FLORIDA PDMP REPORTING FOR CLINICAL TRIALS

Section 893.055(3), Florida Statutes requires dispensers to report controlled substance dispensing information to the system as soon thereafter as possible but no later than the close of the next business day after the day the controlled substance unless an extension or exemption is approved by the department.

- If the clinical trial drug contains a controlled substance in schedules II, III, IV or V, as defined in section 893.03, Florida Statutes or 21 U.S.C., section 812, it must be reported to the PDMP.
- If the clinical trial is a double blind study, as long as it is an FDA/DEA-approved trial, it is not necessary to report, as the dispensing practitioner would not know whether or not he or she has dispensed a controlled substance.