APPENDIX B: INVITATION LETTER

Dear XXXX,

We would like to invite you to participate in a focus group to discuss the usability, clarity, and efficiency of a structured protocol and reporting template for healthcare database studies. This template follows up on the work from a joint task force between the International Society for Pharmacoepidemiology (ISPE) and International Society for Pharmacoeconomics and Outcomes Research (ISPOR) on practices to improve transparency, reproducibility, and validity. This is a joint project conducted by Brigham and Women's Hospital and the U.S. Food and Drug Administration (FDA).

The structured template is being developed to make conduct of database studies more transparent and reproducible. It is based on the ISPE/ISPOR joint task force paper (attached), which catalogued specific study parameters involved in database study implementation, and a paper on graphical representation of study design (attached). The objective of the focus group is to seek qualitative feedback from various stakeholders, including regulatory agencies (including FDA's Sentinel System), the pharmaceutical industry, distributed networks, healthcare delivery systems, patients, scientific journals, professional societies, the international network, contract research organizations, and other organizations involved in research reporting. Information collected from the focus group will be used to improve the template's usability, clarity, and efficiency and to identify barriers to use.

Participation will involve:

1. Review of materials: Structured template + User Guide with example entries (required, attached), discussion questions (required, attached), ISPE/ISPOR joint task force paper (optional), design visualization paper (optional) (30 minutes)

2. A conference call to briefly walk through the structured template and an example, then collect qualitative feedback on the risks, benefits, clarity, usability, and efficiency of using the template from a researcher perspective and/or your ability to evaluate the validity and relevance of evidence from a reviewer perspective (90 minutes)

Joint conference calls will be scheduled for participants from multiple organizations to facilitate discussion.

Your feedback will be used to make the structured reporting template more usable, clear, and efficient for researchers and reviewers. Your contribution will be acknowledged in peer-reviewed publications or reports that describe the structured reporting template, intended use cases, and the process to develop it. You have the option not to be recognized if you wish.

If you would like to participate, please sign the attached consent form and return it to us by DATE.

We look forward to hearing from you,

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