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THE RATIONALE FOR THE USE OF AN INTERNET-BASED CLINICAL TRIAL TO OBTAIN SAFETY, PHARMACOKINETIC AND PHARMACODYNAMIC DATA IN A DOSE-ESCALATION STUDY IN NEONATES, WITH HYPERBILIRUBINEMIA, WHO NEED EXCHANGE TRANSFUSION. J. Mitchel, PhD, B. Levinson, MD, Target Health Inc., Wellspring Pharmaceuticals Corporation, New York, NY.

When experimental drugs are used in the newborn, drug safety is of paramount importance. Unfortunately, there are often relatively large gaps between data collection and the time data are monitored and analyzed. In order to speed up the process of data retrieval and evaluation, an Internet-based electronic data capture module was developed for pharmacokinetic and pharmacodynamic studies, allowing for rapid data entry, viewing and monitoring. The current study is a dose-escalation clinical trial of stannosporfin for the treatment of neonates, with hyperbilirubinemia, who are undergoing phototherapy. The goal of the study is to evaluate the ability of stannosporfin to eliminate/reduce, the need for exchange transfusion. As part of an agreement with the FDA, the sponsor could not escalate to the next dose without a safety review by the sponsor and the FDA. An Internet-based data entry application, with full edit checks and a query communication system, was designed so that safety data could be viewed anytime by the Medical Monitor, Data Safety Monitoring Board (DSMB) and the FDA. The presentation will illustrate the system's key features leading to the maximization of the quality and timeliness of data retrieval and analysis. Study implementation was characterized by the following: (1) transformation from paper was seamless; (2) no software installation was required; (3) the hospitals' computer systems were used; (4) study start-up was not delayed; (5) quality was improved; and (6) overall costs were reduced.