



***By Electronic Delivery***

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Public Comments  
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**Patient-Centered Outcomes Research Institute (PCORI) Draft National Priorities and Research Agenda**

15 March 2012

Dear Dr. Selby,

AstraZeneca Pharmaceuticals LP is pleased to submit the following comments on the Patient-Centered Outcomes Research Institute's (PCORI) Draft National Priorities and Research Agenda, published on the organization's website on January 23, 2012.<sup>1</sup> AstraZeneca is a global innovation-driven biopharmaceutical company that discovers, develops, manufactures and markets prescription medicines in six areas that target many of the world's most serious illnesses: cancer, cardiovascular, gastrointestinal, infection, neuroscience, and respiratory and inflammation.

AstraZeneca supports PCORI's goal of increasing the availability of accurate, scientific evidence to inform clinical decision-making. Two of the proposed national priorities are of particular interest to AstraZeneca because we have initiatives underway that are aligned with PCORI's objectives:

- Accelerating patient-centered and methodological research.
- Assessment of prevention, diagnosis, and treatment options, and addressing disparities.

**Accelerating patient-centered and methodological research.** One of PCORI's proposed research topics under "accelerating patient-centered and methodological research" involves research that determines the validity and efficiency of data sources commonly used in patient-centered outcomes research (PCOR) and provides as an example: "research that seeks to improve the volume, completeness, comprehensiveness, accuracy, and efficiency of use of clinical data collected across healthcare systems, clinical data networks, registries, or payer databases and the utility of this data for conducting longitudinal studies of patient outcomes."

AstraZeneca has embarked on a unique collaboration with HealthCore, the health outcomes research subsidiary of WellPoint, which is aligned with PCORI's interest in advancing patient-centered research.

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<sup>1</sup> <http://www.pcori.org/assets/PCORI-Draft-National-Priorities-and-Research-Agenda.pdf>.

AstraZeneca and HealthCore have joined forces on a “Real-World Evidence (RWE)” collaboration to determine the most effective treatments for chronic illnesses and other diseases in an effort to improve health outcomes and manage care.

RWE studies use observational, naturalistic and pragmatic data such as electronic medical records, integrated public/private claims information and patient/healthcare provider surveys. By examining longitudinal and cross-sectional data associated with the delivery of care, real-world analyses can assess treatment impact on healthcare utilization (e.g., hospital length of stay, readmissions), quality of care, overall health status, and other key evidence-based outcomes that may have profound health policy implications.

The RWE studies planned by AstraZeneca and HealthCore will utilize real-world patient data, subject to all appropriate confidentiality protections, including electronic medical records, claims information, and lab and pharmacy data from both WellPoint, as a large private insurer, and certain public payers (e.g., the state of Delaware will contribute Medicaid data). Information from these studies will also be used to help direct the development and delivery of medications, as well as other types of treatment options and plans (e.g., medical, surgical).

AstraZeneca and HealthCore are currently expanding the collaboration into a broader consortium of private and public healthcare organizations in communities that are already using integrated data to improve health. By including a variety of key stakeholders committed to making meaningful changes in the delivery and quality of healthcare, AstraZeneca and HealthCore hope to accelerate national and regional investment in evidence-based strategies for improving health outcomes.

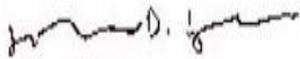
**We would welcome the opportunity to talk with members of the PCORI Board of Governors and staff about the RWE collaboration, and encourage PCORI to consider RWE as a model for truly innovative and integrated patient-centered research.**

**Assessment of prevention, diagnosis, and treatment options; addressing disparities.** AstraZeneca also has initiatives underway that align with the statutory criteria that PCORI must conduct research that addresses impact on individuals and populations, as well as inclusiveness of different sub-populations. We support the overarching goal of conducting research to assess the impact of treatments on individuals and populations. We hope PCORI will recognize the important role of individualized medicine in advancing this goal and that the organization will draw upon industry expertise in personalized health care and biomarkers moving forward.

In 2010-11, AstraZeneca entered a new phase in optimizing health outcomes with the creation of a new Personalized Healthcare and Biomarkers function. With the introduction of advanced novel therapeutic options and biomarker technology, personalized healthcare biomarkers may be identified to further define the appropriate patient population for a particular therapy. In addition, biomarkers can be used to enhance the drug development process. AstraZeneca has multiple drug programs in clinical development using biomarkers or diagnostic tools to optimize patient therapy. These programs are across a range of therapeutic areas, including respiratory, inflammation, and oncology. AstraZeneca’s investment in this area reflects our commitment to selecting the right patient populations for our medicines.

AstraZeneca appreciates the opportunity to offer these comments. We look forward to working with PCORI to address these critical issues in the future and welcome the opportunity to meet with you to further discuss our efforts in developing Real World Evidence and personalized healthcare. Please feel free to contact Bela Sastry at 202-384-2942 if you have any questions or if we can be of further assistance. Thank you for your attention to this very important matter.

Yours sincerely



**John Yee, MD, MPH**  
Vice President & US Head Medical Officer