

Observational Medical Outcomes Partnership Epidemiology Design Decision Inventory and Evaluation (EDDIE)

You are invited to participate in a research study conducted by the Observational Medical Outcomes Partnership (OMOP, <http://omop.fnih.org/>). The Observational Medical Outcomes Partnership is funded by the Foundation for the National Institutes of Health through generous contributions from the following: Abbott, Amgen Inc., AstraZeneca, Bayer Healthcare Pharmaceuticals, Inc., Bristol-Myers Squibb, Eli Lilly & Company, GlaxoSmithKline, Johnson & Johnson, Lundbeck, Inc., Merck & Co., Inc., Novartis Pharmaceuticals Corporation, Pfizer Inc, Pharmaceutical Research Manufacturers of America (PhRMA), Roche, sanofi-aventis, Schering-Plough Corporation, and Takeda.

Your participation in this study is entirely voluntary. You should read the information below and ask questions about anything you do not understand, before deciding whether or not to participate. You are being asked to participate in this study because you are familiar with observational data.

• PURPOSE OF THE STUDY

The purpose of the project is to capture (using a web-based survey) and analyze the potential decisions that an epidemiologist, statistician, or clinician would make when designing an epidemiology study to determine the association between a series of drugs and events (for example ACE inhibitor and Angioedema). We hope to use what we learn from the survey to better understand the decision making process used when thinking about a particular safety issue.

• PROCEDURES

If you volunteer to participate in this study, we will ask you to do the following:

1. To fill-out a web-based questionnaire within your own setting / location and you can stop the questionnaire at any time. The survey for completing one drug-outcome pair may take approximately 10 – 15 minutes. Therefore, if you choose to complete 6 drug-outcome pairs it is expected to take less than 60 minutes. If you decide to complete ALL the drug-outcome pairs available within the survey (30 pairs in total), it may take you several hours. Completing additional drug-outcome pairs is entirely optional.
2. It is not required that you complete the survey in one session. You have the ability to save your progress on the survey, close out and continue at a later time.

• POTENTIAL RISKS AND DISCOMFORTS

We expect that any risks, discomforts, or inconveniences will be minor and we believe that they are not likely to happen. If discomforts become a problem, you may discontinue your participation at any time.

- **POTENTIAL BENEFITS TO SUBJECTS AND/OR TO SOCIETY**

It is not likely that you will benefit directly from participation in this study, but the research should help to learn how to better evaluate previous OMOP research methods and findings and increase our understanding of pharmacoepidemiologic reasoning.

- **PAYMENT FOR PARTICIPATION**

There is no cost to you for participation. Amazon.com gift cards are available thru multiple random drawings and winners will be notified within 2 weeks of the survey close date. Respondents will also receive individualized reports that compare their responses to an anonymized composite summary of all respondents for the same drug-outcome pairs.

- **CONFIDENTIALITY**

Any information that is obtained in connection with this study will remain confidential. We will not use your email we get from the survey in any of the research reports or analysis. The analysis of the survey will be used for scientific conferences and publications. Any information we use for publication will not identify you individually and only aggregated data will be used in publications.

- **PARTICIPATION AND WITHDRAWAL**

You can choose whether or not to participate in the survey. If you volunteer to participate in the survey, you may stop at any time without consequences of any kind.

- **IDENTIFICATION OF INVESTIGATORS**

If you have any questions or concerns about the research, please feel free to contact:

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- **RIGHTS OF RESEARCH SUBJECTS**

The Indiana University Institutional Review Board has reviewed OMOP's request to conduct this project, Protocol #: 1107006236; IRB-03, IRB00000228.