



## **PPD Awarded U.S. Food and Drug Administration Contract to Evaluate FDA's Spontaneous Adverse Event Surveillance System**

### ***Providing drug safety and pharmacoepidemiology expertise to assist agency in fulfilling PDUFA IV commitment***

**WILMINGTON, N.C.** (October 27, 2009) - PPD, Inc. (Nasdaq: PPDI) today announced it has been awarded a contract by the U.S. Food and Drug Administration (FDA) to evaluate the agency's Center for Drug Evaluation and Research (CDER) post-market spontaneous adverse event surveillance system. The company will conduct a thorough evaluation of the value of the spontaneous adverse event reports to support safety-related regulatory actions and report its findings to the FDA and the public.

The award of \$2.7 million for year one, is part of a two-year project of FDA's Initiative for Maximizing the Benefit of Passive Adverse Event Collection throughout a Product's Life Cycle (IMPACT). IMPACT, launched in 2008, is intended to fulfill a Prescription Drug User Fee Act (PDUFA) IV commitment.

Under the contract, PPD will comprehensively evaluate this FDA public health surveillance system. First, the system will be described, including key objectives, components and the regulatory framework (e.g. relevant laws). The focus of the evaluation is the review and analysis of the system's role to support safety-related regulatory actions and the provision to FDA of a report detailing study results, conclusions and recommendations for maximizing the system's ability to support safety-related regulatory actions for drugs and therapeutic biologics throughout a product's life cycle. This complex and unprecedented evaluation of the FDA spontaneous adverse event surveillance system will involve the development and implementation of innovative methodologies. The FDA will use these findings to develop an implementation strategy for ensuring optimal use of the system as part of its pharmacovigilance efforts to protect public health.

PPD will apply [drug safety and pharmacoepidemiological expertise](#) integral to its industry-leading safety services, which include signal detection, global expedited case processing period report development, risk management plans/REMS, pregnancy registries, endpoint adjudication, safety monitoring committees, and adverse event and medical information contact centers.

"Epidemiology is important to evaluating drug safety risks, and we are pleased the FDA recognized our strong capabilities and commitment to patient safety and regulatory compliance," said Christine Dingivan, M.D., chief medical officer of PPD. "The contract enables us to assist the FDA in this important endeavor and demonstrates our breadth of drug safety and pharmacoepidemiology services."

David Brown, Ph.D., M.P.H., executive director of global epidemiology at PPD, will lead the evaluation and serve as principal investigator. Dr. Brown will collaborate with three renowned drug safety and pharmacoepidemiology experts, including Alexander Walker, M.D., Dr.P.H., principal, World Health Information Science Consultants, LLC (WHISCON); Stephen A. Goldman, M.D., FAPM, DFAPA, managing member, Stephen A. Goldman Consulting Services, LLC; and Robert Nelson, Ph.D., FISPE.

PPD is a leading global contract research organization providing discovery, development and post-approval services as well as compound partnering programs. Our clients and partners include pharmaceutical, biotechnology, medical device, academic and government organizations. With offices in 38 countries and more than 10,000 professionals worldwide, PPD applies innovative technologies, therapeutic expertise and a commitment to quality to help its clients and partners maximize returns on their R&D investments and accelerate the delivery of safe and effective therapeutics to patients. For more information, visit our Web site at <http://www.ppdi.com>.

*Except for historical information, all of the statements, expectations and assumptions contained in this news release, including expectations and assumptions about being selected by the FDA to evaluate its safety surveillance system, are forward-looking statements that involve a number of risks and uncertainties. Although PPD attempts to be accurate in making these forward-looking statements, it is possible that future circumstances might differ from the assumptions on which such statements are based. In addition, other important factors which could cause results to differ materially include the following: the ability to attract and retain key personnel; risks associated with and dependence on collaborative relationships; competition within the outsourcing industry; rapid technological advances that make our services less competitive; contract cancellation; economic conditions and outsourcing trends in the pharmaceutical, biotechnology, medical device, academic and government industry segments; and the other risk factors set forth from time to time in the SEC filings for PPD, copies of which are available free of charge upon request from the PPD investor relations department.*

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