Effects of eSource in Multi-National Clinical Trials

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Using eSource may increase the efficiency of data collection in clinical trials. However, adoption of eSource has been slow. We reviewed over 100 large multinational clinical trials to analyze how eSource use correlated with trial size, duration, and delays. We searched ClinicalTrials.gov for completed, interventional, Stage II-IV clinical trials with posted results and an uploaded study protocol document. This produced 3,962 trials. We identified all studies with over 1,200 participants and sites in multiple countries (or at least 100 sites in one country). After eliminating ten studies with duplicate protocols, we had a database of 123 trials. From the ClinicalTrials.gov listing, the study protocol, and any published papers, we determined the start, end, and publication dates, data collection protocol, sponsors and collaborators, and any reasons given for delays for each trial. Of our 123 trials, 60 (48.7%) used eSource, 48 (39.1%) used paper source documentation, and 15 (12.2%) used some combination. We found no statistically significant difference between eSource and non-eSource trials in terms of trial delay (p=0.43), time to publish (p=0.33), collaboration status (p=0.54), number of participants (p=0.36), or number of countries (p=0.12). However, our analysis was limited by what data was publicly available. To investigate the effects of eSource on site efficiency, data accuracy, and data security, which are three major factors behind the FDA's 2013 eSource recommendation, we would need access to proprietary information from trial sponsors.