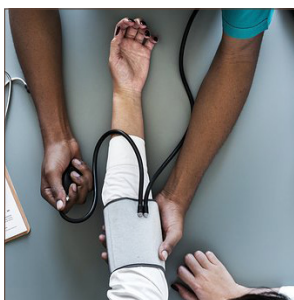

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Matching clinical trials with patients: Global patient search and identification using de-identified EHRs

Background: Patient recruitment for clinical trials is a well-known problem that has been extensively documented. Challenges in patient recruitment are the most prominent reason for clinical trial delays. Such delays have a knock-on effect on the entire drug development process, costing pharma companies lost sales revenues. Beyond financial considerations, delays also result in avoidable suffering of patients. These challenges can be overcome by introducing a technology-assisted process for finding patients who could benefit from inclusion in a clinical trial.

Objective: We propose a technology-assisted process for finding de-identified patients who could benefit from inclusion in a clinical trial; this process accelerates recruitment, the most prominent reason for trial delays, which result in avoidable suffering of patients and cost pharma companies' sales revenues.

Method: We implemented a system compatible with hospital information systems which performs real-time, Big Data analytics on de-identified electronic medical records from connected hospitals. The system can perform data-assisted protocol optimization to speed up the protocol development process, site feasibility evaluation to improve site strategy (fewer sites with more patients) and searches the EHR for potentially eligible patients for clinical trials and allows authorized research staff to reidentify them for recruitment.

Results: The system is operational in more than 100 healthcare institutions in 16 countries. We present three example cases which demonstrate the system's primary benefits during the

critical patient recruitment phase:

1. Rescue study: recruitment for an ongoing dyslipidemia trial was behind schedule and stalled at one-third of the required numbers; with the system, recruitment was completed within 6 weeks after screening of 15% of the system's proposed candidates.
2. Faster recruitment: recruitment for an atherosclerosis trial was completed 6 months ahead of schedule
3. Efficient recruitment: in several trials the pool of identified and potentially eligible patients consistently exceeded the investigators' expectations by 10-30 times.

Conclusion: The electronic "patient network explorer" system addresses the critical bottleneck of slow patient recruitment. The system enables search and identification of suitable clinical trial candidates using the electronic records of multiple hospitals – in real time. The system has been shown to find 10-30x more patients than traditional methods. As the system uses de-identified patient data, patient privacy is also preserved.

Speaker Biography

Barış Erdoğan is the country manager of Clinerion, Turkey. He studied computer engineering at the Middle East Technical University and holds M.Sc. and Ph.D. in educational technology. His expertise and experience include management of innovative medical informatics projects and implementation of end-to-end healthcare IT enterprise information systems, both in the public and private sectors.

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