Woodcock Outlines Changes Needed to Connect Clinical Research and Healthcare

By Suz Redfearn

The clinical research enterprise is “at best the sickest link” in the chain between patients, the healthcare system, and science that can and should bring cures and better therapies, according to Janet Woodcock, director of the FDA’s Center for Drug Evaluation and Research (CDER).

“We have a sicker population, we have expensive new interventions and we have wonderful new science that is begging to get translated and evaluated,” said Woodcock in her keynote address at the recent Bridging Clinical Research and Clinical Health Care conference. “All these forces are coming together and converging on the clinical research enterprise. We must bridge clinical research and healthcare, or the entire enterprise is going to fall down.”

To illustrate how little research is getting translated into new directives for healthcare providers, Woodcock explained that only about 15 percent of professional guidelines for healthcare providers in the U.S. are based on evidence from evaluation of trials or actual data; the rest are based on expert opinion. Innovations abound, she said, but we still lack the means to evaluate their impact, and that is a shortcoming of the clinical research space.

“We keep trying things and changing things, but we aren’t ever really sure whether we’ve gone in the right direction or...”

see Woodcock on page 4 »

Industry Approaching Inflection Point in Consolidation Towards Large Health Systems

By Conor Hale

The clinical research business is approaching an inflection point similar to the shifts seen over the past 25 to 30 years, only now the trends are toward consolidation in larger health systems and their affiliates that can take a more patient-centric approach, according to Ken Getz, director of sponsored research programs at the Tufts University Center for the Study of Drug Development.

“So many of the conditions that existed 25 years ago are analogous to where we are now,” Getz said last week at the Bridging Clinical Research and Clinical Health Care conference in National Harbor, Md.

Historically, academia and clinical practices viewed participation in research as a hobby, or as a way to get closer to the cutting edge of medicine. Today it’s seen as a mission-critical source of revenue, driven in large part by patient demand for new treatment options, he said.

Industry moved away from academia because it is overly bureaucratic, with high fixed costs, and lacking the speed and efficiency being developed in the community-based investigator and contract research settings.

Now, the trend is toward health systems that are making strategic investments in clinical research infrastructure, looking to expand their service areas and gain a competitive advantage amid intense revenue...”

see Inflection Point on page 5 »
FDA Outlines Considerations for Enrolling Pregnant Women in Clinical Trials

The FDA published a new draft guidance on the scientific and ethical considerations for including pregnant women in clinical trials, telling sponsors that data are needed to inform safe and effective treatment during pregnancy, and that it is appropriate to enroll pregnant women in certain situations. The agency said it considers it ethically justifiable to include pregnant women in clinical trials when adequate nonclinical studies have been completed, and when the trial holds the prospect of direct benefit to the women and/or the fetus that cannot be obtained by any other means. In the postmarket setting, an established safety database in nonpregnant women should be available, and inclusion should be allowed when efficacy cannot be extrapolated or safety cannot be assessed through other study methods.

For women that become pregnant during the course of a clinical trial, unblinding should occur so that counseling may be offered based on whether the fetus was exposed to the investigational drug, placebo or control, the FDA said. The risks and benefits of continuing can also be reviewed; those who choose to continue should undergo a second informed consent process. Sponsors should also gather reproductive and developmental toxicology data in nonclinical models, and consider the gestational timing of exposure. “Historically, pregnant women have been an understudied population, and there have been barriers to obtaining data from pregnant women in clinical trials, including concerns about protecting women and their fetuses from research-related risks,” the FDA said. Currently, collection of safety data on drugs used during pregnancy is largely gathered after approval. The agency said it hopes the draft guidance will advance scientific research in pregnant women, within the framework of human subject protection regulations, and serve as a focus for discussion among sponsors, manufacturers, institutional review boards and the academic community. The draft guidance is available here: www.fdanews.com/04-06-18-PregnantWomen-Guidance.pdf.

Gottlieb Outlines Plan for Incorporating Patient Experience Data in Regulatory Decisions

FDA Commissioner Scott Gottlieb announced a formal initiative for incorporating patient perspectives into the agency’s risk-benefit analysis framework used in regulatory decision-making. The proposal, outlining steps under PDUFA VI from fiscal 2018 to 2022, includes new guidance by June 2020 articulating how patient experience data gathered by sponsors can be used to support approvals.

“The FDA recognizes a need to learn about the clinical context more comprehensively and directly from the perspective of the patients who live with the disease and their caregivers,” Gottlieb said, including information on the severity of the disease, patient-centered endpoints and the degree of unmet medical need. The agency is planning several efforts to systematically incorporate patient experiences into the framework — such as hosting patient-focused drug development public meetings; encouraging external, stakeholder-led meetings; and providing more channels for patients, caregivers and advocates to provide meaningful input into drug development and regulatory decision-making. In addition, the agency plans to build a repository of risk-benefit frame-work examples to serve as references for its reviewers. “Industry stakeholders have indicated that having a clear understanding of FDA’s thinking can help inform a sponsor’s internal decision-making about their drug development programs, particularly early in the product development,” the agency said. The FDA’s proposed plan is available here: https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM602885.pdf.

Project Data Sphere Names GSK Alum Bill Louv as President

Bill Louv, former VP at GlaxoSmithKline, was named president of Project Data Sphere, an independent, not-for-profit cancer data sharing initiative of the CEO Roundtable on Cancer’s Life Sciences Consortium. Project Data Sphere, launched in 2014, is a free digital library and cancer research platform, warehousing patient-level data from cancer clinical trials linked to more than 120,000 participants. More than 1,700 registered users download the data for research use in tumor types such as bladder, breast, colorectal, gastric, kidney, lung, melanoma, pancreatic and prostate. Louv served as senior VP of core business services at GSK from 2010 to 2015, and has over 30 years of experience in the pharmaceutical industry, working in statistics, epidemiology and information technology.

FDA Proposed Fiscal 2019 Spending Including Steps to Foster Drug Development

The FDA published its justification for the Trump administration’s fiscal 2019 budget, which includes new guidance by June 2020 articulating how patient experience data gathered by sponsors can be used to support approvals. The proposal, outlining steps under PDUFA VI from fiscal 2018 to 2022, includes new guidance by June 2020 articulating how patient experience data gathered by sponsors can be used to support approvals. The plan, which the agency considers it ethically justifiable to include pregnant women in clinical trials when adequate nonclinical studies have been completed, and when the trial holds the prospect of direct benefit to the women and/or the fetus that cannot be obtained by any other means. In the postmarket setting, an established safety database in nonpregnant women should be available, and inclusion should be allowed when efficacy cannot be extrapolated or safety cannot be assessed through other study methods.

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request, explaining what the agency would do with the funding, and listing its priorities to boost pharmaceutical research and development, among other regulatory initiatives. An increase of $400 million for medical product innovations would advance competition among drugmakers to lower drug development costs and foster innovation and investment in developing treatments for unmet medical needs, according to the FDA. The agency would also direct $58 million to promote domestic manufacturing with the goal of accelerating targeted therapies and enhancing the quality of products, as well as devote $21 million to modernize the FDA’s offices and laboratories nationwide. The administration unveiled its budget request in mid-February, calling for a 13 percent increase in budget authority for the FDA and $190 million in additional user fees, for a total budget of $5.8 billion. The 346-page FDA budget justification is available here: https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM603315.pdf.

FDA Holding Public Meeting on Inclusion, Exclusion Criteria

The FDA is hosting a public meeting April 16 in Washington, D.C., to evaluate inclusion and exclusion criteria in clinical trials, under a cooperative agreement with Duke University, with the goal of gathering information to assist in the development of formal agency guidance on the subject. The meeting was prescribed by the PDUFA reauthorization bill passed last year. “Certain eligibility criteria in clinical trials can exclude patient subgroups, resulting in the enrollment of study populations that may not be fully representative of that broader patient population,” the FDA said, stating continued efforts to encourage greater diversity in clinical trial populations, such as requirements that sponsors provide analyses of difference demographics and subgroups. Discussion topics will include: the risks and benefits of trial participation; potential regulatory, geographic and socioeconomic barriers; and the rationale for eligibility criteria, as well as the impact of exclusion criteria on the enrollment of infants, children, pregnant and lactating women, the elderly, individuals with advanced disease and individuals with comorbid conditions. In addition, the FDA would like to hear about alternative trial designs that may increase enrollment of more diverse patient populations, how changes to eligibility criteria may impact the complexity and length of clinical trials and opportunities for using data from expanded access trials.

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Woodcock (continued from page 1)

actually taken a step backward," Woodcock said. "For new pharmaceuticals, despite the billions of dollars spent developing them, we often lack important information when they come on the market about how they're going to perform in the real world. And we don't really have a good way of evaluating how they're performing in the real world."

The crux of the problem, she said, is that the goals sought by each sector of the healthcare and clinical research arenas have far more to do with other priorities — such as financial gain, tenure, business goals — than they do the kind of collaborative learning that will bring new cures.

"Currently I think almost all the incentives, financially or otherwise, in this whole vast healthcare ecosystem are aligned against collaborative learning," she said.

Woodcock listed the stakeholders that interact with patients and study subjects, explaining where they err.

For academic clinical researchers, she said, the focus is often primarily on tenure, obtaining grant support and productivity in the clinic. And insurers and payers, while they could benefit from increased knowledge from clinical research about what works best, do not focus on learning. "It's not their business," said Woodcock. "It's not how their incentives are aligned."

Healthcare providers, meantime, work in a fee-for-service environment that is antithetical to research, adding, though, that she expects large healthcare networks to eventually emerge as entry points for bridging research into healthcare more rapidly.

The medical product industry, she said, is now mired in increased research complexity coupled with an overarching desire to create new revenue streams, and these get in the way of maintaining a pure focus on learning and quickly sharing new information gleaned from research.

So NIH then? Well, no. NIH, said Woodcock, has spent the last 40 to 50 years building up the basic biomedical research enterprise, and now that must be sustained.

"The enterprise is like a hundred and fifty baby birds — it has to be fed," said Woodcock, mentioning laboratories, thousands of post docs, securing of grants and research centers all across the U.S. "I don't think you can look to NIH and say they are going to fund this enterprise and bring about these transformations. They have other incentives, other pressures on them," said Woodcock.

Given all these badly misaligned pressures on the industry's key stakeholders, Woodcock offered her thoughts on how to proceed in building "a nice, sturdy bridge instead of this very flimsy and teetering bridge."

1. Put the patient and the treating practitioner in the center of the efforts. "That's what this enterprise is supposed to be about: people who need treatment," said Woodcock.

She added that ignoring community physicians and not sharing study results with them is part of the problem, and must stop. "Their marginalization has lead to the fact that most people are not referred into clinical research in any way because their healthcare practitioners are marginalized from this enterprise and don't want anything to do with it," she said.

2. Information collection on patients in trials should be well integrated into their overall healthcare. "The clinical research from the trials are often in a different universe that doesn't hinge on real life, real doctor visits, real patient visits, or patient's lives," Woodcock said.

3. The data collected must be robust by design or intent, not by quality control, she said, adding that data produced only to satisfy quality control requirements alienates the whole enterprise from the actual flow of data. The best case scenario: a world in which we verify key elements in integrated fashion into the health record so that we can rely upon those elements, and in a way that no one needs to repeat input efforts, said Woodcock. But we're not there yet.

4. Currently, consent documents are long and unwieldy. Patients don't understand them. Most don't read them. Said Woodcock, we need to figure out how to do consent and randomization seamlessly within a digital environment so that potential subjects are not turned off to research right out of the gate. "It's a nut that will have to be cracked in order to do more efficient learning in healthcare," she said.

5. We need rapid knowledge terms, said Woodcock. She pointed to pilot programs, taking small steps, garnering quick feedback and quick confirmation on whether one is on the right path or not, then communicating that to all stakeholders.

Said Woodcock, "People are really eager for answers; They don't just want to wait ten years to hear: do this. But right now, what do we tell them? 'Here's what we found in this study but more research is needed.' How does that help a practitioner or patient? We need to say, 'This is what we know now, and if you participate, in one year we’ll know more and we can feed that back to you and to your doctors, and we will build on that so the knowledge we gained from you will count. It will make a difference.'"

If those in clinical research can do that, the rapid knowledge feedback loop will start sustaining itself, she said.
Inflection Point  (continued from page 1)

pressures and declining margins. In addition, many smaller and specialty practices are being absorbed and integrated into larger corporate structures.

When viewed alongside the constant need to recruit more patients from wider geographic areas, with catchment being automated through electronic medical records and other databases, it’s easy to see these factors pushing a convergence between research and care delivery within the clinic, he said.

“The infrastructure now, heavily supported by rich data and robust analytics, is the engine behind the patient-centric environment that puts the health care provider, as well as the larger health systems, at the core of this new shift and the opportunities that exist,” Getz said.

And with the increasing complexity of clinical trials and growing focus on rare diseases, it will become more difficult to find experienced physicians, as well as relevant patient populations, across a fragmented landscape. That will drive the need to better use data to pinpoint study resources, and leverage affiliate relationships with specialty providers.

In addition, there are currently about 35,000 unique investigators working on at least one clinical trial, according to the FDA, with most only conducting a single study, with high churn rates.

This fragmentation brings its own problems — with many of the solutions being siloed themselves. Fixes are usually tailored to specific, individual issues as companies try to close out studies as quickly as possible, and

“A high percentage of physicians tell us that they do refer patients — but the number they refer, as a percentage of the total number they see in a given year, is remarkably low.”

—Ken Getz, director of sponsored research programs at the Tufts CSDD

the advancements aren’t spread through the industry.

Meanwhile, the vast majority of clinical trials are led by smaller companies outside the top 50 pharmaceutical and biotech giants. And, because many may not have experience managing clinical trials on their own, more are engaging CROs for support. These companies have shown to be more willing to innovate and challenge the traditional practices implemented at the larger, more established pharma companies, Getz said.

“There’s some important news there,” he added. “This may become a valuable driver for us as we look to move more research into the larger health system and healthcare setting.”

Patients are also pushing for clinical care and clinical research to be seamlessly integrated.

“We continue to gather a lot of data that not only underscores the tremendous trust patients place in their healthcare provider, but their desire to first learn about a clinical trial as part of their routine care,” Getz said.

And contrary to popular belief, providers are generally comfortable talking about clinical research with their patients, he added. Many are familiar with it from professional society meetings, or through their own medical or nursing training. However, the challenges lie in referrals.

“A high percentage of physicians tell us that they do refer patients — but the number they refer, as a percentage of the total number they see in a given year, is remarkably low,” he said. Physicians often don’t know where to find the information to help them make a referral with confidence, and don’t have the time to fully process that information once they have it.

To bridge the gap, industry should take new approaches to informing physicians of their options, said Craig Lipset, head of clinical innovation at Pfizer.

“Over half of physicians are in a health system,” Lipset said. “And we still engage them as solo practitioners.”

Companies should look for existing principal investigators in already planned studies that are part of health systems, which may offer connections to thousands of researchers under a single medical group, he said. And leveraging their health IT infrastructure can assist in patient identification or even electronically sourcing data in parallel with the study.

“How many times do you see where patients exist with no way to reach them?” he asked, adding that health systems already have permission to reach out to those patients. “You don’t have to wait for a bridge to get built.”

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Three Questions

Sue Vestri, Greenphire

CWWeekly presents this feature as a spotlight on issues faced by executives in clinical research. This week we hear from Sue Vestri, CFO of Greenphire.

Q How has the finance team’s role evolved over the years and why is it important to ensure that the finance team plays an integrated role in the clinical trial process?

A Regardless of industry, the role of the finance department continues to evolve into a dynamic cross-functional component of the organization. Where it was once seen as the “bean counters” in the back office, the finance team is now a critical resource for data, insights, and performance metrics. The finance team of today, and that of the future, will be required to be more analytical and strategic than ever before.

Within the clinical research industry, the finance team is a key partner to the Operations team, particularly around investigator grant payments. The finance team is expected to be responsive and the source of real-time information around the status of payments and invoices. The team’s ability to execute payments in a timely manner is essential to support site performance and satisfaction.

Additionally, high-performing finance teams need to be more involved with trial timelines to accurately and effectively support budgeting and forecasting for the business. As the clinical trial industry continues to automate various processes, it is important that the finance team be involved in these decisions so that the outputs continue to support their function and the systems deliver the ROI needed for optimization value. Automating one manual process may deliver an advantage for one team but create a host of inefficiencies for another. Implementing a solution that is proven to enhance end-to-end workflows is key.

Q What impact does the finance team have on trial timelines and performance?

A Strong, trusting, collaborative partnerships are the cornerstone to success in any business, and clinical research is no exception. Studies continue to show that delayed, inaccurate site payments have numerous negative impacts on a site’s performance and ability to deliver quality data. When a finance team can support monthly payments to their investigator sites with full visibility into the details and status of the payment, this burden is completely removed, and site performance is positively impacted.

The finance team can optimize site payment processes by collaborating with clinical operations teams to identify the points of manual efforts that can be eliminated and optimized. More and more finance teams at both CROs and Sponsors are identifying the areas of invoicing, site inquiries, reconciliation and reporting as critical resource drains that are prime for optimization and automation.

Q What role does process automation have in improving the workforce and how can you determine which processes should be automated?

A Optimizing the finance role starts with understanding and constantly examining areas that can be automated or outsourced. Manual, error-prone processes that limit an employee’s growth and ability to be more strategic and analytical are the ideal processes to automate. It is critical to look at automation, rather than outsourcing opportunities, as the level of data that can be derived from the software available today is substantial. When processes are automated, speed improves, and finance teams become more empowered and reliable to their clinical operations teams.

If processes are simply outsourced without an automated advantage, there may be short-term efficiencies gained, but the long-term cost is not scalable and quality issues will likely arise. Partnering with best-in-class providers that are committed to quality with a scalable solution designed to meet the evolving needs of clinical research will deliver both short-term efficiencies and long-term strategic business advantages across finance and clinical operations.

Sue Vestri, CFO, Greenphire

“It is critical to look at automation, rather than outsourcing opportunities, as the level of data that can be derived from the software available today is substantial.”

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<td>Amgen</td>
<td>Blincyto (blinatumomab)</td>
<td>B-cell precursor acute lymphoblastic leukemia (ALL)</td>
<td>FDA approval granted</td>
<td>amgen.com</td>
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</table>
Allergan and Richter Announce Positive Topline Results for Bipolar I Depression Trial

Allergan and Gideon Richter announced positive topline results for RGH-MD-53, a Phase III study of cariprazine for the treatment of adults with major depressive episodes associated with bipolar I disorder (bipolar I depression). RGH-MD-53 and RGH-MD-54 were identical Phase III, randomized, double-blind, placebo-controlled, parallel-group, multicenter, fixed-dose clinical trials in adult patients with bipolar I depression. A total of 584 patients were randomized to evaluate the efficacy, safety and tolerability of cariprazine 0.75 mg, 1.5 mg and 3 mg compared to placebo in the treatment of outpatients with bipolar I depression. Patients underwent a no-drug screening period of approximately 7-14 days, followed by 8 weeks of double-blind treatment and a one-week, no-investigational product safety follow-up period. Cariprazine was generally well tolerated in the trial. The overall incidence of patients who experienced adverse events was 51 percent for the cariprazine 1.5 and 3 mg dose groups, and 46 percent for the placebo group. The majority of adverse events were mild to moderate and led to discontinuation in approximately 5 percent of cariprazine-treated patients versus three percent of placebo-treated patients.

Synlogic Doses First Patient in Phase Ib/Ila Trial

Synlogic announced that the first patient was dosed in its Phase Ib/Ila clinical trial of SYNB1020. This randomized, double-blind, placebo-controlled study is designed to evaluate the safety and tolerability of SYNB1020, as well as its ability to lower blood-ammonia levels in patients with cirrhosis and elevated blood ammonia. This Phase Ib/Ila study had two parts. In Part I of the trial, an initial sentinel open-label cohort of subjects with cirrhosis and a Model for End-Stage Liver Disease (MELD) score <12 received orally administered SYNB1020 (5 x 1011 CFU TID) for six days. Part 2 of the trial comprised a randomized, double-blinded, placebo-controlled study in patients with cirrhosis and hyperammonemia. Eligible subjects were admitted to an inpatient facility for a run-in diet and 24-hour ammonia profile, and those with an elevated ammonia level proceeded with randomization and received either placebo or orally administered SYNB1020 (5 x 1011 CFU TID) for six days.

Lilly Announced CYRAMZA Met Overall Survival Endpoint

Eli Lilly announced top-line results from its Phase III REACH-2 study of CYRAMZA® (ramucirumab) as a single agent in the second-line treatment of people with hepatocellular carcinoma (HCC), also known as liver cancer. The trial met its primary endpoint of overall survival (OS) as well as the secondary endpoint of progression-free survival (PFS). REACH-2 is a global, randomized, double-blind, placebo-controlled Phase III study of CYRAMZA and best supportive care (BSC) compared to placebo and BSC in hepatocellular carcinoma (HCC) patients who were intolerant to, or that had disease progression while on or following treatment with sorafenib and had a high alpha-fetoprotein (AFP-High), defined as an AFP of ≥ 400 ng/mL. REACH-2 is the first positive Phase III HCC trial in a biomarker-selected patient population. The REACH-2 study has confirmed the hypothesis generated by the REACH trial results, which showed that a pre-specified subgroup of advanced HCC patients who were AFP-High derived a survival benefit from treatment with CYRAMZA following first-line treatment with sorafenib.

Wize Pharma Enrolls First Patient in Study for Treatment of Dry Eye Syndrome

Wize Pharma announced that it enrolled the first patient in its Phase IV clinical trial in Israel for LO2A in the symptomatic treatment of dry eye syndrome (DES) in patients with Sjögren’s syndrome. This randomized, double-masked study will evaluate LO2A versus Alcon’s Systane Ultra UD, an over-the-counter lubricant eye drop product used to relieve dry and irritated eyes. Approximately 60 patients with Sjögren’s syndrome who are experiencing DES are being randomized in a 1:1 ratio to one of two treatment groups, LO2A or Systane® Ultra UD. Drops will be administered topically to the eye over a three month period. The primary endpoint of the study is the change in corneal/conjunctival staining score using the National Eye Institute (NEI) Industry Grading System after 3 months of study treatment. Secondary endpoints include corneal/conjunctival staining score after one month of treatment and change in Ocular Surface Disease Index (OSDI) score after one and three months of treatment.

Medical Device SOP

SOP for Good Clinical Practice by Sponsors of Medical Device Clinical Trials reflects best practices, and addresses FDA Guidance and device regulations to minimize regulatory exposure and comply with industry standards.
## Research Center Spotlight

Research Center Spotlight is a monthly selection of clinical research centers who have Research Center Profile pages posted on CenterWatch.com. Included in their annual subscriptions, company profiles are randomly selected to appear in this section, providing added exposure for their expertise and services in conducting and managing clinical studies.

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### Advanced Medical Concepts PSC

Cidra, Puerto Rico  
(787) 739-3376  
research@clinicalzone.com

Advanced Medical Concepts PSC is a medical center, in practice for over 25 years, dedicated to direct outpatient care and clinical trials. We also administer an alliance of centers that also perform direct outpatient care as well as clinical trials.

### ALAS Science Clinical Research

Las Vegas, NV  
(702) 951-1375  
info@alasscience.com

Alas Science Clinical Research, conducts clinical trials in diabetes and other health-related conditions (Cardiovascular, metabolic disorders, neuropathies, obesity and medical devices). The organization has been conducting clinical trials since September 2004.

### AMAC Research Institute

North Dartmouth, MA  
(508) 717-8205  
seifler@amactrials.com

AMAC Research Institute is a dedicated research site that provides state-of-the-art facilities including a sleep lab, which offers inpatient capabilities.

### Aventiv Research

Columbus, OH  
(614) 501-6164  
mrood@aventivresearch.com

Aventiv Research, formerly Columbus Clinical Research, was founded by Dr. Samir Arora, a proven leader with more than 13 years of clinical research experience. They are an independent, multi-therapeutic outpatient clinical research center with three locations specializing in Phase I-IV clinical trials.

### Beacon Clinical Research

Quincy, MA  
(774) 462-6610  
raymond@beaconclinical.com

Beacon Clinical Research (BCR) is a full-time independent clinical research facility. BCR is a multi-specialty site specializing in Phase II-IV clinical trials. BCR was started in 2000 and has conducted over 500 studies to date for a wide range of clients.

### Einstein Clinical

Phillipsburg, NJ  
(704) 315-1796  
mmoran@einsteinclinicaltrials.com

Einstein Clinical is a stand-alone, fully equipped research center. This location provides a diverse patient population and is located within a heavily populated medical community of many sub-specialties with a concentration on Neurological and Psychological disorders.

### Florida Premier Research Institute

Winter Park, FL  
(407) 740-8078  
garcia@fpcresearch.com

Florida Premier Research Institute, LLC, and Florida Pulmonary Research Institute, LLC, are state-of-the-art, multi-speciality facilities conducting Phase I-IV pharmaceutical research.

### FXM Research Miramar / Francisco Flores, M.D.

Miramar, FL  
(954) 430-1097  
info@fxmresearch.com

FXM Research is a privately owned and operated Clinical Research Site that conducts Phase II, III and IV clinical research trials specializing in Dermatology and Aesthetics/Cosmetics.

### Grossmont Center for Clinical Research

La Mesa, CA  
(619) 589-4100  
info.gccr@gmail.com

Grossmont Center for Clinical Research is a dedicated research facility specializing in women’s healthcare.

### Insearch

Tampa, FL  
(727) 544-4842  
vnapoli@insearchgroup.net

Insearch is a clinical business development company that offers personalized service, at no charge, to Pharma and CROs looking for appropriate PIs/sites for their trials. Insearch represents only the highest quality Principal Investigators and Clinical Research Organizations.