CTTI: Instituting Quality Measures Early in Trial Design Pays Off in the Long Run

By Conor Hale

At a symposium marking the Clinical Trials Transformation Initiative’s 10th anniversary, industry and regulatory discussed the progress made by its Quality by Design initiative and the additional work needed to encourage the research industry to be more focused on trial quality and efficiency.

Quality in clinical trials is defined as the absence of errors that matter, said Ann Meeker-O’Connell, head of bioresearch quality and compliance at Johnson & Johnson.

While inflexible, one-size-fits-all approaches to quality can undermine the development of specific strategies for a given study, Meeker-O’Connell said CTTI’s Quality by Design project recommended sponsors examine clinical trials prospectively and take early action to protect critical factors from affecting outcomes.

More than anything, the design of the trial should be streamlined wherever possible, she said, with the study’s planned activities and data collection narrowed down to those essential for the trial’s objective. But efforts to create a company culture that values and rewards critical thinking about clinical trials quality should go beyond reliance on checklists and other tools, Meeker-O’Connell said.

Implementing quality measures early into clinical trial design has not been an easy task for the research industry, said the FDA’s Robert Temple, CDER’s deputy director for clinical science. However, reducing costly protocol

Principal Investigator Eligibility – GCP Questions, FDA Answers

FDA regulations provide that sponsors select principal investigators (PIs) qualified by training and experience. The regulations do not, however, provide answers for every possible contingency sponsors face in PI selection or management.

FDA’s Office of Good Clinical Practice responds to questions from the public interpreting FDA’s position, offering advice on how to proceed and pointing out key documents and resources that provide more guidance.

The following examples of questions and OGCP answers regarding PI eligibility are excerpted from the book GCP Questions: FDA Answers.

Principal Investigator Eligibility

We have a PI, principal investigator who has moved from a Pennsylvania clinical research facility to a Missouri facility. His license in Pennsylvania is current and active and he has applied and is waiting for his Missouri license to be issued. May he be used by a Pharma Sponsor to be PI for a clinical trial in Missouri? My understanding is this is left to the sponsors but I wanted to inquire if the FDA would have any issues with this.

A

The regulations are very broad. The regulations require that sponsors choose investigators qualified by training and experience (see 21 CFR 312.53(a)). The regulations also

In this issue

Industry Briefs…2

The Pulse on CRO-Site Relationships…5

Drug & Device Pipeline News…6

Eighteen drugs and devices have entered a new trial phase this week.

Trial Results…7

CenterWatch reports on results for three drugs.

Research Center Spotlight…8

Research center profiles.
**EMI Draft ‘Strengthens’ Guidance on Safety Follow-Up for Advanced Therapies**

The EMA published a draft revision to its guideline for clinical trials follow up of advanced therapy medicinal products, including gene therapies, cell therapies and tissue engineered products. The draft strengthens and clarifies the EMA’s 2008 guideline, and includes more details on designing post-authorization safety and efficacy follow-up studies. Sponsors need to provide safety and efficacy follow-up data in their marketing applications, including long-term data to analyze the benefits and risks of products. Objectives for safety follow-ups should be based on specific product characteristics than on its classification, such as whether it is a cell- or gene-based therapy, or a combination. The evaluation of the long-term efficacy is a key issue for gene therapies as premarket clinical trials typically include a limited number of patients and with a limited duration. The EMA suggested sponsors provide long-term follow-up data in several situations, such as for cell therapies with a short shelf life, which may require monitoring of efficacy and the need for re-administration. Immunogenicity is also a critical consideration for the efficacy assessment of a cell-based product. The EMA’s draft guideline is available here: [http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/02/WC500242959.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2018/02/WC500242959.pdf).

**NIH Partners with Industry to Identify Parkinson’s Disease Biomarkers**

Citing the numerous failures in clinical trials, the NIH will collaborate with government, biopharmaceutical, life science and nonprofit organizations to help advance the development of Parkinson’s disease (PD) treatments, as part of the NIH Accelerating Medicines Partnership. The initiative will focus on identifying and validating biomarkers to track the progression of PD and could serve as biological targets for the development of new drugs. “Advancing treatments for Parkinson’s disease is hampered by insufficient understanding of biological networks; drugs aimed at seemingly promising therapeutic targets fail in clinical trials,” said NIH Director Francis Collins. Due to increased life expectancies, the number of people with PD worldwide is expected to nearly double by the year 2030, according to the NIH. No disease-modifying drugs have yet been approved. The program will include Celgene, GlaxoSmithKline, The Michael J. Fox Foundation for Parkinson’s Research, Pfizer, Sanofi and Verily, which plan to invest a combined total of $12 million over five years through the Foundation for the NIH, which will manage the project. The groups plan to share de-identified data and findings among themselves and the research community, analyzing datasets from more than 3,000 cases and 1,700 healthy controls from studies funded by NINDS and MUF, including the Parkinson’s Progression Markers Initiative.

**SPIRIT Publishes 16 PRO Additions to Protocol Checklist**

An international collaboration of clinical trialists, methodologists, journal editors and ethicists developed a new series of consensus-based guidelines for including patient-reported outcome measures in study protocols. The SPIRIT Group (Standard Protocol Items: Recommendations for Interventional Trials) identified 16 new PRO-related additions and changes for its 2013 checklist, which recommends a minimum set of evidence-based provisions that should be included in trial protocols. The extension was published in JAMA. The 16 items — including the specification of eligibility criteria, sample sizes, data collection plans, analysis methods and the individual responsible for PRO content — should be routinely addressed in all clinical trial protocols where PROs are a primary or secondary outcome, the group said. Other items recommend justifying the instrument used, including descriptions of the number of items, scaling and scoring, as well as plans for handling multiplicity issues. In an accompanying editorial, three researchers from the Icahn School of Medicine at Mount Sinai said the SPIRIT guidance will enable a more uniform approach to the collection and reporting of PRO data. They wrote, “PROs are essential as important outcome measures that matter to patients and will need to be incorporated in a systematic and standardized way in clinical trial protocols.” SPIRIT’s PRO extension is available: [https://jama-network.com/journals/jama/fullarticle/2671472](https://jama-network.com/journals/jama/fullarticle/2671472).

**EMA Prevails Against Drugmakers Seeking to Block Release of Clinical Trial Data**

A European Union court ruled the EMA can offer access to clinical trial data in a blow to three drugmakers who argued this would hurt their business. The EMA had announced the release of the documents in response to third-party requests in accordance with European Commission transparency regulations. Merck and PTC Therapeutics had argued the EMA was not entitled to allow access to the trial data as it would risk their trade secrets, while Pari Pharma attempted to block the release of an EMA committee report on one of its drugs based on similar claims. However, the Court of Justice of the European Union ruled the companies did not provide sufficient evidence the releases would hurt their business. The EMA will “continue to diligently assess each individual request for access to documents submitted under the Transparency Regulation and in accordance with its policy on access to documents,” the agency said, following the decision.
amendments — as well as the possibility of errors that may impact patient safety or the study’s final results — are worth the effort.

CTTI — founded in 2007 as a public-private partnership between the FDA and Duke University — developed a toolkit, including templates, guidelines, workshops and videos, to help companies implement the recommendations.

“People need to see examples of simplifications and design features that did or did not work as hoped,” alongside their ultimate effects on the trial and outcomes, to convince companies to adopt the quality measures, Temple said.

For instance, CTTI addressed on-site trial monitoring and error prevention because it is a main cost driver in conducting clinical studies, he said. Errors that mean amending the protocol in later stages can be incredibly expensive. According to the Tufts Center for the Study of Drug Development, the total cost of a single, substantial amendment to a Phase III protocol — such as changes on a global level that would require approval from a review board or regulatory authority — can reach over $500,000 each.

CTTI recommends sponsors institute electronic data collection systems that allow sponsors to monitor at a distance, with problems being detected centrally. The system can also reduce and target site visits to problematic locations and identify high-risk issues — such as misdefined endpoints, too many study dropouts or too little variability.

Sponsors should take the time to develop thought-out clinical trial protocols, with endpoints that can be measured well at each site, even with additional training, and potentially use real-world data to ease patient burdens and promote adherence, Temple said. Protocol adjustments could be site-specific as well, with a focus on sub-sites that are having problems. Companies could consider using endpoints that are already collected as part of an electronic health record — and using past records to find concomitant treatments and previous health experiences, as well as ways to schedule patient visits or guide assessments, Temple said.

In addition, enrichment strategies could help identify high-risk patients, likely treatment responders, and those most likely to comply with a study protocol, he said.

**Amgen Case Study**

Julie Dietrich, director of Amgen’s Development Design Center, presented a case study to the symposium of how her company integrated CTTI’s recommendations into its trial design process.

To get departments focused on streamlining clinical trials, a popular metaphor Dietrich used was that of a new, fresh Christmas tree. As more and more people place their ornaments on it, it runs the risk of becoming a mess, or even falling over, she said.

“We would be meeting with large, cross-functional teams,” Dietrich said. “Medical, safety, economics… and they would all have pet interests that they wanted to learn from the study.”

But you have to keep your eye on how those additions are relevant to the final product, she said. “Adding things could add chances for errors that matter… In the end, delays don’t serve the patients or the stakeholders.”

Another challenge at Amgen was communicating the value of planning ahead. Everyone is focused on reducing time to first patient enrollment, but they may not see that thorough trial design can reduce the time to database lock and analysis — the time that really matters, Dietrich said.

For example, red flags were identified early in the trial design process when a study included over-reliance on a daily, patient-completed diary for the development of study data. It was unclear if enough patients would complete the tasks on schedule, she said.

Instead, Amgen adopted methods of obtaining data through usual care — to reduce the patient’s burden for data collection during study visits — and shortened the period of diary collection, she said.

“We have quite a wealth of information available to us,” Dietrich said. “The challenge is knitting together different data sources and having it tell some kind of story, so that decision makers known what to do with it.”

---

**Quality in clinical trials is often defined as the absence of errors that matter, and that inflexible, one-size-fits-all approaches can undermine the development of specific strategies for a given study.**

—Ann Meeker-O’Connell, head of bioresearch quality and compliance, Johnson and Johnson
Principal Investigator Eligibility (continued from page 1)

require that investigators commit themselves to personally conduct or supervise the investigation (see 21 CFR 312.53(c)(1)(vi)(c)).

Please see the guidance document, “Frequently Asked Questions – Statement of Investigator:
[ICH E6 – Good Clinical Practice Consolidated Guidance] states:]

4. Must the investigator be a physician? The regulations do not require that the investigator be a physician. Sponsors are required to select only investigators qualified by training and experience as appropriate experts to investigate the drug (21 CFR 312.53(a)). In the event the clinical investigator is a non-physician, a qualified physician (or dentist, when appropriate) should be listed as a sub-investigator for the trial and should be responsible for all trial-related medical (or dental) decisions.

Training, education, and experience required for sponsor personnel may necessarily, and appropriately, vary depending on the type of product, the indication, the study being conducted, and its associated risk. FDA’s regulations are not explicit as to what constitutes adequate training, education and experience, nor do they outline specific qualifications, including whether such personnel must hold an active medical license. Moreover, sponsors have discretion in determining what qualifications are needed in certain positions based on the general recognition that this would include education, training and experience pertinent to the particular clinical study and its design and execution, as well as familiarity with human subject protection (HSP) regulations, recordkeeping, data integrity, and good clinical practice (GCP) standards and requirements. Whether or not certain sponsor personnel should hold an active medical license depends on the considerations outlined above.

It might be helpful for you to review FDA’s guidance on Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects.

FDA would expect physicians to follow state and local laws regarding medical licensure and medical practice requirements in addition to sponsor requirements.

Backup Principal Investigator

Is there any guidance or regulatory requirement for a clinical site to have a backup for the PI, with same/similar credentials to take over if needed?

A

Thank you for your question. While not a regulatory requirement most clinical study sites do have sub-investigators. The requirement that the sub-CI have the same credentials as the PI would be up to the sponsor and state and local laws governing licensing. The investigator (also referred to as the principal investigator or PI) is responsible for supervising the conduct of the clinical investigation and to protect the rights, safety, and welfare of participants in drug and medical device clinical trials. PI’s commit themselves to personally conduct or supervise the investigation. It is common practice for investigators to delegate certain study-related tasks to employees (including the sub-CI), colleagues, or other third parties, but the investigator remains responsible for providing adequate supervision of those to whom tasks are delegated. Essentially, the PI may delegate tasks on a given study, but they may not delegate their role or responsibilities as PI.

FDA encourages each study site to have their own CI, who signs a 1572, for the conduct of the study at the specific site. Sub-investigators are intended to assist the CI conduct the study at a specific site and not to substitute for the CI. The intention of FDA regulations are for the CI to conduct and/or supervise all aspects of a clinical study for which he/she agrees to conduct, according the investigational plan and applicable regulations, when he/she signs the 1572.

FDA’s definition of investigator is found at 21 CFR 312.3:

“Investigator means an individual who actually conducts a clinical investigation (i.e., under whose immediate direction the drug is administered or dispensed to a subject). In the event an investigation is conducted by a team of individuals, the investigator is the responsible leader of the team. “Subinvestigator” includes any other individual member of that team.”

FDA has a guidance document for industry titled, “Investigator Responsibilities - Protecting the Rights, Safety, and Welfare of Study Subjects.” This guidance was developed to clarify for investigators and sponsors FDA’s expectations concerning the investigator’s responsibility (1) to supervise a clinical study in which some study tasks are delegated to employees or colleagues of the investigator or other third parties and (2) to protect the rights, safety, and welfare of study subjects.

Clinical trials professionals can ask OGCP their own questions via email to gcp.questions@fda.hhs.gov.
The complexities involved in conducting clinical trials extend well beyond clinical trial protocols and study design and into a realm where we often find the greatest return — relationships. The relationship between a research site and a CRO is particularly unique and gaining more attention in the clinical research industry.

The need to establish long-term, mutually beneficial relationships is important to nearly every business. Clinical sites and CROs are no exception to this rule. In this instance, the potential return of a well-developed relationship between a site and CRO is priceless, and potentially provides life-changing therapies to others.

Working with a small-to-midsize CRO has afforded me the opportunity to work closely with investigators and study site staff on numerous trials. As studies progress, the critical nature of these relationships and the direct effect they have on successful study outcomes becomes more evident. Most, if not all, of our success as a CRO can be attributed to our mutually invested relationships with clinical research sites.

When a CRO emphasizes a site-focused approach and considers the site’s needs as a top priority, sites are able to focus on patients, thus ensuring needs are met across the board. Equally, when a site has the full support of a CRO, investigators and study staff are set up to deliver successful study outcomes. This translates to optimized startup, increased study efficiencies and meeting (or exceeding) enrollment targets.

Making the time to evaluate and understand these relationships is almost as important as the relationship itself. There is no shame in declining to participate in a study if previous experience has led to a negative return. This allows the ability to focus on opportunities to work with a site or CRO that shares a common focus on quality in a collaborative environment.

When calculating returns, zooming in on the time invested in a relationship is a good place to start. In relationship terms, time should be evaluated from the perspective of quality versus quantity. A 30 minute weekly meeting can be equally or more productive than an hour-long call every few days, as long as both sides are tuned into each other’s needs and communicating effectively.

The potential for future growth is another factor in calculating the relationship return. A mutually beneficial relationship invites a reciprocal commitment to evolving the CRO/site relationship as a whole, with the end goal of effectively bringing new treatment options to patients.

The potential return of a well-developed relationship between a site and CRO is priceless. A reciprocal commitment to evolving the CRO/site relationship will ultimately benefit the research community as a whole, with the end goal of effectively bringing new treatment options to patients.

Building relationships is arguably the most important element in business and identifying the relationship ROI is the first step. Once a relationship is established, both parties can find areas for shared improvement. Sites and CROs have no limit in terms of elements to focus on strengthening the relationship — study feasibility, patient recruitment and monitoring strategy, to name a few. Fostering open, two-way communication between investigative sites and CROs is essential to identifying key areas for improvement in the relationship.

A reciprocal commitment to evolving the CRO/site relationship will ultimately benefit the research community as a whole, with the end goal of effectively bringing new treatment options to patients.

Brittany Parker is the Director of Marketing and Communications at Total Clinical Trial Management. She works closely with research sites and study staff to execute current programs and develop ongoing, long-term relationships. Please visit www.totalcro.com for more information.
### Drug & Device Pipeline News

**Company** | **Drug/Device** | **Medical Condition** | **Status** | **Sponsor Contact**  
--- | --- | --- | --- | ---  
Fibrocell Science | FCX-013 | moderate to severe localized scleroderma | IND submitted to the FDA | fibrocell.com  
Daiichi Sankyo | U3-1402 | metastatic or unresectable epidermal growth factor receptor-mutated non-small cell lung cancer | Phase I trials initiated enrolling 60 subjects globally | daichisankyo.com  
Palatin Technologies | PL-8177 | ulcerative colitis and other inflammatory bowel diseases | Phase I trials initiated enrolling 52 subjects | palatin.com  
Phosplatin Therapeutics | PT-112 | relapsed or refractory multiple myeloma | Phase I/II trials initiated | phosplatin.com  
Gemphysphere | gemcabene | pediatric nonalcoholic fatty liver disease | Phase IIa trials initiated enrolling 40 adolescent children between the ages of 12 and 17 | gemphysphere.com  
OncBioMune Pharmaceuticals | Proscavax | advanced prostate cancer | Phase II trials initiated | oncbiomune.com  
Xcovery | ensartinib (X-396) | advanced malignant melanoma harboring alterations in ALK | Phase II trials initiated | xcovery.com  
Endo International | collagenase clostridium histolyticum | cellulite | Phase III trials initiated enrolling 840 women in the U.S. | endo.com  
Pharma Two B | P2B001 | early Parkinson’s disease | Phase III trials initiated enrolling 525 subjects | pharma2b.com  
Tessa Therapeutics | T cell immunotherapy | nasopharyngeal cancer | Phase III trials initiated enrolling 35 subjects | tessatherapeutics.com  
GlaxoSmithKline | Bexsero | meningitis B vaccine | Breakthrough Therapy designation granted by the FDA | gsk.com  
Sage Therapeutics | SAGE-217 | major depressive disorder | Breakthrough Therapy designation granted by the FDA | sagerx.com  
Zogenix | ZX008 (low-dose fenfluramine) | seizures associated with Dravet syndrome | Breakthrough Therapy designation granted by the FDA | zogenix.com  
MeiraGTx | AAV2/8-hCARp. hCNGB3 (A002) | achromatopsia due to mutations in the CNGB3 gene | Rare Pediatric Disease designation granted by the FDA | meiragtx.com  
Adhesys Medical | VIVO | surgical sealant | Expedited Access Pathway designation granted by the FDA | adhesys-medical.com  
Alnylam Pharmaceuticals | patisiran | hereditary ATTR amyloidosis | NDA accepted and Priority Review granted by the FDA | alnylam.com  
Allergan | Avycaz (cefazidime and avibactam) | hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia | Expanded use approved by the FDA | allergan.com  
Ferring Pharmaceuticals | Zomacton (somatropin) | human growth hormone deficiency | FDA approved | ferringusa.com  

For news on trial results, FDA approvals and drugs in development, Join the LinkedIn Drug Research Updates group!
**Phase III PROSPER Trial Shows positive results for XTANDI**

Astellas Pharma and Pfizer announced results from the Phase III PROSPER trial in patients with non-metastatic (M0) Castration-Resistant Prostate Cancer (CRPC). The Phase III randomized, double-blind, placebo-controlled, multi-national trial enrolled approximately 1,400 patients with M0 CRPC. The primary endpoint of the PROSPER trial, metastasis-free survival (MFS), is a measure of the amount of time that passes until a cancer can be radiographically detected as having metastasized, or until death, within 112 days of treatment discontinuation. Secondary endpoints included time to PSA progression, time to first use of antineoplastic therapy and overall survival. The results show that the use of XTANDI (enzalutamide) plus androgen deprivation therapy (ADT) significantly reduced the risk of developing metastases or death by 71 percent compared to ADT alone. The median for the primary endpoint MFS, was 36.6 months for men who received XTANDI compared to 14.7 months with ADT alone (n=1401; HR=0.29 [95 percent CI: 0.24-0.35]; p<0.0001). XTANDI plus ADT prolonged the median time to first use of new antineoplastic therapy by 21.9 months versus ADT alone (39.6 months [95 percent CI: 37.7-NR] vs. 17.7 months [95 percent CI: 16.2-19.7]), a 79 percent relative risk reduction (HR=0.21 [95 percent CI: 0.17-0.26]; p<0.0001). Marketing applications based on the results of the PROSPER study have been submitted to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

**Allergan Announces Positive Top Line Phase III Results for Ubrogepant**

Allergan announced positive results from ACHIEVE I (UBR-MD-01), the first of two pivotal phase III clinical trials evaluating the efficacy, safety and tolerability of orally administered ubrogepant 50 mg and ubrogepant 100 mg compared to placebo in a single migraine attack in adults. The ACHIEVE I study included 1327 U.S. adult patients randomized (1:1:1) to placebo, ubrogepant 50 mg and 100 mg respectively, who were treated for a single migraine attack of moderate to severe headache intensity. The ACHIEVE I trial is a Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel-group study. The co-primary efficacy parameters were pain freedom (PF) at two hours after the initial dose and absence of the most bothersome migraine-associated symptom (photophobia, phonophobia or nausea) at two hours after the initial dose. Both doses showed a statistically significant greater percentage of ubrogepant patients achieving pain freedom at two hours after the initial dose as compared to placebo patients (50 mg vs placebo, p=0.0023, 100 mg vs placebo, p=0.0003) and a statistically significant greater percentage of ubrogepant patients achieving absence of the most bothersome migraine-associated symptom at two hours after the initial dose as compared to placebo patients (50 mg vs placebo, p=0.0023, 100 mg vs placebo, p=0.0023). Uburogepant was well tolerated with an adverse event profile similar to placebo. The most common adverse events were nausea, somnolence, and dry mouth, none of which were reported with a frequency of ≥5 percent.

**Genentech’s TECENTRIQ and Avastin Reduced the Risk of Kidney Cancer Worsening**

Genentech announced results from the positive Phase III IMmotion151 study of TECENTRIQ and Avastin (bevacizumab) as a first-line treatment for advanced or metastatic renal cell carcinoma (mRCC). IMmotion151 is a Phase III multicenter, randomized, open-label study to evaluate the efficacy and safety of TECENTRIQ and Avastin versus sunitinib in people with inoperable, locally advanced or metastatic renal cell carcinoma (RCC) who have not received prior systemic active or experimental therapy. The study met its co-primary endpoint of investigator-assessed progression-free survival (PFS) in people whose disease expressed the PD-L1 (programmed death-ligand 1: expression ≥1 percent) protein. Those who received TECENTRIQ plus Avastin had a 26-percent reduced risk of disease worsening or death (PFS) compared to people treated with sunitinib (median PFS [mPFS]; 11.2 vs. 7.7 months; HR=0.74; 95 percent CI 0.57, 0.96; p=0.02). Safety for the TECENTRIQ and Avastin combination appeared consistent with the known safety profile of the individual medicines and what was previously reported in the Phase II IMmotion150 study. No new safety signals were identified with the combination. The rate of treatment-related Grade 3-4 adverse events was lower with the TECENTRIQ and Avastin combination (40 percent) than with sunitinib alone (54 percent) in all treated patients.
### 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.

To learn more about becoming a Research Center Profile page subscriber, contact Sales at (617) 948-5100 or sales@centerwatch.com.

<table>
<thead>
<tr>
<th>Research Center</th>
<th>Location</th>
<th>Contact Information</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Advanced Gastroenterology Associates</td>
<td>Palm Harbor, FL</td>
<td>(727) 216-0768 <a href="mailto:research@advancedgastro.com">research@advancedgastro.com</a></td>
<td>Advanced Gastroenterology Associates specialize in the body's internal digestive organs, utilizing the most up to date endoscopic techniques that offer less inconvenience and a faster recovery time for our patients.</td>
</tr>
<tr>
<td>AMCR Institute, Inc.</td>
<td>Escondido, CA</td>
<td>(877) 567-2627 <a href="mailto:sponsors@amcrinstitute.com">sponsors@amcrinstitute.com</a></td>
<td>AMCR Institute is a clinical research center engaged in Phase I-IV trials in the field of endocrinology and metabolism. It focuses on drug and medical device studies for diabetes type 1 and type 2 and other metabolic disorders.</td>
</tr>
<tr>
<td>Center for Neurosciences</td>
<td>Tucson, AZ</td>
<td>(520) 320-2147 <a href="mailto:mpazzi@neurotucson.com">mpazzi@neurotucson.com</a></td>
<td>Our board-certified neurologists are experts in their respective specialties and have extensive clinical research experience in a broad range of neurologic diseases affecting adults and children.</td>
</tr>
<tr>
<td>DCOL Center for Clinical Research</td>
<td>Longview, TX</td>
<td>(903) 238-8854 <a href="mailto:scoppinger@dcolresearch.com">scoppinger@dcolresearch.com</a></td>
<td>DCOL began conducting clinical trials in 2005. It is a dedicated research department within a large, multi-specialty group practice consisting of over 90 physicians. The group practice has an active database of over 140,000 patients.</td>
</tr>
<tr>
<td>Einstein-Montefiore Institute for Clinical and Translational Research</td>
<td>Bronx, NY</td>
<td>(718) 430-2500 <a href="mailto:lctr@einstein.yu.edu">lctr@einstein.yu.edu</a></td>
<td>The Einstein-Montefiore Institute enhances the discipline of clinical and translational research by promoting multidisciplinary collaboration, addressing translational ‘blocks’ in research and providing infrastructure.</td>
</tr>
<tr>
<td>Elite Clinical Studies, LLC</td>
<td>Phoenix, AZ</td>
<td>(602) 788-3437 <a href="mailto:debbie@eliteclinicalstudies.com">debbie@eliteclinicalstudies.com</a></td>
<td>Elite Clinical Studies has an updated database with over 18,000 subjects and utilizes a central IRB.</td>
</tr>
<tr>
<td>Health Concepts</td>
<td>Rapid City, SD</td>
<td>(605) 348-4141 <a href="mailto:healthconcepts104@hotmail.com">healthconcepts104@hotmail.com</a></td>
<td>Health Concepts is a state of the art research center built in 2009 with complete technology for a wide range of research studies. Health Concepts has infusion capabilities and recent construction lends itself for device research.</td>
</tr>
<tr>
<td>Los Alamitos Cardiovascular</td>
<td>Los Alamitos, CA</td>
<td>(562) 430-7533, ext. 223 <a href="mailto:riar@losalcardio.com">riar@losalcardio.com</a></td>
<td>Los Alamitos Cardiovascular has been involved in Phase II, III and IV clinical research services for the pharmaceutical, nutritional and medical device industries. The site can use either a local IRB or a central IRB.</td>
</tr>
<tr>
<td>Memorial University Medical Center</td>
<td>Savannah, GA</td>
<td>(912) 350-8707</td>
<td>Memorial Health has more than 50 physicians in various specialties participating in research. All principal investigators are board certified in their specialties. Many have 10 to 15 years of experience in clinical trials.</td>
</tr>
<tr>
<td>Sterling Research Group, Ltd.</td>
<td>Cincinnati, OH</td>
<td>(513) 381-4100 <a href="mailto:dperscy@sterlingresearch.org">dperscy@sterlingresearch.org</a></td>
<td>As a leading clinical research site in Greater Cincinnati, Sterling Research has successfully completed more than 500 trials in a variety of therapeutic areas.</td>
</tr>
</tbody>
</table>