Clinical Trial Patient Inclusion and Exclusion Criteria Need an Overhaul, Say Experts

By Suz Redfearn

Clinical trial patient inclusion and exclusion criteria are far too rigid, often based on outdated notions, and the whole subject needs to be reimagined to include a more representative sample of the population.

That was the consensus at a public workshop sponsored by the FDA and Duke University last week that evaluated inclusion and exclusion criteria.

The inclusion of individuals who have what has been traditionally seen as confounding conditions makes research harder to do, but the result is study outcomes that more accurately reflect the population, said many who spoke at the meeting.

By James Miessler

HHS issued a proposed rule that would delay its revisions to the Common Rule for another six months and opened up discussion on the permitting of three burden-reducing provisions in the 2018 requirements for regulated entities.

The proposed rule, issued Friday, pushed back the revision implementation date, from July 19, 2018, to Jan. 21, 2019.

The burden-reducing provisions up for discussion center on the 2018 requirements’ definition of “research,” which deems certain activities not to be research, the elimination of annual continuing review of certain categories of research, and the elimination of the requirement that institutional review boards review grant applications related to the research.

Another common thread: More inclusive studies also assure populations typically excluded from studies that the drugs that get approved are safe for them specifically because they were represented in the trials.

Up to 59 percent of the U.S. population is made of groups who are usually not included in clinical trials, said Catherine Spong, deputy director of the National Institute for Child Health and Human Development (NICHD) at the meeting.

The groups most often excluded? Children, the elderly, pregnant women, lactating women, people with chronic diseases, people with intellectual or physical disabilities, people with mental health diagnoses.

HHS Proposes Common Rule Delay and Asks for Comment on Burden Reduction Provisions

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FDA to Launch Pilot Program on Model-Informed Drug Development

The FDA announced a new pilot program in which drug sponsors can meet with agency officials to discuss strategies for model-informed drug development (MIDD) to make their clinical trials more efficient and increase the chances of regulatory approval. Under the pilot, each applicant whose proposal is approved will receive two meetings with the relevant agency center to discuss approaches to applying MIDD, which uses quantitative analysis to assess the risk-benefit profile of in-development drug products. “The goal of the early meeting discussions granted under this pilot program is to provide advice on how specific, proposed MIDD approaches can be used in a specific drug development,” the FDA said. The agency plans to accept two to four meeting requests per fiscal quarter from the fourth quarter of 2018 to the fourth quarter of 2022. Because of the limited number of meeting slots, the agency will prioritize requests that focus on dose selection/estimation, clinical trial simulation and predictive or mechanistic safety evaluation.

Applicants should be drug or biologic manufacturers with a relevant IND or pre-IND number. The meeting requests should include the product name, application number, chemical name/structure and proposed indications or context of product development. Applicants should also include a brief overview of the purpose and objectives of the potential meeting, proposed MIDD approaches for the product and a list of issues for discussion with the agency. The submission package should also address drug development issues such as dosing, safety predictions or clinical trial design and the proposed MIDD approach. The pilot will be administered jointly by CDER’s Office of Clinical Pharmacology and CBER’s Office of Biostatistics and Epidemiology. Read the Federal Register notice here: www.fdanews.com/04-16-18-Pilot.pdf.

Oracle Launches New Platform for Collection of Electronic Patient Data for Clinical Trial Use

Oracle Health Sciences launched a new service that will allow researchers to collect electronic patient data for use in clinical trials. The new service links existing clinical systems to patient engagement sources, with the goal of helping therapeutic teams access patient data on areas such as medication dosing habits during clinical trials. Oracle will collaborate with companies including MC10, CM and Validic on the service, called the mHealth Connector Cloud Service. The company is also exploring integration efforts with solution integrators and developers such as Accenture and POSSIBLE Mobile. “Being able to take what used to be patient-recorded data and outcomes via paper forms and site visits can now be done via mobile health sensors and wearables that have the potential to shorten trial times and reduce costs, while allowing sick patients to remain in the comfort of their homes versus traveling to and from trial sites,” said Oracle Health Science General Manager Steve Rosenberg. “To improve patient enrollment in clinical trials, study teams must put the patient at the center of everything they do, and emerging technologies such as wearables and sensors hold the key.”

Six Health Systems Establish Consortium to Expand Clinical Trial Access in NJ and PA

Six regional health systems announced the creation of a nonprofit clinical research consortium – Partners in Innovation, Education and Research (PIER Consortium) – a regional clinical trial system that will span New Jersey and Pennsylvania. The consortium comprising Atlantic Health System, Drexel University, Einstein Healthcare Network, Geisinger including AtlanticCare, Main Line Health and Thomas Jefferson University was formed to expand clinical trial access to larger numbers of patients and bring new treatments to market faster. The consortium believes “having contracts in place and physicians identified” could allow trials to begin and reach participation capacity sooner and notes that 80 percent of clinical trials do not finish on time. “The expertise shared across sites through PIER will allow clinical researchers to enroll patients in trials more quickly, and streamline the clinical trial process across institutions,” it said.

Vivli Beta Tests Clinical Trial Data Sharing Platform

Moves to increase clinical trial data transparency gathered momentum this week with the release by Vivli of the beta version of its clinical trial data-sharing platform to the public prior to its full rollout on July 19. The Vivli platform offers clinical researchers a way to store, request and analyze anonymized, secure clinical trial data with built-in privacy protections. Vivli promises to “host data for stakeholders that do not have the ability to do so, enable interoperability of data from multiple sources, coordinate and integrate existing data-sharing initiatives.” Johnson & Johnson is one of the companies feeding data into the new Vivli platform. “We hope that new
platforms, such as that being created by Vivi, will lead to a broadening of engagement by other stakeholders in the R&D ecosystem,” said J&J’s Chief Medical Officer Joanne Waldstreicher. “We believe that the goal of data sharing — advancing science and medicine for the benefit of patients — will only fully be realized when all stakeholders who generate clinical data participate,” Waldstreicher said. Other groups are also tracking progress. Clinical trial transparency advocacy group AllTrials uses its TrialsTracker tool to monitor clinical trials that missed the transparency deadline. In the first two days of the FDA requirement going into effect, the tool identified 12 out of 117 trials that failed to show results. Since February, the FDA has required the sharing of clinical trial results on ClinicalTrials.gov, with possible fines of more than $10,000 daily for sponsors failing to publish the data.

Tufts Medical Center Joins TriNetX Health Research Network

Tufts Medical Center has joined the TriNetX health research network and will use the platform to help recruit eligible patients into clinical trials and to identify new ideas for trials. The cloud-based network gives biopharmaceutical companies and contract research organizations aggregate views of patient data allowing them to identify institutions such as Tufts as potential research partners. Clinical researchers at client institutions can offer their own patients opportunities to participate in clinical trials. Tufts Medical Center, the principal teaching hospital for the Tufts University School of Medicine, was selected in part for its history of scientific research and clinical advances, including research that led to the discovery of drugs that safeguard the body against rejecting transplanted organs. “We look forward to using TriNetX’s query and analytics capabilities to dig deeper into our clinical data both to recruit eligible patients into clinical trials and to generate new hypotheses for investigation,” said Will Harvey, Tufts Medical Director/Clinical Informatics and CTSI Director of Informatics Integration. “Additionally, we hope to attract more sponsored research studies that seek to take advantage of our unique patient populations.”

European Regulators Approve CRISPR Technology Trial for Beta Thalassemia for 2018

CRISPR Therapeutics has slated a European clinical trial of its gene-editing technology for a common blood disorder this year. Researchers aim to use the tool for patients with the inherited blood disorder beta thalassemia, which can cause bone deformities and anemia and affects thousands of children every year. Researchers will harvest stem cells from patients and engineer them with a goal of increasing levels of fetal hemoglobin, after which they will return the cells to the patients’ bodies. If the procedure is successful, beta thalassemia will be the first human disease treated with the gene-editing technology in Europe. Researchers have not yet established a specific location for the trials. “Certainly, 2018 promises to be the big year for clinical trials using CRISPR-based genome editing. Results presented by [CRISPR Therapeutics] at a hematology meeting showed that the method dramatically increased fetal hemoglobin in beta thalassemia patients’ cells,” geneticist Helen O’Neill of University College London told the Telegraph. “The therapy successfully edited over 90 percent of blood stem cells removed from patients, which were re-transfused.” The announcement comes after a January decision by the European Patent Office to revoke the main patent on CRISPR-Cas9 as filed by the Broad Institute of MIT and Harvard University, after it was found to have omitted the name of one of the inventors listed on previous applications. Chinese universities, meanwhile, have used CRISPR technologies on dozens of patients in clinical trials since 2015. The first U.S. CRISPR clinical trial began this year, sponsored by the University of Pennsylvania.
Clinical Trial  (continued from page 1)

and those in organ failure, said Spong and others at the meeting.

Explained Dawn Corbett, inclusion policy officer in the National Institutes of Health's Office of Extramural Research, NIH's research on exclusion shows that those who take part in research are younger and healthier than the population that will eventually have access to the drug being studied. They are also more heavily skewed toward Caucasians.

To move toward more inclusiveness, Corbett said, the research sector has to stop relying on "cut and paste exclusions" — just using the exclusion guidelines that have often been employed in the past instead of thinking through the exclusions that actually make sense for individual studies.

“We have exclusion criteria that are unjustified,” said Rebecca Dresser, medical ethicist and professor at Washington University in St. Louis, and author of the 2017 book Silent Partners: Human Subjects and Research Ethics. “They are bad when based on tradition or a narrow minded view.”

For example, children have historically been left out of trials due to research gone awry in the 1930s that resulted in more than 100 deaths. The 1938 Food, Drug, and Cosmetic Act has kept kids out of trials that may harm them.

But, now kids are excluded from trials that help determine whether medicines are safe for them, said Robert “Skip” Nelson, senior director for pediatric drug development at Johnson & Johnson. That leaves researchers having to extrapolate results from adults onto kids, which is an inexact science, to say the least. And it leaves kids taking medicines at doses that may not be right for them.

Seniors are usually left out of trials too, because of the oft-used cut-and-paste inclusion stand-by of “18 to 65,” said Mark Supiano, chief of the geriatrics division at the University of Utah School of Medicine. The irony there is that so many drug therapies are aimed at seniors and their functionality. To better target seniors, researchers have to be better about including them, he said.

“We can’t just extrapolate from the adult population of 40 year olds to 80 and 90 year olds,” Supiano said. “We need to have involvement early on in order to get these functional measures across. I encourage the early involvement of experts in geriatrics and gerontology in the design of trials across the lifespan.”

—Dawn Corbett, inclusion policy officer, the National Institutes of Health's Office of Extramural Research

The exclusion of patients with chronic diseases also makes little sense but it is common, said Anand Parekh, chief medical advisor at the Bipartisan Policy Center. Parekh said that approximately 66 percent of Medicare beneficiaries have two or more chronic conditions, and that 15 percent have six or more. And they are usually excluded from research, though this is the population that has shown it is quite willing to participate in research, according to a recent survey of 1,440 people, he said.

To be more inclusive, one could place participants into low-risk and high-risk groups and perform essentially two trials, one using a randomized controlled method and the other, a single-arm cohort trial, suggested Rajeshwari Sridhara, director of the biometrics division in the biostatistics office at the FDA’s Center for Drug Evaluation and Research.

Or, he said, researchers could consider performing a phase I study in the low-risk group only, and if all went well, marry high-risk and low-risk groups for the phase III study.

While those in the field consider new, more inclusive designs and approaches, those who watch the space say it’s going to take more of a large, cultural shift.

“We need to think through this and not just look for the easiest people to get into the study,” said the NIH’s Corbett. “We understand that this is going to take more effort, but while we make our trials easier, we’re limiting the external validity of them. This is really going to be a culture change for us. It’s going to take the entire scientific community.”

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“...Studies planning to recruit some subjects on or after Jan. 21, 2019 would have to meet the new requirements...”

—David Borasky, vice president of IRB compliance, WIRB-Copernicus Group

The informed consent of those subjects," it said. "In contrast, for studies whose remaining activities consist only of completing data analyses, the new requirements for informed consent generally would not be applicable.

The proposed rule also seeks comments about an alternative decision to delay the effective and general compliance date until Jan. 21, 2019, without the option of implementing the provisions.

There has been a degree of uncertainty about the implementation of the revised Common Rule ever since its release in January 2017. Days after the final rule was adopted, it was subject to a regulatory freeze imposed by the new Trump administration. Then in October, OMB posted a proposal for a one-year delay in the implementation date of the Common Rule revision while allowing the use of three unspecified burden-reducing provisions during the delay year. On January 4 of this year another proposed rule appeared suggesting implementation of the complete rule could be delayed.

Finally, the federal government pushed back its revisions to the Common Rule for an additional six months — making the announcement less than 36 hours before the changes were set to take effect Jan. 19 — and warned the public to expect additional delays down the line.

"If an IRB elects to start implementing these burden-reducing provisions to a study that is active right now, once the rest of the regulations go live in January 2019, you then have to comply with the rest of the new regulations," he noted.

He also noted that the applicability of the rule would be limited to federally funded research not regulated by the FDA. The FDA is not allowing the three burden-reducing provisions.

But, he noted that some IRBs could decide that the burden reducing provisions are worth it.

"If you have a continuing review requirement and it’s eligible for that burden reducing measure, that’s great until next January, when you’d be required to apply every other aspect of the rule," he said.

"For example, studies planning to recruit some subjects on or after Jan. 21, 2019 would have to meet the new requirements for obtaining the informed consent of those subjects," it said. "In contrast, for studies whose remaining activities consist only of completing data analyses, the new requirements for informed consent generally would not be applicable.

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Three Questions

Alison Liddy, ICON

CWWeekly presents this feature as a spotlight on issues faced by executives in clinical research. This week we hear from Alison Liddy, Senior Vice President, Clinical Risk & Data Management, ICON Clinical Research Services.

Q How are clinical trials evolving and what impact does this have on the complexity of data management?

A The blurring of the lines between phase I and II trials, coupled with the rapid expansion of study cohorts based upon flexible study designs, have significantly decreased timelines for drug development in a number of therapeutic areas, including oncology. Multi-arm trials provide the flexibility of being able to reduce the number of study arms depending on the benefit shown or to add arms as new treatments become available. As the use of these types of adaptive studies has become more widespread, data management functions have had to become more adaptable and sensitive to adjusting timelines.

Risk-based monitoring directs the focus to the areas of greatest need, with particular attention to those activities that have the most potential to impact patient safety and data quality. This requires varying approaches for Source Data Verification (SDV). Source Data Review (SDR) must be managed and tracked by highly skilled, agile data analysts that understand the impact of these strategies in delivering quality data within given timelines.

Another way clinical trials are changing is the increased focus on personalized care. Pharmaceutical companies are showing interest in the “site-less” or direct-to-patient model and are building alliances with various likeminded companies such as “Science37”. Companies similar to “PatientsLikeMe,” which offers a real-time research platform, are starting to gain traction in the industry.

Clinical trials and clinical trial design have been getting more complex over the last five years with the introduction of approaches such as flexible study designs and risk-based monitoring. Despite the industry’s best efforts to improve protocol design, they are becoming increasingly more intricate, which result in an increase of amendments during the study.

The explosion of the amount and variety of data being generated has resulted in the increasingly complex, time-sensitive data collection process, which involves cleaning and delivery to clients combined with evolving innovation and trial design.

“Data cleaning strategies and data review tools using analytical software can enable data to be cleaned in keeping with the patient schedule and monitoring strategy and provide a more holistic view of data cleanliness across various sources.”

Q What can CROs do to help sponsors with the increase in data complexity?

A Integrated technology solutions: CROs are increasingly using integrated technologies and real-time access to data to improve data integration and exchange and achieve clean database lock more rapidly. Data cleaning strategies and data review tools using analytical software can enable data to be cleaned in keeping with the patient schedule and monitoring strategy and provide a more holistic view of data cleanliness across various sources. By using a unified integrated platform, CROs can deliver a more streamlined process for managing complex data, resulting in efficiencies and transparency for sponsors.

Protocol optimization: Full service CROs can provide multidiscipline specialists in protocol design, clinical development and regulatory, to help stress test the operational viability of the protocol to answer research questions. This service can help the sponsor to ensure the final protocol is both in line with research requirements and meets the quality of scientific data needed for better outcomes. This approach enables the collection of the right data for the right questions and provides the balance in data volume over value. Specialists in this area can also provide advice on collecting the most appropriate, optimum amount of data to leverage emerging biomarkers and imaging in the early stages of clinical development to enable better decision-making around the compound.

Q Is technology improving the way data is managed in complex trials?

A Many of the data management complexities are due to multiple data sources and the laboratory types involved. Skilled laboratory data experts use integrated technology that allows for the management of laboratory normal ranges. The unification of medical imaging and electronic data capture (EDC) platforms enables image data to be brought into the study, which reduces data reconciliations between imaging and clinical databases, therefore the images can be tracked in real time.

It has been a longstanding challenge to integrate patient data from electronic medical record systems (EMRs) with EDC systems for clinical studies. The value this could bring to data management and in the reduction of burden for sites and Sponsors creates a clear business case that drives ambition to resolve the issues. CROs and technology vendors are working to provide potential solutions to overcome this challenge in certain areas, for example, by interrogating EMR data to identify sites with suitable patient populations to conduct studies.

The use of artificial intelligence is also likely to have a role to play in future trials. There will be a need to build advanced analytics systems based on predictive modelling to handle the inflow of real-time data and then manage the outflow of relevant, clean data.
### Drug & Device Pipeline News

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Syros Announces New Preclinical Ovarian Cancer Study
Syros Pharmaceuticals announced new preclinical data showing that SY-1365, its first-in-class selective cyclin-dependent kinase 7 (CDK7) inhibitor currently in a Phase I trial in patients with advanced solid tumors, demonstrated potent anti-tumor activity in multiple models of heavily pretreated ovarian cancer. The ongoing Phase I trial of SY-1365 is a multicenter, open-label trial enrolling patients with advanced solid tumors. The primary objective of the trial is to assess the safety and tolerability of escalating doses of SY-1365, with the goal of establishing a maximum tolerated dose and a recommended Phase II dose and regimen. The dose-escalation phase is open and expected to enroll approximately 35 solid tumor patients for whom standard curative or palliative measures do not exist or are no longer effective. SY-136 showed induced cell death in numerous ovarian cancer cell lines and inhibited tumor growth in 10 of the 17 treatment-relapsed ovarian PDX models studied, including inducing complete regressions. Syros expects to open the expansion phase of the trial in mid-2018.

Bristol-Myers Squibb Announces Initial Results from the Phase III Study
Bristol-Myers Squibb announced initial results from the pivotal Phase III study, CheckMate -227, evaluating the Opdivo (nivolumab) 3 mg/kg plus low-dose Yervoy (ipilimumab, 1 mg/kg) combination in first-line advanced non-small cell lung cancer (NSCLC) patients with high tumor mutational burden. CheckMate -227 is an open-label Phase III trial evaluating Opdivo-based regimens versus platinum-doublet chemotherapy. In the study, the combination demonstrated a superior benefit for the co-primary endpoint of progression-free survival (PFS) versus chemotherapy (HR 0.58; 97.5 percent CI: 0.41 to 0.81; p=0.0002). The PFS benefit was observed regardless of PD-L1 expression levels and in both squamous and non-squamous tumor histology. Of all randomized TMB-evaluable patients, 444 (44 percent) had TMB ≥10 mut/Mb, including 139 patients randomized to Opdivo plus Yervoy and 160 patients randomized to chemotherapy. In the trial, TMB was assessed using the validated assay, FoundationOne CDx. Additionally, overall survival was observed with the combination versus chemotherapy in patients with high TMB. There are two co-primary endpoints in Part 1 for the Opdivo plus Yervoy combination: overall survival (OS) in patients whose tumors express PD-L1 (assessed in patients enrolled in Part 1a) and progression-free survival (PFS) in patients with high tumor mutational burden (TMB) ≥10 mut/Mb across the PD-L1 spectrum (assessed in patients enrolled across Parts 1a and 1b). The primary endpoint in Part 2 is OS.

Novocure Reports Positive Results from STELLAR Phase II Trial
NovoCure announced positive top-line results from its STELLAR phase II pilot trial in mesothelioma demonstrating clinically meaningful improvements in overall survival and progression free survival among patients who received Tumor Treating Fields. Plus standard of care chemotherapy, pemetrexed and cisplatin or carboplatin, compared to historical control data of patients who received standard of care chemotherapy alone. The final data exceeded the results of the interim analysis. The STELLAR trial is a phase II pilot single-arm, open-label, multi-center trial consisting of 80 patients with unresectable, previously untreated malignant pleural mesothelioma. The one-year survival rate of patients treated with Tumor Treating Fields combined with pemetrexed and cisplatin or carboplatin was 80 percent (compared to 50 percent in pemetrexed and cisplatin-alone historical controls). Median progression free survival in the Tumor Treating Fields-treated group was 7.3 months (compared to 5.7 months in pemetrexed and cisplatin-alone historical controls) and one-year survival rate was 79.7 percent (compared to 50.3 percent in pemetrexed and cisplatin-alone historical controls). No device-related serious adverse events had been reported to date.

Esketamine Demonstrated Improvements in Depressive Symptoms
The Janssen Pharmaceutical Companies of Johnson & Johnson announced that data from a Phase II proof of concept clinical study of esketamine nasal spray showed that treatment with esketamine resulted in a statistically significant, clinically meaningful improvement in depressive symptoms at four hours, including a measure of suicidal ideation, in patients with major depressive disorder who were at imminent risk for suicide, compared to placebo. This 12-week Phase IIa, randomized, double-blind, placebo-controlled, multicenter study conducted in the U.S. enrolled 68 adults. The participants were randomized in a 1:1 ratio to one of the two treatments: esketamine nasal spray 84 mg (N=36) plus standard of care or placebo nasal spray (N=32) plus standard of care. The study consisted of a screening evaluation performed within 24 to 48 hours prior to the Day 1 dose, immediately followed by a 25-day double-blind treatment phase (Day 1 to 25) with twice-weekly dosing sessions, and a 56-day follow up phase (Day 26 to Day 81). A statistically significant difference in the MADRS total score favoring esketamine was also seen at 24 hours (p=0.015; effect size=0.65), but not at the double-blind endpoint. The most common (>20 percent) treatment-emergent adverse events during the double-blind phase were: nausea (37.1 percent), dizziness (34.3 percent), unpleasant taste (31.4 percent), dissociation (31.4 percent), headache (31.4 percent), and vomiting (20.0 percent).
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<td>Alliance for Multispecialty Research, LLC</td>
<td>Knoxville, TN</td>
<td>(615) 591-0211</td>
<td><a href="mailto:amrteam@amrllc.com">amrteam@amrllc.com</a></td>
<td>AMR is an industry-leading clinical research company with 17 locations across the U.S., enrolling over 145,000 subjects and completing more than 7,700 Phase I-IV clinical trials.</td>
</tr>
<tr>
<td>Palm Beach CRO</td>
<td>West Palm Beach, FL</td>
<td>(561) 200-3344</td>
<td><a href="mailto:info@palmbeachcro.com">info@palmbeachcro.com</a></td>
<td>Palm Beach CRO is a therapeutically focused CRO that provides clinical support to pharmaceutical (RX and OTC), biotechnology, nutraceuticals and medical device companies.</td>
</tr>
<tr>
<td>Summit Research Network Management, Inc.</td>
<td>Portland, OR</td>
<td>(503) 972-9818</td>
<td><a href="mailto:jhockley@summitnetwork.com">jhockley@summitnetwork.com</a></td>
<td>Summit Research Network is an independent medical research organization with an out-patient facility.</td>
</tr>
<tr>
<td>PRA Health Sciences</td>
<td>Raleigh, NC</td>
<td>(919) 786-8200</td>
<td><a href="mailto:prahsciences@prahs.com">prahsciences@prahs.com</a></td>
<td>With 13,000+ employees covering 80+ countries, PRA has been conducting clinical research for over 30 years across a range of compounds, from niche treatments to blockbuster drugs and biosimilars treatments.</td>
</tr>
<tr>
<td>LabConnect LLC</td>
<td>Seattle, WA</td>
<td>(206) 322-4680</td>
<td><a href="mailto:info@labconnectllc.com">info@labconnectllc.com</a></td>
<td>LabConnect, with more than 4,000 validated tests across their network, has an extensive test menu that includes specialized oncology assays, biomarker analysis, pharmacokinetic analysis and method development services.</td>
</tr>
<tr>
<td>PRC Clinical</td>
<td>San Bruno, CA</td>
<td>(877) 519-6001</td>
<td><a href="mailto:info@prcclinical.com">info@prcclinical.com</a></td>
<td>The team has been involved in both small and large clinical programs, from orphan drug designated trials to large clinical registries of 3000+ patients.</td>
</tr>
<tr>
<td>Palm Beach Research Center</td>
<td>West Palm Beach, FL</td>
<td>(561) 689-0606</td>
<td><a href="mailto:david@palmbeachresearch.com">david@palmbeachresearch.com</a></td>
<td>Palm Beach Research Center is 6,875 square feet of dedicated research space. There are separate branches for recruitment, regulatory, quality assurance and patient screening.</td>
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</tbody>
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