



Clinical research participation as a care option

Driving patient experience and satisfaction

Jane Shen, PharmD, Senior Director of Innovation, PMG Research, Inc.

Allen Buechler, MBA, CPA, Strategy and Operations, Eli Lilly & Co.

Jennifer Byrne, CEO, PMG Research, Inc.

Jeanne Hecht, MBA, PMP, Senior Vice President, Site & Patient Networks, Quintiles

Jeff James, CEO, Wilmington Health

Bradley Pancratz, Director, The Advisory Board Company – Consulting & Management-PEP

Introduction

Patient engagement and experience is increasingly recognized as a vital element in healthcare, and mounting evidence confirms the influence of patient engagement with improved outcomes and reduced costs.¹ As a way to improve patient engagement, we feel that clinical research participation offers an innovative care option which supports the goals of the “triple aim” – improving both the patient experience of care and population health, while reducing the per-capita cost of healthcare.

Table of contents

Introduction	1
Methods	5
Results	6
Discussion	7
Conclusion	8
Appendix 1	9
References	10
About the authors	11

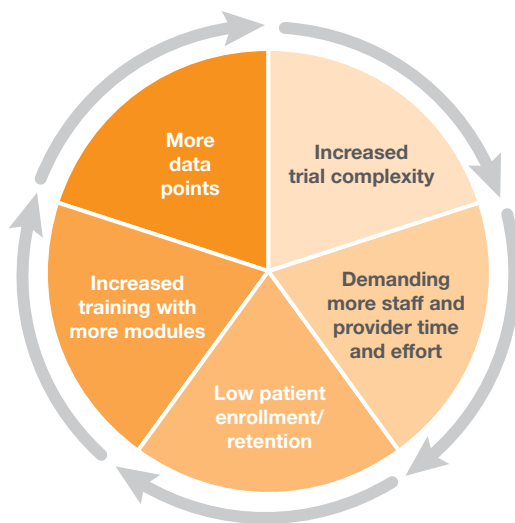
The value of integrating clinical research into the overall continuum of care, however, is often lost on health care organizations. Typically, clinical research is transactional in nature, not an integrated part of a healthcare organization's care options, and in some cases is conducted by investigators unbeknownst to the healthcare institutions employing them.

The impact of this disconnect cannot be overstated. Large quantities of clinical research study data that could be transformed by healthcare systems to actionable information used to analyze and improve population health are ignored – thus limiting the impact of research spend. Further, as a result of the lack of integration of clinical research as a care option, patients typically do not learn about clinical research from their physicians unless their physicians are directly engaged in a clinical trial.

Today, less than 1% of the U.S. population participates in clinical trials, yet 72% say they would participate if recommended to do so by their doctor.² Currently, patient and physician awareness of clinical trials is hindered by the complexity of the healthcare system and the lack of an integrated approach. New technologies and partnerships have the potential to help build integrated networks and to support the triple aim, offering potential for innovative organizations to drive change. Such partnerships may also enhance the trust placed in clinical research by both health care providers⁴ and the public.⁵

In addition, the current process of drug development is increasingly complex, inefficient and in need of disruption (Figure 1). In an effort to improve, sponsors and Clinical Research Organizations (CROs) are looking increasingly to move clinical trials into settings that have the infrastructure and support of electronic medical records (EMRs). At the same time, individual sites face an increasing financial burden, with the average trial site start-up costs estimated at \$25,000.⁶ The healthcare landscape as a whole is also changing, with a shift from physicians owning their own practices to physicians hired as full-time employees for healthcare systems. By 2020, an estimated 80% of all U.S. physicians will be employed by healthcare systems.⁷ Lastly, patients are becoming actively engaged in their healthcare, and there is increased development of new payment models that emphasize higher quality at lower costs.

Figure 1: The dramatic shifts in clinical trial research and the healthcare system



The timing is therefore right to implement a top-down model – including a cultural shift supported by the leadership within healthcare organizations – for integration of clinical research into patient care as a care option. Several elements can be leveraged to integrate clinical research within the patient care cycle, engage and support research physicians with operational infrastructure, and improve the patient experience with meaningful touch points. This model would take advantage of the ongoing revolution in healthcare, with its focus on:

The unmet need for health care

As an indication of the potential for clinical trials to offer a care option, as of January 2015, it was estimated that more than 41 million people, or 15% of nonelderly people in the U.S., lacked health insurance, that 53% of uninsured do not have usual sources of care and 30% of the uninsured went without care.³ A September 2015 report from the U.S. Census Bureau confirmed that even with sweeping healthcare reform, 33 million people, or 10.4% of the U.S. population, lacked health insurance for the whole of 2014.³ Hispanics, blacks and Asians continued to have lower rates of health insurance coverage than non-Hispanic, white Americans, and around 19.9% of Hispanics remained uninsured.



Patient commentary

“I am so much more knowledgeable and aware of my disease.”

- Population health, with integrated organized systems to manage the health of defined populations, such as Accountable Care Organizations (ACOs). In 2011 there were just 64 ACOs, rising to more than 700 covering 23 million Americans in 2015.⁸
- Data and technology, including meaningful use of Electronic Medical Records (EMRs), currently used in patient care at 75% of U.S. hospitals, with around 60% of physicians making meaningful use of EMRs as of Dec. 2014.⁹
- Health consumerism, involving the active engagement of consumers in their own health management.
- New entrants and payment models, designed to emphasize higher quality at lower cost.¹⁰

Looking ahead, a collaborative approach between patients, health care providers, health care systems, drug developers and policy makers has the potential to increase enrollment efficiency for all stakeholders. Patients would see improved access to care, better care, decreased cost and increased engagement. Providers would achieve improved care at lower costs, increased patient engagement, higher patient and physician satisfaction, increased patient market share, and progress towards their triple aim aspiration. The biopharma industry would benefit from accelerated delivery of medicines to patients, access to more patients, regulatory risk mitigation and improved data. Further, such a collaborative approach would also increase predictability and reliability while reducing the volatility in clinical research. CROs would gain additional data for pre-feasibility, optimized site startup times, improved operating margins and greater predictability and reproducibility of success.

Methods

To assess the influence of an integrated, collaborative approach to healthcare, a survey (see Appendix 1) was designed to investigate the levels of satisfaction with clinical research-related care among diabetic patients participating in an ongoing diabetes clinical trial, DM40. The DM40 study is scheduled to continue for four years, and participants will be surveyed annually in January each year. The initial survey took place in January 2015, and will be repeated in January 2016, 2017 and 2018. An interim survey was also completed during the last three weeks of July 2015.

A national average baseline was created by utilizing patient survey results from all Advisory Board Company healthcare systems members that have responded to the same survey question set from January 1, 2013 through July 31, 2015. This included 125,461 surveys conducted for 11 multi-specialty healthcare systems located across the nation. These systems range in size from 50 to 200 providers.

To establish a baseline measurement for Wilmington Health, survey data captured by this group between January 1, 2013, and June 30, 2013, were compiled with a total of 4,313 patient surveys completed. From these, two baselines were created based on ICD9 codes, one involving 3,453 patients who are not considered diabetic (2013 Non-Diabetes) a second involving 860 patients who are considered diabetic (2013 Diabetes Dx). The 2013 time frame was chosen because it predates the DM40 clinical study activity. A third baseline was created based upon surveys completed prior to the randomization date (termed DM40 Pre-Random) from 17 of the DM40 study participants.

A total of 45 patients were randomized for the DM40 study; with three patients since deceased, leaving 42 active study participants as of August 1, 2015. Surveys were completed for all remaining (42) active participants during this survey episode (100%). As of August 1, 2015, the 42 survey respondents had an average of 15.01 months duration in the study.

The DM40 survey data are compared to all three baseline data sets. The survey is conducted by telephone, with a live interviewer utilizing a script. Ten questions were asked related to the various aspects of an ambulatory office visit, which the patient rated on a five-point Likert scale (5 being excellent, 1 being poor). The final question was free text encouraging patients to provide any improvement suggestions or feedback.



Patient commentary

“I am glad that I was advised to participate in the study. I am more cognizant of my condition and my motivation has increased tremendously.”

“Made me more motivated about what I need to do.”

“Better information and a better understanding of my A1C.”

“Education that I was not expecting.”

“Being better aware of how to manage my condition.”

The first 10 Likert score questions have historically been used in patient satisfaction surveys over the past six years, with references to “doctor” and “staff” replaced with “your study team,” allowing for comparison and analysis to baseline data.



Patient commentary

“Gives me the enthusiasm to help myself get better.”

“It made me much more motivated to work on my diabetes.”

“The way that we monitor and do things is much more frequent that it was with my regular doctor.”

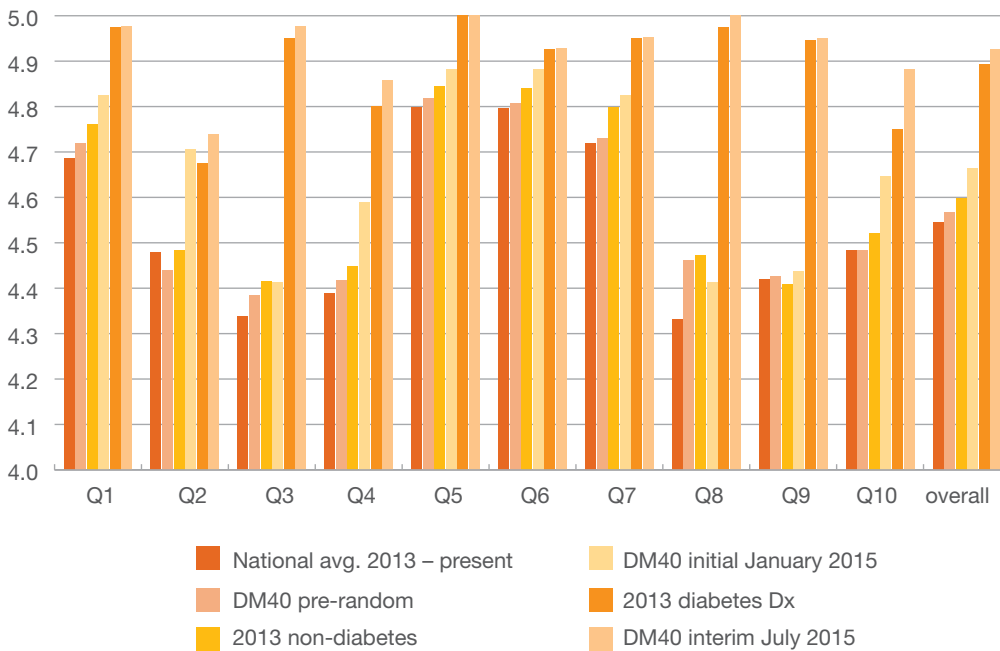
“The whole system has done me a world of good.”

“Study participation has allowed me to manage my diabetes better than I ever have before.”

Results

The surveys conducted in January and July 2015 indicate a high and increasing level of patient satisfaction and engagement with clinical research.^{11,12} Overall, the results demonstrate a positive experience across all dimensions for clinical research participants, with significantly higher levels of satisfaction in many patient-important dimensions such as access to care, efficiencies in care delivery and qualities of care received from the research team.

Figure 2: Overall patient experience

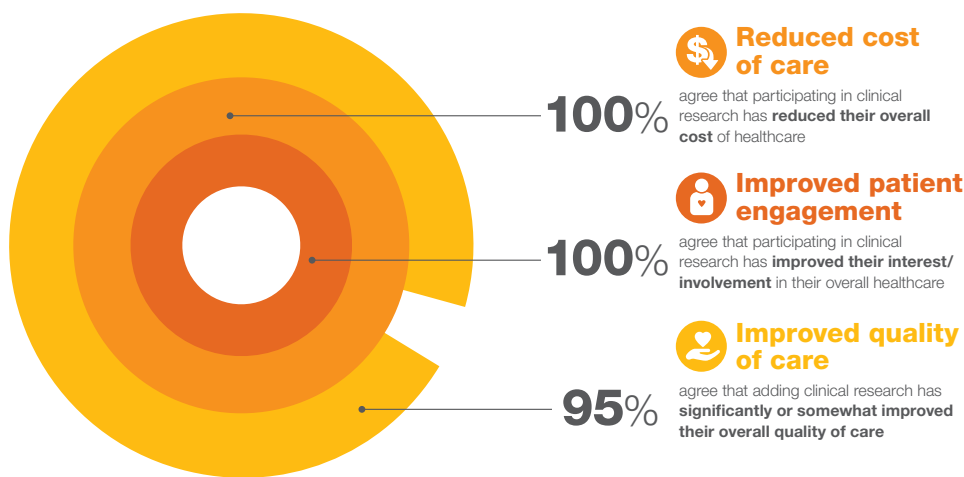


	n	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Overall
National Avg. 2013-Present	125461	4.687	4.478	4.337	4.388	4.799	4.795	4.718	4.331	4.420	4.483	4.545
2013 Non Diabetes	3453	4.720	4.440	4.384	4.418	4.817	4.807	4.730	4.461	4.427	4.483	4.566
2013 Diabetes Dx	860	4.760	4.483	4.415	4.448	4.844	4.841	4.798	4.472	4.409	4.521	4.598
DM40 Pre-Random	17	4.824	4.706	4.412	4.588	4.882	4.882	4.824	4.412	4.438	4.647	4.665
DM40 Initial Jan 2015	40	4.975	4.675	4.950	4.800	5.000	4.925	4.950	4.974	4.946	4.750	4.893
DM40 Interim July 2015	42	4.976	4.738	4.976	4.857	5.000	4.929	4.952	5.000	4.950	4.881	4.926

Of particular interest to the clinical research community were four additional questions that gauged study participant perceptions of their clinical research experience. Three dimensions were assessed: (1) patient engagement in their own healthcare, (2) quality of care during clinical trial participation, and (3) cost benefits associated with clinical trial participation.

When asked whether participating in the clinical study improved the patients' interest and involvement in their overall healthcare, an astounding 100% of the patients said yes. This equates to a 5% increase from the initial survey conducted six months prior. In addition, when asked how adding clinical research has impacted the overall quality of care compared to current care received, 95% of study patients responded that their overall quality of care was significantly or somewhat better. Finally, 100% of the surveyed patients responded that participating in clinical research reduced the overall cost of their healthcare.

Figure 3: Benefits of clinical trial participation



Reduced cost of care

agree that participating in clinical research has **reduced their overall cost** of healthcare

Improved patient engagement

agree that participating in clinical research has **improved their interest/ involvement** in their overall healthcare

Improved quality of care

agree that adding clinical research has **significantly or somewhat improved their overall quality of care**



Patient commentary

“They even include my spouse into the meetings and care plans.”

“What it’s done is it’s made me much more regimented. I was never near as regimented. It keeps me engaged. Numbers have never been better. Great experience. Financial benefits were one of the reasons I joined the study, but even if I was paying, it would be worthwhile to me.”

“Clinical research participation definitely makes me more aware.”

Discussion

The high levels of patient satisfaction are likely related to the meaningful experience with the research study team coupled with the team’s skill set and access. This supports a need for increased collaboration among healthcare stakeholders to better communicate the value of clinical research as a care option and further enhance the trust placed in clinical research by the public and the health care sector. This would align with the mission of new healthcare delivery models such as accountable-care organizations (ACOs), which challenge physicians and healthcare systems to work together to coordinate and improve patient care, and to reduce costs and inefficiencies. Thus, there is a need for greater integration of clinical research as a care option.

Additionally, large quantities of clinical research study data that could be transformed by healthcare systems into actionable information used to analyze and improve population health are ignored – with the potential to leverage clinical research data not being fully realized. For example, an estimated total of 929,203 data points are collected in a typical Phase III study.¹³

Further, the lack of integrating clinical research as a care option into healthcare systems results in patients that are not informed of clinical research from their physicians unless their physicians are directly engaged in clinical research.

From a biopharma industry perspective a collaborative and integrated approach to clinical research touches on four areas of particular importance to the industry:

- Population health improvement: A common goal for all healthcare stakeholders.
- Patient advocates for research: With positive experiences patients become advocates for clinical research, leading to greater acceptance and participation.
- Trial effectiveness: With the right engagement and strongly managed processes, trials become more effective.
- Trial efficiency and cost management: A collaborative approach to clinical trials can greatly improve the efficiency and speed of a trial while reducing costs.

This approach leads to improved patient experiences, based on high levels of engagement by all stakeholders, including physicians and organizations. Optimized support for patients and physicians, coupled with high quality, standardized processes, allows the right physician to connect the right patient to the right trial. This improved patient matching reduces the frequency of screen failures, improves retention rates and enables positive patient experiences.

Conclusions

The survey results described above suggest that through participation in clinical research, patients are more engaged in managing personal health, and also suggest that an integrated approach to clinical research may lead to a decrease in the total cost of care, improve population health and increase patient satisfaction.¹⁴

Collaboration among all stakeholders – patients, health care providers, health care systems, drug developers and policy makers – must be increased to better communicate the value of integrating clinical research into the overall continuum of care, and to further enhance public trust in and patient engagement with clinical research.

Looking ahead, further research is needed to quantify the influence of integrated clinical research on patient satisfaction, population health and cost. Data from patients across several therapeutic categories at several value-based health care systems could generate further evidence supporting meaningful integration of clinical research as a care option.



Patient commentary

“It’s really good that they are connected with my doctor. Without that I would have never have known about the study.”

Appendix 1: Survey Instrument

1. Using a scale of 5 to 1, five being Excellent and one being Poor, how would you rate the friendliness and helpfulness of your study team?
2. Using the same scale of 5 to 1, how would you rate the comfort of the waiting area?
3. With five being Excellent and one being Poor how would you rate how long you had to wait in the waiting area?
4. With five being Excellent and one being Poor how would you rate how long you had to wait in the exam room?
5. Again, five being Excellent and one being Poor how would you rate the personal manner of your study team?
6. With five being Excellent and one being Poor, how would you rate the skills of the study team?
7. Again, using the same 5 point scale, what is the likelihood/chance you would recommend your study team to family or friends?
8. With five being Excellent and one being Poor how would you rate getting an appointment as soon as you wanted?
9. With five being Excellent and one being Poor when you call the study team, how would you rate getting the help or advice you need?
10. This question uses a slightly different scale. Thinking about your total experience with clinical research, would you say that you are: completely satisfied, very satisfied, somewhat satisfied, somewhat dissatisfied, or very dissatisfied?
- 11a. Has participating in clinical research improved your interest/involvement in your overall healthcare? 1. Yes, 2. No
- 11b. When thinking about your previous healthcare service experience alone, how has adding clinical research impacted the overall quality of care that you now receive? Is it: 5 – Significantly better, 4 – Somewhat better, 3 – About the same, 2 – Somewhat worse, 1 – Significantly worse, A – Don't Know
- 11c. Has participating in clinical research provided you with additional perks or advantages that you would not have expected from the study? 1. Yes, 2. No. Explain if necessary (free text).
- 11d. Has participating in clinical research reduced your overall cost of healthcare? 1. Yes, 2. About the Same, 3. No

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About the authors



Allen Buechler, MBA, CPA
Strategy and Operations, Eli Lilly & Co.

Allen Buechler has more than 21 years of financial management experience in the pharma and medical diagnostic industries. The past 17 years with Eli Lilly & Co. holding various roles of increasing responsibility across Research & Development. During this period, he led the financial management of the Oncology business unit and was integral in the valuation and management of the portfolio. In the most recent five years, he served as the Financial Director for the Medicines Development Unit managing the financial aspects of clinical development including clinical operations, product development, data management, biostatistics, regulatory, safety and clinical innovation. During this period, he played an integral role in implementing functional partnerships with external CRO's across Lilly's clinical development organization. In 2015, he was named to lead the strategy development, operations and six sigma efforts for Lilly Oncology. Allen holds a Masters of Business Administration from Butler University with a bachelor degree in Accounting from Indiana University and is a Certified Public Accountant.



Jennifer Byrne
CEO, PMG Research, Inc.

Jennifer Byrne is Chief Executive Officer of PMG Research, Inc. (PMG) and serves on its Board of Directors. In this role, Jennifer is responsible for driving the company's growth as a leader of one of the largest wholly owned and operated Integrated Site Networks in the U.S. PMG Research delivers a standardized clinical research infrastructure to large physician practices and mid-market organized systems of care with a commitment to deliver improved care, decreased costs, and improved patient satisfaction through clinical trial participation as a care option. Jennifer spends much of her time with health care providers learning more about the challenges they face in connecting the right patients to the right trials. This understanding leads to better solutions for both the health care system and the Pharma and CRO clients of PMG. Jennifer has concentrated her career in the clinical research site sector for over 25 years. During her long-term tenure at PMG she and her team have completed over 7,200 Phase I-IV clinical trials which have included over 100,000 research volunteers. Jennifer was recognized as a CenterWatch Top 25 Innovator and currently serves as an Advisory Board member to CISCRP and the Wake Forest Institute of Regenerative Medicine, and Board member of the Hospice Foundation and The Greater Gift Initiative. Jennifer earned her bachelor of science in Nutrition at Texas A&M University.

About the authors



Jeanne Hecht, MBA, PMP

Senior Vice President, Site & Patient Networks, Quintiles

Jeanne Hecht is Senior Vice President and Global Head of Site and Patient Networks at Quintiles, a position she was appointed to in October 2014. In this role, Jeanne is responsible for leading, implementing, and driving a site and patient network-centric global strategy that leverages leading-edge technology. In addition, she is responsible for leading a team that builds outpatient recruitment implementation models, personalized medicine and disease specific networks, clinical partnering strategies and fit-for-purpose partnering models. Prior to assuming this role, Jeanne was the Senior Vice President and Global Head of Sales at Quintiles. During her career with Quintiles, Jeanne has served in many roles across a number of disciplines and honed her international experience by residing in Singapore for almost two years to lead Quintiles' Asia Sales and Strategic Planning team. In this role, Jeanne was instrumental in the development and acceleration of growth within the domestic markets. Before moving to Asia, Jeanne served as Vice President, Strategic Accounts for Quintiles. Jeanne has more than 20 years of experience in the healthcare industry and is also a certified Project Management Professional (PMP). Earlier in her career, Jeanne was a founding member of a company utilizing biomarkers for companion diagnostic purposes. The product was designed, branded and launched under her leadership as Vice President of Marketing and Sales. Jeanne earned her Master of Business Administration and bachelor's degree in biology from the University of Michigan.

About the authors



Jeff James
CEO, Wilmington Health

Jeff James is currently the CEO of Wilmington Health in Wilmington, NC. Wilmington Health is a multispecialty clinic with 161 providers covering 37 specialties in 22 locations. He is responsible for the strategic vision and its deployment as well as all financial and operational aspects of the practice. Under his leadership, Wilmington Health was named an honoree for the prestigious Acclaim Award, by the American Medical Group Foundation in 2013. Jeff is a frequent national speaker on a diverse range of subjects including: Lean/Process Improvement in Healthcare, Cultural Transformation, Aligning Incentives, Physician Leadership and Healthcare Finance. He is a physician advocate and healthcare executive with over 20 years of strategic and operational experiences. He has lead or facilitated several physician organizations in their individual pursuits of continuous improvement, quality, and financial strength. His professional areas of interest include: Healthcare finance/economics, strategic planning and implementation, delivery system redesign, vertical and horizontal collaboration/integration, transparency. He is responsible for the development of multiple Accountable Care Organizations (ACO) and is currently the CEO of "Physician Healthcare Collaborative (PHC)". In 2014, PHC was ranked 7th in the country in reported quality among the other approximately 220 Medicare ACO's and 4th in cost among all ACO's that started in 2013. He has participated as an active Board Member on several community and healthcare related organizations including: American Medical Group Association, Coastal Connect Health Information Exchange, the Economic Development Corporation, Wilmington Chamber of Commerce and the North Carolina State Medical Society's ACO Steering Committee. Jeff holds a Master of Business Administration Degree and is a Certified Public Accountant.

About the authors



Bradley Pancratz
Director, The Advisory Board Company –
Consulting & Management-PEP

Bradley Pancratz brings more than 15 years of experience to his role with The Advisory Board Company – Consulting & Management survey division. His areas of expertise include survey consulting, client services and teleservices communication – with proven success helping large multispecialty groups focus on patient and provider experience to enhance clinical, operational, and financial outcomes.



Jane Shen, PharmD
Senior Director of Innovation, PMG Research, Inc.

Jane Shen is responsible for the development of corporate strategic alliances and partnerships as well as strategic innovations. Dr. Shen collaborates with PMG Leadership team to lead efforts in the development of innovative initiatives and utilization of technology platform to transform clinical research execution. During a career spanning more than 17 years as a clinical researcher and clinical trialist, she has held positions of responsibility involving clinical program design, strategic planning, corporate operations, pharmaceutical business activities, and mitigation of operational & development risks. Prior to joining PMG Research, she served as Clinical Trial Leader at Novartis Pharmaceuticals Corporation and as Senior Vice President of Clinical Operations at TransTech Pharma. Dr. Shen earned her Pharm.D. at the University of Southern California. Dr. Shen completed her post-doctoral research fellowship with Rutgers University, New Jersey. During her post-doctoral fellowship, she completed her clinical training at the National Cancer Institute, NIH.



Contact us

Direct: +1 336 608 3500

Website: www.pmg-research.com

Email: info@pmg-research.com