INSPECTION OF THE PHARMACEUTICAL COMPANIES IN IRAN BY INSPECTION SOFTWARE
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OBJECTIVES: This study was investigating of costs and consequences of two manual and computerized systems for management of information during 2008–2009 for inspection of pharmaceutical industries in Iranian Drug Regulatory Affairs.

METHODS: To compute costs of processes following items had been considered: Cost of filling and archiving, data collecting (person-hour), reporting (person-hour), transport, software and serverware (main server computer, computer system), stationeries. To evaluate the efficacy following outputs and outcomes was considered: Time of information recovering, ability of ranking, preventing of data missing, capacity building and tracking and monitoring. RESULTS: The cost of running the new system is 35,000 US Dollars. Comparison in new method and conventional are 5000 and 1000 US Dollars respectively. Cost of inspection in computerized management of information system (MIS) is decreased to 250 US Dollars from 600 US Dollars for each inspection process. Moreover, cost of inspection is increased by using computerized system. CONCLUSIONS: It seems that beside overhead cost of new computerized system that is more than conventional method; considering capacity building; due to decreasing the cost of inspection and increasing of outputs and outcomes indicators, the new system is more efficient.

COMPETITIVENESS OF HUNGARY IN INTERNATIONAL CLINICAL TRIALS
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OBJECTIVES: Patients, health service providers, payers and the society also gain from intensive clinical trial participation, however the majority of benefits are intangible. According to a recent survey Hungary generates 0.13% of the GDP from clinical trials and the activity is therefore the economic importance of this area is acknowledged by the Hungarian government. The clinical trial activity is traditionally strong in the country, however the growth rate of clinical trials is lower than in other Central-Eastern European countries. Our objective was to explore how Hungary can improve its competitiveness in attracting clinical trials.

METHODS: We conducted a literature review, searched for publicly available documents and interviewed key stakeholders in Hungary to explore potential fields for intervention. RESULTS: We identified seven key target areas for intervention to improve the competitiveness of Hungary in clinical trials: the simplification of legal framework for clinical trial related activities, development of infrastructure at main potential sites, organizational development with special focus on SMOs, the simplification of rules and processes for financing clinical trials, investment into developing databases to support the set-up of clinical trials, and finally the enhancement of international promotion of Hungary and its sites to sponsors of clinical trials. CONCLUSIONS: The area of international clinical trials is a very competitive market. Hungary can strengthen its market position, if legislators, competent authorities and management teams of investigational sites—by acknowledging the professional and financial benefits of these studies—support the successful implementation of clinical trials in coordinated actions.