Title: Considerations when Leveraging Electronic Health Records to Address Comparative Effectiveness Questions: A “Create Your Own Data” Adventure

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Abstract: Many investigators have discovered the utility of electronic health records to conduct secondary data analyses in medical research. Particularly of interest are questions surrounding the real-world effectiveness of specific drugs and/or therapies. These analyses, if conducted naively, are subject to many biases, such as selection bias, immortal time bias, and confounding, that can distort the effect estimates beyond recognition. The “target trial” is a tool used in causal inference that eases communication barriers between clinical investigators and statisticians. Through the design process, a target trial elucidates these biases and allows investigators to adapt accordingly. Here we will 1) define the components of a target trial; 2) explore how those components are affected by the use of electronic health records; and 3) discuss an example of a target trial evaluating the addition of a novel biologic or targeted synthetic disease modifying anti-rheumatic drug to methotrexate to treat rheumatoid arthritis, designed and conducted in a major urban healthcare system.