MAPS Data Management

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There are many key players in the design and conduct of a clinical trial: the doctors, nurses, patients, regulatory agencies, ethical committees, etc. One of the most important players, which may sometimes not be considered from the lay perspective, is the data. Every step in a clinical trial is geared towards fostering the collection of high quality data–to support the protocol hypothesis, and to demonstrate that the drug is safe. My role is to take care of the data, from the very inception of the trial, to the final study report. I am a Clinical Data Manager (CDM).

The CDM is a behind-the-scenes player in the world of Clinical Trials. Typically, it is my job to design the data collection forms, to build the database(s), to enter the data, and to review the data ensuring that it is complete, clear, and consistent. The CDM works with raw data, in various forms, to prepare it for statistical analysis and reporting. I have been a CDM for many years in the pharmaceutical and biotech industry; this is my first time working with MAPS.

With the imminent completion of the first pilot MDMA study at Dr. Michael Mithoefer's clinic in South Carolina, it is now time for MAPS to collect, database, review, and analyze their results. Over the past few months I have been working diligently to design a database for MAPS to use in storing data from this, and other MAPS trials. I have also been reviewing the data in paper form and entering them into the new database system. Once the data entry is complete, I will review the data to ensure that they are complete and consistent. Missing information or inconsistencies will be investigated and resolved by sending formal queries to the investigative site for clarification. After all queries are resolved, the data will be put through a quality control step and the database "locked," so that no further changes can be made. At that time, the data will be ready for formal unblinding, analysis, and reporting by the MAPS statistician: a highly anticipated first step on the road to FDA approval.

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