
  - b. What does a regulatory agency seek in terms of Minimum Important Difference (MIM; see attached documents - Patient Reported Outcomes; Guyatt et al., 2002).