ISCTM
THE INTERNATIONAL SOCIETY FOR CNS CLINICAL TRIALS AND METHODOLOGY

Non-Adherence Working Group

Shiovitz/Bain

Focused discussion on where and how to act to mitigate the effects of nonadherence during screen and after randomization including:

- PK and urine sampling of biomarkers and homeopathic doses of IP;
- Identifying non-adherent subjects through use of registries and medication adherence technologies.
- A spirited discussion arose around case examples of who could reasonably be excluded from the final data analysis. Specifically, the ITT can be defined in such a way that, based on biomarkers or PK sampling during a run-in period, even randomized subjects can later be excluded from the final analysis. Subjects identified as nonadherent *after* randomization can be counseled or removed from the study, and if removed it should be done sooner rather than later, but their data usually must be included in the final analysis

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because it is hard to be absolutely sure that no IP has been taken. Steps can also be taken to mitigate the effects of nonadherence after randomization, but more discussion on this to come.

Deliverables:

- White Paper in 2016
  - Short-term, a final draft of the section on Where and How to Act to Mitigate the Effects of Nonadherence by April 1st 2015, a draft of Regulatory issues in May and a first draft of the complete white paper by fall 2015.
- Session February 2016