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USING THE INTERNET TO ENTER DATA AND MANAGE A MULTINATIONAL CLINICAL TRIAL IN DEEP DERMAL AND THIRD-DEGREE BURNS

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Global Internet-based clinical trials (G-IBCTs) can offer convenient, cost-effective solutions for streamlining aspects of the clinical research process. Areas affected by G-IBCTs include study startup, monitoring, implementation of protocol amendments, medical review of safety data, data management, query management, and project management. By decreasing time to database lock, companies can reduce overall development costs, accelerate the decision-making process, and decrease the time it takes to submit the marketing dossier. The study was a multicenter, multinational, clinical trial designed to evaluate a new debriding agent for the treatment of deep dermal and third-degree burns. Clinical research sites were in the United States, Europe, Eastern Europe, Israel, and India. Wound location was tracked electronically, so at follow-up visits, the appropriate wound locations automatically appeared. As new sites were added, the investigator and site personnel registered online and had rapid access to the case report forms (CRFs). As protocol amendments were approved by individual countries and individual institutional review boards, revised CRFs were immediately made available through a centrally controlled server. The key challenges for the study were (1) to create a user-friendly CRF, (2) for the clinical sites to enter the data in a timely manner, and (3) for the monitors to work closely with the sites to manage the implementation of this new paradigm in clinical research. For the majority of sites, we were able to monitor enrollment, safety, and key outcome variables in "real-time" and quickly intervene if problems arose. These major advantages allowed for an overall successful execution of the study.

Nothing to disclose.

P212 J AM ACAD DERMATOL