Nonadherence Working Group

Data-Sharing Initiative Pilot

Hypotheses:

- Nonadherence (NA) in clinical trials contributes to study failure
- Size of a clinical trial is an independent determinant of study success
- Rates of NA vary between small and large studies and between Ph2 and Ph 3

Specific Question:

- What is the rate of medication NA in studies?

Sponsor Request:

- For the indications listed below, please supply anonymized:
  - General Study Info: Indication, Phase, total n, n in each treatment arm, duration, route/freq of dosing (e.g. PO BID or IV Qweek), t1/2 of IP, study outcome
  - PK data: Number of subjects in each arm with: No BLQ PK samples, Any BLQ PK samples, >50% BLQ PK samples, All PK samples BLQ

Indications:

Addiction
Bipolar
GAD
Primary Insomnia
MDD
Migraine
Schizophrenia

Caveats:

- Getting sponsors to comply with the data requests will require ISCTM oversight, a formal proposal, contracts that assure privacy/security and allow for publication of anonymized data, and ideally, someone on the inside to help move it through.
- ISCTM does not/will not have the infrastructure to accept, format and collate raw study data. If sponsors provide answers to the specific data queries in the formats requested, there would still be (TBD) FTE data manager or statistician services required for 18 mos and TBD $ in software/hardware purchases.

Additional Suggestions:

- Encourage Journals not to accept publications that do not include PK data

Action: Follow up with WG by e-mail (and possibly one teleconference) to tighten these recommendations and submit to the Scientific Committee within 2 mos.