

A paperless, distributed data management system for multi-center clinical trials

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ABSTRACT

We present a paperless, distributed data management system designed and implemented in the multi-center Pediatric Brain Tumor Consortium (PBTC). PBTC was formed by the National Cancer Institute in 1999 to improve the treatment of primary brain tumors in children. The Consortium implemented a paperless data management system starting with its first clinical trial. All data communication between the clinical sites and the Operations office in Memphis, TN occurs via Virtual Private Network (VPN) connections. Patient registration is implemented with an online, web-based system. Ten clinical sites collect data using laptops and upload the patient database to the Operations office to generate the central database, PedBraTum. With PedBraTum, we have set-up automated, online data-reports for investigators. Automated systems monitor the PedBraTum database for delinquent data on a daily and weekly basis, and send email reminders to the sites to ensure timely data collection.

We have implemented auxiliary databases in the Operations office for regulatory data, administrative data, invoice data for patient/research costs, and data from correlative studies namely pharmacokinetics, biology, neuro-pathology and neuro-imaging. The auxiliary databases link with the PedBraTum database to provide a comprehensive system for paperless data management in this clinical trials setting. The Consortium designed and implemented, in 2001, the first all-electronic neuro-imaging studies' transport and archival system for the PBTC Neuro Imaging Center at Boston.

In the early years, the regulatory and consent documents were paper-faxed from clinical sites to the Operations office. 3 years ago, we implemented a fax-server system that receives the faxed papers as electronic documents on our network. These electronic faxes are hyperlinked within our databases to enable easy access for the Operations office staff. This paperless, distributed data management system has successfully facilitated 22 clinical trials to-date, ensuring timely data collection for 747 patients, HIPAA compliance for data security and patient confidentiality.