

Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee

The committees will discuss the following issues in reference to each imaging modality:

1. How is the surrogate imaging modality best validated?
2. If one uses an imaging modality to support a disease-modifying effect claim, how does one establish that such an effect occurs?
3. Has any surrogate imaging modality been validated at the present time?
4. Even if no surrogate imaging modality has currently been validated, is it appropriate to use one or more such modalities as primary or ancillary outcome measures of efficacy in Phase 3 clinical trials?