Supplementary Table 1. FDA Center for Tobacco Products “Biomarkers of Potential Harm” Workshop Sessions, April 4-5, 2016

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| Session/title | Presenter | Organization |
| Session 1: Biomarkers of Potential Harm Overview |  |  |
| Characterization of Biomarkers of Potential Harm: Perspective from a Clinical Scientist | Dorothy K. Hatsukami, PhD | University of Minnesota |
| Utility of Biomarkers of Potential Harm in Tobacco Product Regulation | Kimberly Frost-Pineda, PhD, MPH, CPH | Altria Client Services |
| Surrogate Markers at FDA – Lessons Learned | Robert Temple, MD | FDA Center for Drug Evaluation and Research |
| Session 1 Panel Discussion | Dorothy K. Hatsukami, PhD | University of Minnesota |
|  | Kimberly Frost-Pineda, PhD, MPH, CPH | Altria Client Services |
|  | Robert Temple, MD | FDA Center for Drug Evaluation and Research |
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| Session 2: Cardiovascular Disease (CVD) |  |  |
| Biomarkers of Potential Harm: Tobacco-induced Cardiovascular Disease | Neal L. Benowitz, MD | University of California, San Francisco |
| Biomarkers of Potential Harm Among Users of Different Tobacco Products:  Results of Two Studies Compared with Published Literature | Bobbette A. Jones, DrPH, CCCRP | RAI Services Company |
| Biomarkers of Cardiovascular Disease | Thomas J. Wang, MD | Vanderbilt University Medical Center |
| Biomarkers of Cardiovascular Injury Due to Tobacco Product Use | Aruni Bhatnagar, PhD, FAHA | American Heart Association/University of Louisville |
| Tobacco and Biomarkers of Cardiovascular Harm: Many Questions Remain | Shari Targum, MD, MPH, FACC | FDA Center for Drug Evaluation and Research |
| Session 2 Panel Discussion on CVD | Neal L. Benowitz, MD | University of California, San Francisco |
|  | Bobbette A. Jones, DrPH, CCCRP | RAI Services Company |
|  | Thomas J. Wang, MD | Vanderbilt University Medical Center |
|  | Aruni Bhatnagar, PhD, FAHA | American Heart Association/University of Louisville |
|  | Shari Targum, MD, MPH, FACC | FDA Center for Drug Evaluation and Research |
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| Session 3: Chronic Obstructive Pulmonary Disease (COPD) |  |  |
| Tobacco Use and COPD: Overview | James D. Crapo, MD | National Jewish Health |
| Imaging Biomarkers of Potential Harm: CT and MRI | R. Graham Barr, MD, DrPH | Columbia University Medical Center |
| Biological Biomarkers of Tobacco-Related Harm in the Lung | Stephen I. Rennard, MD | University of Nebraska Medical Center/AstraZeneca, United Kingdom |
| Tobacco Exposure-Induced Biomarkers of Harm in Human Airway Epithelia | Robert Tarran, PhD | University of North Carolina at Chapel Hill /The UNC School of Medicine TCORS Program |
| Forced Expiratory Volume in 1 Second: a Multifunctional Biomarker of Lung Function | Erika Torjusen, MD, MHS | FDA Center for Drug Evaluation and Research |
| Session 3 Panel Discussion on COPD | James D. Crapo, MD | National Jewish Health |
|  | R. Graham Barr, MD, DrPH | Columbia University Medical Center |
|  | Stephen I. Rennard, MD | University of Nebraska Medical Center/AstraZeneca, United Kingdom |
|  | Robert Tarran, PhD | University of North Carolina at Chapel Hill /The UNC School of Medicine TCORS Program |
|  | Erika Torjusen, MD, MHS | FDA Center for Drug Evaluation and Research |
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| Session 4: Cancer |  |  |
| Biomarkers of Potential Harm Associated with Cigarette Smoking | Stephen S. Hecht, PhD | Masonic Cancer Center/University of Minnesota |
| Cigarette Smoking and Variation in Circulating Markers of Inflammation and Immunity | Meredith Shiels, PhD | NIH National Cancer Institute |
| Epigenetic Biomarkers of Tobacco Smoke Exposure | Douglas A. Bell, PhD | NIH National Institute of Environmental Health Sciences |
| Airway Epithelial Biomarkers of Tobacco Exposure and Risk | York E. Miller, MD | University of Colorado School of Medicine/Denver Veterans Affairs Medical Center |
| The Airway Transcriptome as a Biomarker of Tobacco Smoke Exposure and Lung Cancer Detection | Avrum Spira, MD, MSc | Boston University School of Medicine |
| Session 4 Panel Discussion on Cancer | Stephen S. Hecht, PhD | Masonic Cancer Center/University of Minnesota |
|  | Meredith Shiels, PhD | NIH National Cancer Institute |
|  | Douglas A. Bell, PhD | NIH National Institute of Environmental Health Sciences |
|  | York E. Miller, MD | University of Colorado School of Medicine/Denver Veterans Affairs Medical Center |
|  | Avrum Spira, MD, MSc | Boston University School of Medicine |
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| Session 5: New Areas of Research |  |  |
| Use of Biomarkers of Early Effect in Occupational Exposure Limit Setting | D. Gayle DeBord, PhD | CDC National Institute for Occupational Safety and Health |
| Biomarkers and AOPs: Bridging Toxicity Pathways & Regulatory Decision Making | Stephen Edwards, PhD | US Environmental Protection Agency |
| Utility of Biomarkers of Potential Harm as End-Points for the Disease Relevant Assessment of Novel Tobacco and Nicotine Products as Potentially Reduced Risk Products | Christopher Proctor, BSc (Hon), PhD | British American Tobacco |
| Tobacco Use and the Human Microbiome | Emily Vogtmann, PhD, MPH | NIH National Cancer Institute |
| Biomarkers of Potential Harm: Tools to Differentiate Tobacco Product Classes | G. L. Prasad, PhD | RAI Services Company |
| Biomarker Qualification at CDER, FDA | Shashi Amur, PhD | FDA Center for Drug Evaluation and Research |
| Session 5 Panel Discussion | D. Gayle DeBord, PhD | CDC National Institute for Occupational Safety and Health |
|  | Stephen Edwards, PhD | US Environmental Protection Agency |
|  | Christopher Proctor, BSc (Hon), PhD | British American Tobacco |
|  | Emily Vogtmann, PhD, MPH | NIH National Cancer Institute |
|  | G. L. Prasad, PhD | RAI Services Company |
|  | Shashi Amur, PhD | FDA Center for Drug Evaluation and Research |