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Streamlining clinical trial conduct in a national healthcare system towards pragmatic cardiovascular clinical trials

Pragmatic clinical trials (PCTs) aim to reduce the burden on patients, investigators and the clinical research ecosystem, without losing effectiveness compared to traditional or explanatory clinical trials. Various elements of a clinical trial can be pragmatized depending on the therapeutic hypothesis being tested. The Veterans Affairs Healthcare System (VAHS) offers unique resources for conduct of cardiovascular clinical trials including a large patient population with cardiovascular disease, a nationwide database with advanced search capabilities to identify eligible participants at participating sites, a pool of highly experienced investigators and study coordinators, established support services including research pharmacists and research administration, and a strong institutional commitment to conduct of research. We are leading an effort to streamline the conduct of traditional clinical trials in the VAHS by a focus on centralization, pragmatization, and innovation. We are pioneering a centralized approach to identifying sites, contracting and payments, and regulatory approvals to streamline trial onboarding for sites and trial sponsors. We have utilized the national VA database to identify lists of potential subjects at each VA site to enhance recruitment. In addition, a fully pragmatic trial funded by the VA with centralized patient recruitment and follow-up is also underway. Overall, a national healthcare system with a comprehensive and connected patient care database has the potential to revolutionize clinical trials and make them more pragmatic and less costly without losing effectiveness to answer key therapeutic questions. In addition, the Million Veteran Program also offers the opportunity to conduct trials of personalized medicine based on genotype-phenotype correlations.

Biography

Jacob Joseph is an Associate Professor of Medicine at Harvard Medical School and Faculty of the Cardiovascular Divisions of Veterans Affairs Boston Healthcare System and Brigham and Women's Hospital. He has published over 80 articles and edited a book. He is a Clinical Trial Leader of national VA consortia for major international clinical trials; and a Member of the Executive Committee of the NIH-funded influenza vaccine to effectively stop cardio-thoracic events and decompensated heart failure (INVESTED) trial, and the Steering Committee of the International Pemafribrate to reduce cardiovascular outcomes by reducing triglycerides in patients with diabetes trial.

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