PPD®

HELPING DELIVER LIFE-CHANGING THERAPIES

ACCELERATED
ENROLLMENT SOLUTIONS

APPLYING INNOVATION TO SPEED SITE AND PATIENT RECRUITMENT, CREATE GREATER PATIENT ENGAGEMENT AND MAXIMIZE VALUE

The industry is experiencing increased pressure to improve recruitment timelines, minimize the burden on sites and patients, and increase patient engagement and insights.

Innovation has become a key part of this effort. PPD applies new methodologies in study startup and site and patient recruitment to create greater efficiency and provide you increased value. This commitment to innovation is strengthened by the development of our accelerated enrollment business, which helps us deliver patient-focused enrollment solutions through our strategic relationships with Acurian, the global enrollment and retention specialists, and Synexus, one of the world's leading site networks. Through accelerated enrollment solutions, we deliver proven accelerated approaches, including PatientAdvantage and the just-in-time oncology enrollment enhancement solution provided through Optimal Research.

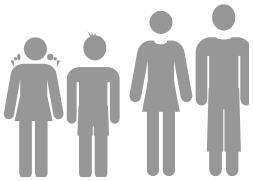
PatientAdvantage accelerates clinical development by **delivering all the patients, with fewer sites, in less time.**

Optimal Research just-in-time approach **enrolls patients within two weeks of identification** and reduces the percentage of non-enrolling sites.

Through our Accelerated Enrollment Solutions business, we offer site and enrollment solutions through industry leaders Synexus, Acurian and Optimal Research. Our goal is to ensure that the patient's voice is heard during planning and execution of studies and to operationalize informed recruitment and retention strategies, thus making sure that patient insights is central to clinical development.

Our *Accelerated Enrollment Solutions* encompasses many parts of site and patient recruitment, allowing us to deliver differentiation in chronic, ambulatory and oncology indications.

PPD OFFERINGS



PATIENTADVANTAGE

ONCOLOGY RECRUITMENT ENHANCEMENT

RESULTS*

- Delivery of all patients needed with fewer sites and in half the time using patient-centered approach
- Greater cost and time certainty in trial delivery

- Patient enrolled within two weeks of identification
- Treated in their own community
- Mitigates risk of slower enrolling sites
- Reduces the percentage of non-enrolling sites

* Applies to certain ambulatory and oncology indications

DEMONSTRATED VALUE OF APPLYING OUR PATIENTADVANTAGE MODEL AT STUDY START

Greater enrollment and budget certainty, speed and costs savings

30-50% reduction in total sites. Significant reduction in timelines and increased enrollment of 30-50%

Improved data quality from high-performing sites

This solution significantly reduces timelines and can provide up to 100% of the total patients required, thereby delivering greater enrollment and budget certainty, speed, cost savings and increased data quality.

PatientAdvantage combines PPD, Acurian and Synexus services to create a patient-centered, innovative approach to clinical development. This model delivers patient enrollment and budget certainty, speed and cost savings by removing inefficiencies and unknowns in patient enrollment and site selection.

PatientAdvantage changes traditional planning and feasibility by identifying the patients first. Acurian defines the number of patients it can recruit based on its highly predictive and proven enrollment models.

Early engagement with Acurian is critical to unleash the power of PatientAdvantage. Recruitment efforts focus on identifying qualified patients directly from the general population, with less reliance on site-acquired patients to enroll a study. We are then able to remove low-performing sites and drive patients directly to sites enrolling for the specific trial. Synexus defines the location and number of sites based on the identified patient population.

The following examples in uterine fibroids and hypertension shows how our client engaged Acurian in the last several months of study enrollment. Acurian significantly increased enrollment (.78 compared to .23 in uterine fibroids study). Applying PatientAdvantage at the start would have delivered the same number of patients with 41% fewer sites for both studies. The uterine fibroids study would have recruited in half the time, while the hypertension study would have saved nine months recruitment.

	Actual Study Results (using traditional model): Limited Contribution from Acurian; No Synexus				PatientAdvantage Solution: Fewer sites, all the patients, half the time			
Uterine fibroids	**Patients**	**Sites**	**Months Involved**	**ER (Flat)**	**Patients**	**Sites**	**Months Involved**	**ER (Flat)**
TOTAL	589	82	31	0.23	589	49	15.5	0.78
Combined Contribution	28%				82%			
Hypertension	**Patients**	**Sites**	**Months Involved**	**ER (Flat)**	**Patients**	**Sites**	**Months Involved**	**ER (Flat)**
TOTAL	5,316	412	22	0.59	5,316	247	13	1.66
Combined Contribution	17%				85%			

ONCOLOGY ENROLLMENT ENHANCEMENT: YOUR FIRST PATIENT IN, FASTER

Applying our oncology enrollment enhancement solution, we are able help overcome the challenges of recruiting oncology patients, ensuring more patients and faster enrolling sites. This model is designed to augment your existing approach with pre-qualified sites and pre-qualified patients. Leveraging a network of 250+ sites with pre-negotiated contracts, we are able to recruit patients for oncology trials through a just-in-time approach that identifies patients first, followed by rapid site activation in a pay for performance model. Through this model we can identify and enroll patients within 14 days and eliminate non-enrolling sites—sites are only activated when a suitable patient is identified.

DAYS FROM PATIENT IDENTIFIED TO ENROLLED:

10	10	4	10	7
Metastatic Breast Cancer	Neutropenia Breast Cancer	ALK+ NSCLC	Basket Trial: Solid Tumors	NSCLC HLAA2+
PHASE II	PHASE III	PHASE III	PHASE II	PHASE III

Initiating patient recruitment for four additional studies:

- Phase II MET + Companion Diagnostic
- Phase II Basket Study: Solid Tumors (RET)
- Phase II MDS
- Phase II Solid Tumor (BRAF)

CASE STUDIES: PROVEN SUCCESS

The following examples demonstrate how we are performing significantly better than industry in study startup when we have applied our PatientAdvantage solution.

Case Study 1

The PPD, Synexus and Acurian team exceeded timelines to deliver strong startup performance across a three study high cholesterol global program. To achieve the enrollment requirements, Acurian and PPD screened 5,299 patients in 114 days and enrolled 3,660 subjects in 126 days. Synexus provided 83 of 277 sites for the three Phase III studies

Study 1

Cycle times (days)	Spain	Canada	South Africa	U.S.	Denmark	Netherlands	Sweden	Czech Republic
FPR to FSA	129	138	156	19	**177**	**177**	**184**	**186**
FRP to FSS	136	148	158	19	177	181	191	193
% Faster than Industry Median	**38.6%**	**53.5%**	**42.9%**	**88.1%**	**28.0%**	**32.2%**	**24.3%**	**19.5%**

Study 2 (U.S.-only)

Cycle times (days)	FPR to FSA	FPR to FSS
PPD cycle time	19	24
% Faster than Industry Median	**88.1%**	**84.9%**

Overall, we saw reduction in startup timelines, against industry benchmark data, of between 24-88%.

Study 3

Cycle times (days)	U.K.	Hungary	Poland	Ukraine	S. Africa	Germany	Czech Republic	Netherlands
FPR to FSA	106	114	125	137	156	159	178	180
FRP to FSS	107	116	128	143	158	165	179	183
% Faster than Industry Median	**64.3%**	**54.2%**	**58.7%**	**70.5%**	**42.9%**	**28.4%**	**38.4%**	**31.0%**

Case Study 2

We have also deployed the same strategy to achieve significant reduction times for a second biopharma partner's Type 2 diabetes mellitus program. Final protocol was received on 3 October with six U.S. Synexus sites targeted for fast activation. SIVs were completed by 29 November (54 days from FPR). PPD activated the five sites on 4 December with an additional site activated on 5 December and first subject screened on 5 December.

Cycle times (days)	FPR to FSA	FPR to FSS
PPD Cycle time	59	60
KMR to Industry Benchmarks	**43.8%**	**52.4%**

Avoided $2M penalty associated with achieving FS randomized

- Sites Activated to Date*: 6
- Subjects Screened to Date: 13
- Subjects Randomized to Date**: 7

* As of 10 January 2018

** 1st Patient randomized on 20 December 2017

PPD®

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