OMB Control No. 0910-0497 Expiration date: 10/31/2020

**APPENDIX A: POTENTIAL STAKEHOLDERS TO CONTACT REGARDING PARTICIPATION FROM MEMBERS OF THEIR ORGANIZATIONS (LIST MAY BE MODIFIED)**

| **Name** | **Title** | **Organization** |
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| **Large Distributed Healthcare Data Networks** |  |  |
| Jeffrey Brown, Ph.D. | Director of Scientific Operations, Associate Professor, Department of Population Medicine, Harvard Medical School | PCORnet, FDA’s Sentinel Program |
| Richard Platt, M.D., M.Sc. | Principal Investigator, Chair of Department of Population Medicine, Harvard Medical School | PCORnet, FDA’s Sentinel Program |
| **Payers, Healthcare Delivery Systems** |  |  |
| Sarah Priddy Alwardt, Ph.D. | Vice President Health Informatics and HEOR | McKesson Specialty Health |
| Troyen Brennan, M.D. | Executive Vice President and Chief Medical Officer | CVS Health |
| Páll Jónsson, Ph.D., M.Res. | Associate Director Research and Development | NICE |
| Will Shrank, M.D. | Chief Medical Officer | UPMC |
| Sarah Emond MPP | Executive Vice President and Chief Operating Officer | ICER |
| Wim Goettsch PhD | HTA-advisor | Dutch National Healthcare Institute |
| **Regulators** |  |  |
| Peter Arlett, B.Sc., M.B.B.S., M.R.C.P., F.F.P.M. | Head of Pharmacovigilance and Epidemiology Department | European Medicines Agency (EMA) |
| Hans-Georg Eichler, M.D., M.Sc. | Senior Medical Officer | European Medicines Agency (EMA) |
| Yoshiaki Uyama, Ph.D. | Director, Office of Medical Informatics and Epidemiology | Pharmaceuticals and Medical Devices Agency (PMDA), Japan |
| David Martin, M.D., M.P.H. | Liaison to the Reagan Udall Foundation IMEDS Program at U.S. FDA Center for Drug Evaluation and Research (CDER) | Food and Drug Administration (FDA) |
| Michael Nguyen, M.D. | FDA Sentinel Liaison, CDER | Food and Drug Administration (FDA) |
| Richard Swain, PhD | Acting Team Leader, Office of Surveillance and epidemiology, CDER | Food and Drug Administration (FDA) |
| Christian Hampp, PhD | Master Reviewer, Office of Surveillance and epidemiology, CDER | Food and Drug Administration (FDA) |
| Efe Eworuke, PhD | Team Leader, Office of Surveillance and epidemiology, CDER | Food and Drug Administration (FDA) |
| Clara Kim, PhD | Team Leader, Office of Translational Sciences, CDER | Food and Drug Administration (FDA) |
| Elande Baro, PhD | Statistical Reviewer, Office of Translational Science, CDER | Food and Drug Administration (FDA) |
| Stephanie Krauss, JD MPH | Regulatory Counsel, Office of Regulatory Policy, CDER | Food and Drug Administration (FDA) |
| **Open Science** |  |  |
| John Ioannidis, M.D., D.Sc. | Co-Director, Professor of Medicine and of Health Research and Policy at Stanford University School of Medicine | Meta-Research Innovation Center at Stanford |
| Brian Nosek, Ph.D. | Executive Director, Professor of Psychology, University of Virginia | Center for Open Science |

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| **Journal Editors** |  |  |
| Sean Hennessy, Pharm.D., Ph.D. | Professor of Epidemiology and of Systems Pharmacology and Translational Therapeutics | University of Pennsylvania Perelman School of Medicine |
| Laura Happe | Editor in Chief of Journal of Managed Care and Specialty Pharmacy | Journal of Managed Care and Specialty Pharmacy |
| Christine Laine, M.D., M.P.H., F.A.C.P. | Editor in Chief, Associate Professor, Jefferson Medical College | Annals of Internal Medicine |
| Elizabeth Loder, M.D., M.P.H. | Head of Research, BMJ, Professor of Neurology, Harvard Medical School | BMJ |
| Henrik Toft Sørensen, M.D., Ph.D. | Editor in Chief | Clinical Epidemiology |
| Peter Tugwell, M.Sc., M.D., F.R.C.P.C. | North American Editor, Professor of Medicine and Epidemiology & Community Medicine at the University of Ottawa | Journal of Clinical Epidemiology |
| Wolfgang Winkelmayer, M.D., M.P.H., Sc.D., F.A.S.N. | Associate Editor, Professor of Medicine and Chief, Section of Nephrology, Baylor College of Medicine | Journal of the American Medical Association (JAMA) |
| **Professional Society/Guidelines** |  |  |
| Jesper Hallas, M.D., Ph.D. | President | ISPE |
| Sinead Langan PhD | Wellcome Senior Clinical Fellow and Professor | RECORD guidelines |
| Dick Willke, Ph.D. | Chief Scientific Officer | ISPOR |
| **International Network of Academics** |  |  |
| K. Arnold Chan, M.D., Sc.D. | Director, Health Data Research Center | National Taiwan University |
| Nam-Kyong Choi, B. Pharm., Ph.D. | Assistant Professor, Korea Institute of Drug Safety & Risk Management (KIDS) Advisor, Asian Pharmacoepidemiology Network (AsPEN) Chair-Elect | Ewha Womans University |
| Frank de Vries, Pharm.D., Ph.D. | Head of Research | Department of Clinical Pharmacy, Maastricht UMC+  The Netherlands |
| **Contract Research Organization** |  |  |
| Alison Bourke, M.Sc., F.R.Pharm.S. | Scientific Director, Real World Insights, QuintilesIMS | QuintilesIMS |
| John Seeger, Pharm.D., Dr.P.H. | Chief Scientific Officer | Optum Epidemiology |

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| **Name** | **Title** | **Organization** |
| **Pharmaceutical Industry** |  |  |
| Dorothee Bartels, M.Sc., Ph.D. | Head of Global Epidemiology | Boehringer Ingelheim GmbH |
| Andrew Bate, Ph.D. | Senior Director, Analytics Team Lead in Epidemiology | Pfizer |
| Brian Bradbury, D.Sc. | Executive Director, Center for Observational Research | Amgen |
| Javier Jimenez, M.D., M.P.H. | VP, Global Head RWE and Clinical Outcomes | Sanofi |
| Kris Kahler, Ph.D. | Executive Director and the Global Head of Outcomes Evidence & Analytics | Novartis |
| Joanne Waldstreicher, M.D. | Chief Medical Officer | Johnson & Johnson |