



**FOR IMMEDIATE RELEASE**

**PPD's PatientAdvantage Inverts Traditional Clinical Trial Delivery Method**

*New patient enrollment model helped The Medicines Company significantly accelerate drug development*

**WILMINGTON, N.C. (June 25, 2018)** – Pharmaceutical Product Development, LLC ([PPD](#)) has introduced a new patient enrollment model that significantly reduces the time and cost of conducting clinical trials for pharmaceutical and biotechnology customers. [PatientAdvantage](#) uses data-driven feasibility to identify eligible patients in the population first, then delivers qualified patients to high-performing investigative sites for enrollment – an approach that inverts the steps of the industry's long-practiced trial-delivery method.

“Biopharmaceutical companies typically have used a model that focuses on identifying and starting up sites that are expected to have access to patients with the relevant indication for the trial,” said Roger Smith, senior vice president and general manager of PPD's Accelerated Enrollment Solutions (AES). “Instead of that traditional site-first approach, PatientAdvantage enables us to start by rapidly enrolling community-based patients from our proprietary databases and modeling. Then, after mapping patient locations, we select sites to match patient-rich populations. This patient-centric solution is highly predictive and yields greater enrollment and budget certainty.”

The PatientAdvantage model recently was utilized for three Phase III studies that PPD conducted for [The Medicines Company](#). The studies were part of The ORION Project, confirming the efficacy and safety of inclisiran, an investigational agent that is potentially a first-in-class lipid-lowering drug to reduce LDL-cholesterol (LDL-C) in patients with atherosclerotic cardiovascular disease (ASCVD), ASCVD risk equivalent, HoFH and HeFH. Using this new patient-focused approach, the patients required for The Medicines Company's studies were delivered using fewer sites and in less than half the time.

Overall, the randomization of trial subjects was completed nearly three months early. In addition, a key metric measuring the time between the first protocol for the study being received to the first site being activated was achieved 64 percent faster than the industry standard cycle time. Across the three studies, the timelines between the first and last sites being activated, the first and last subjects being randomized and the first protocol being received to the last subject being randomized were delivered 73 percent, 72 percent and 62 percent faster than industry benchmarks, respectively.

“This achievement is unprecedented and vitally important to the future of cardiovascular drug development,” said Peter Wijngaard, executive vice president and chief development officer of The Medicines Company. “There are few places in the clinical trial process where time can be saved and value created. Through our very productive

collaboration, we set a new standard for what is possible and we could not be prouder as a company and as individuals to have been part of this groundbreaking accomplishment.”

PatientAdvantage is a unique offering for pharmaceutical and biotechnology customers leveraging the clinical development services of PPD, the global contract research organization (CRO), and the capabilities of AES, a business unit of PPD. AES provides both sponsors and CROs best-in-class site and enrollment solutions, with tiered offerings combining the expertise, as needed, of industry leaders Synexus, Acurian and Optimal Research.

Acurian, PPD’s patient recruitment business unit, is pivotal in determining the number of patients who can be recruited from the general population based on its highly predictive and proven enrollment models. Synexus, the world’s leading site network for clinical trials, and Acurian both have proven track records for enrolling patients and study conduct through proprietary, direct-to-patient recruitment methodologies and a global site network. When combined, these services provide a new standard of clinical trial productivity that delivers more patients from fewer sites in less time.

“Early engagement with Acurian is critical to generating the benefits PatientAdvantage offers,” Smith said. “Our recruitment efforts focus on identifying qualified patients directly from the general population, with less reliance on identifying patients at a site to enroll in a study. A key to our success is activating sites in locations near identified patients. This approach significantly reduces timelines and can provide up to 100 percent of the total patients required, thereby delivering greater enrollment and budget certainty, speed and cost savings, as well as enhanced data quality.”

## **About PPD**

PPD is a leading global contract research organization providing comprehensive, integrated drug development, laboratory and lifecycle management services. Our clients and partners include pharmaceutical, biotechnology, medical device, academic and government organizations. With offices in 47 countries and approximately 20,000 professionals worldwide, PPD applies innovative technologies, therapeutic expertise and a firm commitment to quality to help clients and partners bend the cost and time curve of drug development and optimize value in delivering life-changing therapies to improve health. For more information, visit [www.ppd.com](http://www.ppd.com).

## **About Accelerated Enrollment Solutions**

Accelerated Enrollment Solutions is a business unit of PPD that offers both sponsors and contract research organizations best-in-class site and enrollment solutions, with tiered offerings combining the expertise, as needed, of industry leaders PPD, Synexus, Acurian and Optimal Research. These solutions are available as discrete services or integrated to provide a cohesive and highly differentiated trial acceleration strategy for insourced or outsourced clinical studies, all under performance-based commercial terms. The array of integrated solutions includes PatientAdvantage, PPD’s global clinical development services optimized with Acurian and Synexus enrollment capabilities. Acurian and Synexus have proven track records for enrolling patients and

study conduct through proprietary, direct-to-patient recruitment methodologies and a global site network. When combined, these services provide a new standard of clinical trial productivity that delivers more patients from fewer sites in less time.

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## **Forward-looking Statements**

*Any statements made in this news release that are not statements of historical fact are forward-looking statements that involve risks, uncertainties and assumptions that are difficult to predict, and, therefore, you should not place undue reliance on such statements. Forward-looking statements often include words such as “anticipate,” “expect,” “plan,” “believe,” “intend,” “estimates,” “targets,” “projects,” “should,” “could,” “would,” “may,” “might,” “will,” “forecast” and other similar expressions. Although PPD believes these forward-looking statements are based on reasonable assumptions at the time they are made, many factors are beyond PPD’s ability to control or predict and, therefore, the actual outcomes and results might differ materially from those expressed in the forward-looking statements.*

*Additional factors that might materially affect the outcomes and results expressed in the forward-looking statements include, but are not limited to: the competitive nature of the drug development services industry; adverse trends in the biopharmaceutical industry; rapid technological changes that make our services less competitive or obsolete; U.S. or international political, economic and/or regulatory changes impacting the health care industry; our ability to accurately predict and convert our backlog into service revenue; the termination, delay or change in scope of customer contracts; industry, customer or therapeutic concentration; the pricing of and cost management of customer contracts; our failure to comply with contractual, legal and regulatory requirements, including privacy and security requirements, and ethical standards; our ability to attract investigators and enroll patients in clinical trials; competition between existing and potential customers; management of business restructurings and acquisitions; and other factors.*

*PPD assumes no obligation and disclaims any duty to revise or update any forward-looking statements, or make any new forward-looking statement, whether as a result of new information, future events or otherwise, except as required by applicable law.*

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