

PRESS RELEASE

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**Outcome Selected by Agency for Healthcare Research and Quality to
Develop New U.S. Patient Registries Database**

-- *“Registries of Patient Registries” Focused on Creating a Central Repository for
Knowledge Sharing in Observational Studies”*--

--*Outcome to Also Lead Development of AHRQ’s Third Edition “Registries for
Evaluating Patient Outcomes”*--

Cambridge, MA – 30 November 2010 – Outcome Sciences, Inc. (OUTCOME), the leading provider of patient registries, studies, and technologies for evaluating real-world outcomes, today announced that the Agency for Healthcare Research and Quality (AHRQ) has awarded Outcome a task order to design and develop a new Registry of Patient Registries (RoPR) database.

Patient registries are increasingly being used to support a wide range of clinical studies. While clinical trials must be registered in ClinicalTrials.gov, there is no such mandate for observational studies. The goal of the RoPR database is to ensure registries are used in the most efficient manner and to encourage collaboration between patients and consumers, health care providers, researchers, research funding organizations, public health organizations, private health plans, employers, public insurance programs, journal editors, and pharmaceutical and device manufacturers. This project is being funded by the American Recovery and Reinvestment Act (ARRA), which is an economic stimulus package that was enacted by the 111th United States Congress in February 2009.

The main objectives of the RoPR project are to:

- Provide a searchable central listing of patient registries in the United States to enable interested parties to identify registries in a particular area;

- Encourage and facilitate the use of common data elements and definitions in similar conditions – to improve opportunities for sharing, comparing, and linkage – through the listing and searching of such elements;
- Provide a central repository of searchable summary results, including results for registries that have not published their findings in peer-reviewed literature;
- Offer researchers a search tool to locate existing data, from either ongoing studies or closed studies, to request for use in new studies; and
- Serve as a recruitment tool for researchers and patients interested in participating in patient registries.

“A central repository for registries speaks to the evolution of these observational studies and their recognized importance in providing critical information about various disease states and medicines,” said Dr. Richard Gliklich, MD, President and CEO of Outcome. “Outcome is honored to have been chosen by AHRQ to create the RoPR database, which we are confident will promote collaboration, reduce redundancy and improve transparency related to registries among various healthcare stakeholders.”

The AHRQ task order also includes the development of the third edition of the guide, “Registries for Evaluating Patient Outcomes: A User’s Guide,” a Federal publication that provides information on designing, implementing, and evaluating patient registries. The guide addresses the strengths and limitations of patient registries, in addition to explaining how to design a registry, analyze and interpret registry data, and evaluate the strength of a registry and its findings. Outcome led the development of the first and second editions of the patient registries guide. The third edition will provide more timely information regarding new methodological, legal, and operational challenges and advances. The updated guide will cover at least 11 new topics, and will be led by Dr. Gliklich and Dr. Nancy Dreyer, Chief of Scientific Affairs and Senior Vice President for Outcome. It is scheduled for release in 2013.

About Outcome

Outcome is the leading provider of patient registries, studies, quality improvement programs, and integrated technologies for evaluating real-world outcomes. Outcome provides services and technologies focused on evaluating the safety, effectiveness, and quality of healthcare products and services. The company has designed, developed, and managed more than 200 patient registries, including many of the largest and most well-recognized programs for disease outcomes and patient safety.

Outcome is also an Agency for Healthcare Research and Quality (AHRQ) DEcIDE Research Center, a component of the “Effective Health Care” initiative sponsored by the U.S. Dept. of Health and Human Services. Outcome was selected by AHRQ to lead the effort to create the patient registries handbook “Registries for Evaluating Patient

Outcomes: A User’s Guide,” released in May 2007 and updated with a second edition in September 2010. For more information, please visit www.outcome.com.

About AHRQ

The Agency for Healthcare Research and Quality (AHRQ) is the lead Federal agency charged with improving the quality, safety, efficiency, and effectiveness of health care for all Americans. As one of 12 agencies within the Department of Health and Human Services, AHRQ supports health services research that will improve the quality of health care and promote evidence-based decision making. The Effective Health Care Program funds individual researchers, research centers, and academic organizations to work together with the AHRQ to produce effectiveness and comparative effectiveness research for clinicians, consumers, and policymakers. For more information on the AHRQ Effective Health Care Program, please visit <http://www.effectivehealthcare.ahrq.gov/>. For additional information, please contact AHRQ Public Affairs: (301) 427-1998 or (301) 427-1855.

About the User’s Guide

The guide, developed in 2007, is divided into three sections—creating, operating, and evaluating registries—which lay out the basic information on key areas of registry development and operations and highlight the spectrum of practices in each of these areas, including their potential strengths and weaknesses. The final chapter describes the basic elements of good registry practice and potential enhancement that can be used to strengthen the rigor of registries. The second edition, published in September 2010, contained four new sections: Use of Registries in Product Safety Assessment; Planning for the End of a Patient Registry; Interfacing Registries and EHRs; and Linking Registry Data.