subjects overwhelmingly preferred using the paper forms. One reason is that they can be filled out while waiting in an automobile.

Another issue relating to recruitment, as well as to the entire clinical trial, is confidentiality. Clinical trials conducted in the United States are subject to the Health Insurance Portability and Accountability Act (HIPAA), which provides privacy and security safeguards to protect the confidentiality of personal health information of study subjects (65).

The following concerns use of IVRS to manage the supply chain. Kuznetsova (66) described use of IVRS to distribute drugs in a clinical trial, that is, in studies where drug bottles are labeled with unique drug codes, where codes refer, for example, to placebo, 1 mg active drug tablets, and 2 mg active drug tablets. Labeling the bottles with the codes allows appropriate bottles to be sent to any subject for any visit when this type of drug is supposed to be dispensed. IVRS can be used to dispense medication packs to subjects, and to maintain appropriate stock levels at the drug distribution depot, that is, at a pharmaceutical company or at an external packing and distribution agency, and at the study site (67). The IVR system dispenses the medication packs, identifies when the stock at the site for that treatment has fallen to a predefined minimum, and sends a request to the drug distribution depot for additional supplies to be sent to the site. An IVR system can be used to allocate kit numbers to subjects, to allow for stock subtractions to be made and monitor inventories of all medications remaining at each study site (68). In managing clinical supplies, the IVR system also keeps track of drug expiration dates (69). These tasks allow for conducting the trial with a minimum supply of medicines, avoiding overstocking, and for resupplying drugs on a just-in-time basis (70). Additional types of information that can be captured by an IVRS include rate of site initiation (percentage of sites that have initial supplies requested, sites per month initiated), rate of recruitment (over the study to date, over each previous month, by country and by study), screening failure rate, and tracking of endpoints that have been reached, for example number of deaths, number of successful completers (71).

[65] Hathaway CR, Manthei JR, Haas JB, Scherer CA. Looking abroad: clinical drug trials. *Food and Drug Law Journal*. 2008;63:673–681.

[66] Kuznetsova OM. Why permutation is even more important in IVRS drug codes schedule generation than in patient randomization schedule generation. *Control Clin Trials.* 2001;22:69–71.

[67] Byrom B. Using IVRS in clinical trial management. *Applied Clin Trials.* October 2002;36–42.

[68] Clinical Trial Services. Improving clinical trial supply using existing tools. Almac Group, Ltd., 20 Seagoe Industrial Estate, Craigavon, United Kingdom.

[69] Premier Research, Centre Square West, Philadelphia, PA.

[70] Clinical Trial Services. Improving clinical trial supply using existing tools. Almac Group, Ltd., 20 Seagoe Industrial Estate, Craigavon, United Kingdom.

[71] Futcher A. Qualitative and quantitative benefits of IVR and IWR clinical trials. Pharmaceutical Visions, Highbury House Communications PLC, London (date and volume not available) pages 51–54.