

WHY (NOT) GO EAST? COMPARISON OF FDA INSPECTIONS FROM CEE, WE AND US INVESTIGATIONAL SITE INSPECTIONS

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Investigational sites in the countries of Central and Eastern Europe (CEE) have been increasingly utilized by pharmaceutical companies since the mid-1990s due to high levels of subject enrolment into clinical trials. Data quality from CEE clinical trials has been the subject of question. From the FDA's publicly accessible Clinical Investigator Inspection List, an analysis of findings and outcome classifications from FDA inspections during Investigational New Drug (IND) studies was undertaken to compare the results for the CEE region with those of Western European countries and the USA. From the beginning of inspections of sites in CEE in 1994 to the end of 2010, 4865 were routine data audits (DA): 401 in Western Europe, 230 in CEE, 3858 in the USA, and 376 in other countries. In these DA inspections, the average number of deficiencies per inspection ranged from 0.99 in CEE to 1.99 in Western Europe. No deficiencies were noted during 16.6%, 39.0%, and 21.5% of the inspections in Western Europe, CEE and USA, respectively. No follow-up action was indicated following inspections for 36.9% in Western Europe, 55.7% in CEE, and 44.3% in US sites. CEE was the region with the lowest percentage of inspections requiring official or voluntary action. The high productivity of CEE sites appears to be accompanied by regulatory compliance as well as by data quality standards that are not inferior to those in Western regions. Causes for regional differences and limitations of the data will be discussed.