FDA, ICH Seek Comments on “Quality by Design” Draft Guideline

By Leslie Ramsey and James Miessler

Sponsors, CROs and other stakeholders have until September 30 to help shape a critical trial design guideline, according to the FDA’s call for public comment on the revision of ICH E8 last week.

The ICH E8 revision is the latest step in the International Council on Harmonization’s (ICH) efforts to update trial standards, following the revision of ICH E6 — Good Clinical Practices in 2016.

Publishing the document as an FDA draft guidance, the agency last week requested input on the near-total overhaul of the guideline, which was originally issued in 1997.

A brief 17 pages when it was first published, the revised ICH E8 weighs in at 40 pages and is an almost-total rewrite of the original guideline.

Consistent AE Review and Assessment Critical to Successful Device Trials

By Elizabeth Hinkle

The PI and designated research staff are responsible for identifying, investigating, classifying and reporting adverse events (AE) under U.S. and international regulations, as well as IRB policies and specific study protocols.

To identify potential AEs, designated study personnel have many sources, including medical records, abnormal test results, direct research staff observations and subject-reported events. Sites need to develop and follow a consistent, thorough process for reviewing all records for potential adverse events, Bradley Lieberman, manager of clinical monitoring services at IMARC Research, told attendees at a webinar sponsored by the Association of Clinical Research Professionals last week. The frequency of reviews can depend on several factors, Lieberman said, including the rate of patient enrollment, which tends to be heavier at the start of a trial.

Procedures should ensure that the study team has easy access to all medical records, including outside records, as needed. For example, imaging and lab tests should be reviewed, and automated notifications in the electronic medical reporting system can alert site staff to potential AEs. Reviewing medical records before a subject’s next scheduled follow-up visit also can be a good practice, Lieberman said.

Researchers also need to make sure to get patient confirmation of information that can vary across written medical records, such as medication doses and types.

see Consistent AE Review on page 5 »
Clinical Research Group Launches Site Accreditation Program

The Alliance for Clinical Research Excellence and Safety (ACRES) has announced its new global accreditation program for clinical research sites.

The ACRES Site Accreditation and Standards Institute will base its processes on quality standards the nonprofit group developed over the past six years with input from clinical research experts across the industry and in partnership with the British Standards Institution, a global standards organization focused on the aerospace and aviation industries.

The institute also will develop criteria for training specialists to evaluate sites applying for ACRES accreditation.

For more information on the institute, click here: https://bit.ly/2ZnENDP.

FDA Finalizes Guidance on Drugs to Prevent Delayed Kidney Graft Function

Trials of therapies to prevent delayed kidney graft function should have two arms, a new final guidance from the FDA says.

The agency believes sponsors of new drugs should run two trials where an active treatment is compared against placebo, as there are currently no drugs approved for DGF by the agency. It also recommends a pre-approval safety database of at least 300 patients. Under certain circumstances a single trial or a smaller safety database may be allowed, the guidance noted.

The guidance suggests short-term assessment endpoints for trials, including a binary endpoint of whether the patient required dialysis within seven days of transplantation. As an alternative, sponsors can propose the development of a DGF severity scoring system. A sponsor may also select a short-term endpoint based on definitions of suboptimal renal allograft function, the document stated.

Read the guidance here: https://bit.ly/2YzLGUR.

ClinOne to Launch Direct-to-Patient Recruitment Platform

Colorado software company ClinOne will launch a direct-to-patient recruitment platform in late 2019 or early 2020, offering it initially to sponsors at no cost.

Sponsors will test pilot the platform, ClinTrialConnect, on U.S.-based trials in the first quarter of 2020.

The platform will provide patients with information about their disease and include screening questions to match them to specific trials. It also will enable patients to share clinical trial details with family members and include a calendar to manage study appointments, including reminders and Google Maps navigation.

ClinTrialConnect will be integrated with disease associations and include a document library for study documents provided by trial sites. ClinOne also has partnered with Uber to provide patient transportation services to clinical trial sites.

The company plans to expand the program to regions outside the U.S. in the second quarter of 2020.

FDA Issues Draft Guidance on Pharmacology for Neonatal Studies

The FDA issued draft guidance on neonatal studies, which complements the FDA’s 2014 draft guidance on pediatric study considerations, to help drug and biologics sponsors develop studies that keep in mind the special characteristics of neonatal populations.

For example, conventional pharmacokinetic studies that use intensive blood sampling can rarely be used in neonate studies due to their limited circulating blood volume. There’s also a large amount of variability in the study population, as they are rapidly and varyingly maturing, making the collection of clinical pharmacology information difficult.

The agency recommends population pharmacokinetics and physiologically based pharmacokinetic modeling, and/or pharmacokinetic/pharmacodynamic modeling approaches for informing a study’s design and dose selection.

FDA also issued final guidances on efficacy considerations in trials of drugs for treatment of three women’s health issues: bacterial vaginitis, uncomplicated urinary tract infections and vulvovaginal candidiasis.

Read the full neonatal studies draft guidance here: https://bit.ly/2SYXaFE.

Read the bacterial vaginitis final guidance here: https://bit.ly/2GGeqBC.


First U.S. Inside-the-Body CRISPR Study to Launch

Allergan and Editas Medicine will conduct the first inside-the-body gene editing trial in the U.S. beginning in the fall.

Using the experimental gene editing technique commonly known as CRISPR, the trial will focus on altering the DNA of patients to replace the gene that causes Leber congenital amaurosis, an inherited form of blindness.

The trial will enroll up to 18 participants from across the U.S.
**Up and Coming**

This feature highlights changes in clinical research organizations’ personnel.

**Alkahest**
Alkahest has named Robert Klein chief business officer. Klein was previously chief business officer at Complete Genomics.

**Apellis**
Apellis Pharmaceuticals has named Lucia Celona as chief people officer. Celona most recently served as chief HR and communications officer at Bioverativ, a Sanofi company.

**CANBridge Pharmaceuticals**
Marcelo Cheresky has been appointed senior vice president, rare disease commercial operations, at CANBridge Pharmaceuticals. Cheresky was most recently vice president, emerging markets, at Bioverativ, a Sanofi company.

**Epizyme**
Paolo Tombesi has been named chief financial officer at Epizyme. Tombesi was most recently CFO at Insmed.

**G1 Therapeutics**
Mark Avagliano has been appointed chief business officer at G1 Therapeutics. Avagliano was previously vice president, corporate development, at Pfizer.

**Health Union**
Health Union has announced Will Rompala as chief technology officer. Rompala was formerly chief technology officer at Sidecar.

**ImCheck Therapeutics**
Paul Frohna has been appointed chief medical officer at ImCheck Therapeutics. Frohna was previously chief medical officer at Bioniz Therapeutics.

**Maverick Therapeutics**
Maverick Therapeutics has appointed Chulani Karunatilake senior vice president of technical operations. Karunatilake was previously with Nektar Therapeutics, where he established and led the Biologics CMC division.

**Obsidian**
Obsidian Therapeutics has named Catherine Stehman-Breen chief development officer, Ryan Daws has been hired as chief financial officer and head of business development, and Karen Brown has been appointed senior vice president, intellectual property and legal affairs. Stehman-Breen most recently served as chief medical officer at Dyne Therapeutics and Disarm Therapeutics. Daws was most recently managing director in the Healthcare Investment Banking Group with Robert W. Baird & Co. Brown was previously vice president and chief intellectual property counsel at Ironwood Pharmaceuticals.

**Passage Bio**
Passage Bio has announced the appointment of Jill Quigley as chief operating officer and general counsel and Alex Fotopoulos as chief technical officer. Quigley was formerly chief executive officer and general counsel at Nutrinia. Fotopoulos previously held the position of senior vice president, technical operations with Dimension Therapeutics.

**Recursion**
Heather Kirkby has been appointed chief people officer at Recursion Pharmaceuticals. Kirkby was formerly vice president of talent development at Intuit.

**Regulus Therapeutics**
Cris Calsada has been named chief financial officer at Regulus Therapeutics, effective August 30. Calsada was most recently chief financial officer at Sanifit.

**Rubius Therapeutics**
Kris Elverum has been appointed senior vice president of business development and strategy at Rubius Therapeutics. Elverum was most recently SVP of corporate development at Turnstone Biologics.

**SS&C Technologies**
SS&C Technologies Holdings has named Sean Hogan as president of SS&C Health. Hogan was formerly the general manager, healthcare and life sciences, at IBM.

**Sangamo Therapeutics**
Gary Loeb has been named executive vice president and general counsel at Sangamo Therapeutics. Loeb previously was general counsel, corporate secretary and chief compliance officer at Achaogen.

**Tridium**
Tridium has appointed Paul Castaldo senior vice president of corporate development. Castaldo was previously regional behavioral health care leader with Kaiser Permanente.

**Verastem Oncology**
Verastem Oncology has announced the appointment of Brian Stuglik as chief executive officer. Stuglik was previously global vice president and chief marketing officer, oncology, at Eli Lilly.

**Vivera**
Vivera Pharmaceuticals has named Greg Cervantes director of government affairs and Brad Townend has been appointed executive creative director. Cervantes is the former mayor of the city of Coachella, California. Townend previously held the position of creative director at Allergan.

**Ziopharm**
Satyavrat Shukla has been named chief financial officer at Ziopharm Oncology. Shukla most recently served as global head of corporate finance for Vertex Pharmaceuticals.
FDA, ICH Seek Comments

continued from page 1

- Blinding/Masking;
- Types of controls;
- Data quality;
- Endpoints; and
- Procedures supporting endpoints and data integrity.

To help identify quality factors, ICH E8(R1) recommends:

- Engaging all relevant stakeholders, including patients, in study planning and design;
- Ensuring study objectives address relevant scientific questions appropriate for a given study;
- Designing a meaningful comparison of the effects of a drug to the trial’s chosen control groups;
- Conducting a feasibility study to ensure the study is operationally viable;
- Choosing well-defined response variables and assessment methods; and
- Specifying in the protocol information about study subjects that may be important to understanding the benefit/risk of the drug.

The update also addresses the diversity of clinical study designs and data sources, encouraging trials to think outside the traditional box of phases 1-4. “The phase concept is a description, not a set of requirements,” the draft guidance says, and categorizing trials by study objective also is an option.

For example, a progression of studies could be categorized as nonclinical testing, human pharmacology, exploratory, confirmatory and postapproval.

In addition to recommendations on incorporating quality into clinical studies, ICH E8(R1) includes suggestions on study design elements, study conduct and reporting.

For example, it stresses the importance of patient centricity — designing the trial around the patient. By involving patients in the early stage of study design, researchers are likely to “increase trust in the study, facilitate recruitment and promote adherence, which should continue throughout the duration of the study,” ICH says.

The FDA will accept comments on the draft until September 30, and ICH will hold a public meeting to solicit input on Oct. 31 in Silver Spring, Maryland. ICH hopes to have final guidance ready to publish by June 2020.

ICH also is in the process of developing another clinical trial-related guideline, E19 — Optimization of Safety Data Collection, aiming to publish it in 2021 (CenterWatch, July 1, 2019). And the organization is in the initial planning stages for a revision of E20 — Adaptive Clinical Trials.

Read the draft ICH E8(R1) here: https://bit.ly/2MDA8tZ.
Consistent AE Review

Sites need to make sure that those assessing AEs are trained, qualified and clearly designated in AE-related procedures. The PI, a co- or sub-investigator or other trained personnel are commonly used, but sponsor and IRB requirements also can play a role in who is delegated to this task. In some cases, the sponsor might have specific instructions, such as that a physician perform the assessment.

The FDA considers AE data a key indicator of patient risk and study data quality, Lieberman noted, and so focuses on this area during study site inspections. Sites need to be prepared for a regulatory inspection with a comprehensive AE plan tailored to each study, he said.

The agency will examine the study’s/ site’s process for reviewing and reporting AEs, as well as conducting a review of source materials to determine whether AEs have been reported appropriately. For instance, the agency may ask to:

- Review progress notes and confirm whether an AE report was required;
- Review imaging reports and have the PI explain any findings not reported as AEs;
- Review patient discharge summaries to confirm that all serious AEs were reported;
- Have the PI explain why certain events were deemed part of a pre-existing condition and not reported;
- Have the PI explain the process for determining what is and is not a reportable AE; and
- Receive an explanation as to why certain individual AEs or certain types of events were not reported.

Once AEs have been identified, compliance with AE reporting requirements comes down to two steps, said Michael Marcota, project manager at IMARC: assessment of which events meet the definition of a reportable AE; and timely and accurate reporting of AEs to the device sponsor, the IRB or both, as required under applicable regulations, individual study protocols and IRB policies.

In the assessment stage, the goal is to determine which events qualify as reportable AEs under applicable definitions. Not all events will be AEs. For instance, pre-existing conditions generally don’t qualify, nor do abnormal imaging or lab tests that are not “untoward medical occurrences,” a term often seen in regulatory and other requirements. Generally, the assessment should consider whether an event was:

- Unexpected, a known and foreseeable risk or the natural progression of the patient’s underlying condition;
- Related to the device, study procedures, pre-existing or underlying patient conditions or patient participation in the study; and
- Serious, resulting in hospitalization, disability or incapacity, congenital or birth defect or death, or otherwise threatening the patient’s life and health.

How a site reports AEs depends on regulatory definitions and regulations. FDA regulations in 21 CFR 812.3 define unanticipated adverse events (UAEs) that must be reported to the sponsor. The ICH good clinical practices guideline, E6(R2), and ISO standard 14155 likewise define serious AEs. There are some differences among the definitions, so AE review and assessment procedures must account for any that are applicable. In addition, researchers must comply with AE reporting requirements spelled out in the policies of the IRBs responsible for different sites, as well as those in individual study protocols.

This can make it challenging to apply a single AE procedure to different trials that may be subject to different IRBs and protocols, Marcota noted. Even within a single study, if multiple sites are involved, that could mean complying with different IRB policies, since sites may fall under the purview of different IRBs. Timeliness is equally important. Regulations require that UAEs be reported to the device sponsor within 10 days, but specific study protocols or IRB policies may have different requirements.
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## Drug & Device Pipeline News

For news on trial results, FDA approvals and drugs in development, Join the LinkedIn Drug Research Updates group!

<table>
<thead>
<tr>
<th>Company</th>
<th>Drug/Device</th>
<th>Medical Condition</th>
<th>Status</th>
<th>Sponsor Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Miracor Medical SA</td>
<td>PiCSO therapy</td>
<td>heart attack</td>
<td>Phase 1 trial initiated</td>
<td>miracormedical.com</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>enrolling 114 subjects</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>with anterior STEMI, TIMI 0 &amp; 1 Flow, at nine clinical sites in Western Europe</td>
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<tr>
<td>Reflow Medical, Inc.</td>
<td>Temporary Spur Stent System</td>
<td>peripheral artery disease (PAD), occlusive disease affecting below-the-knee (BTK) arteries</td>
<td>Phase 1 trial initiated</td>
<td>reflowmedical.com</td>
</tr>
<tr>
<td>I-Mab Biopharma</td>
<td>TJDS (TJ004309)</td>
<td>advanced solid tumors</td>
<td>Phase 1 trial initiated</td>
<td>i-mabbiopharma.com</td>
</tr>
<tr>
<td>Tracon Pharmaceuticals, Inc.</td>
<td></td>
<td></td>
<td></td>
<td>traconpharma.com</td>
</tr>
<tr>
<td>AC Immune SA</td>
<td>ACI-35.030</td>
<td>Alzheimer's disease (AD)</td>
<td>Phase 1b/2a trial initiated</td>
<td>acimmune.com</td>
</tr>
<tr>
<td>Proteostasis Therapeutics, Inc.</td>
<td>cystic fibrosis</td>
<td>cystic fibrosis (CF)</td>
<td>Phase 2 trial initiated</td>
<td>proteostasis.com</td>
</tr>
<tr>
<td></td>
<td>transmembrane conductance regulator (CFTR) modulator combinations doublet (PTI-808 and PTI-801) and triplet (PTI-808, PTI-801 and PTI-428)</td>
<td>Phase 2 trial initiated</td>
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<td></td>
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<td>enrolling 30 F508del homozygous and 30 F508del heterozygous subjects</td>
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<tr>
<td>Arena Pharmaceuticals</td>
<td>orilinab</td>
<td>gastrointestinal (GI) disorders</td>
<td>Phase 2 trial initiated</td>
<td>arenapharm.com</td>
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<td></td>
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<td></td>
<td>enrolling 240 subjects</td>
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<td></td>
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<td></td>
<td>experiencing abdominal pain associated with IBS, including IBS with constipation (IBS-C) or IBS with diarrhea (IBS-D) in sites across the U.S.</td>
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</tr>
<tr>
<td>Relmada Therapeutics, Inc.</td>
<td>REL-1017 (dextromethadone)</td>
<td>treatment-resistant depression</td>
<td>Phase 2 trial initiated</td>
<td>relmada.com</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>enrolling 62 subjects</td>
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<tr>
<td>BELLUS Health Inc.</td>
<td>BLU-5937</td>
<td>chronic cough</td>
<td>Phase 2 trial initiated</td>
<td>bellushealth.com</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>enrolling 65 subjects</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>with refractory chronic cough at 12 sites in the U.S. and U.K.</td>
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<tr>
<td>Auris Medical Holding Ltd.</td>
<td>AM-125</td>
<td>acute vertigo</td>
<td>Phase 2 trial initiated</td>
<td>aurismedical.com</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>enrolling 138 subjects</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>who suffer from acute vertigo following surgical removal of a vestibular schwannoma in six European countries and Canada</td>
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<tr>
<td>Resolve Therapeutics</td>
<td>RSLV-132</td>
<td>Systemic Lupus Erythematosus</td>
<td>Phase 2a trial initiated</td>
<td>resolvebio.com</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>enrolling 64 subjects</td>
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<tr>
<td></td>
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<td></td>
<td>at 20 sites across the U.S.</td>
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<tr>
<td>Abivax</td>
<td>ABX464-301</td>
<td>moderate to severe active rheumatoid arthritis (RA)</td>
<td>Phase 2a trial initiated</td>
<td>abivax.com</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>enrolling 60 subjects</td>
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<td></td>
<td></td>
<td></td>
<td>in France, Poland, Czech Republic and Hungary</td>
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<tr>
<td>Modra Pharmaceuticals B.V.</td>
<td>ModraDoc006/r</td>
<td>metastatic Castration-Resistant Prostate Cancer (mCRPC)</td>
<td>Phase 2b trial initiated</td>
<td>modrapharmaceuticals.com</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>enrolling 100 subjects</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>with mCRPC eligible for first line systemic chemotherapy at 40 sites in the U.S. and Europe</td>
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### Drug & Device Pipeline News (continued from page 7)

<table>
<thead>
<tr>
<th>Company</th>
<th>Drug/Device</th>
<th>Medical Condition</th>
<th>Status</th>
<th>Sponsor Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biohaven Pharmaceutical Holding Company Ltd.</td>
<td>verdiperstat</td>
<td>Multiple System Atrophy (MSA)</td>
<td>Phase 3 trial initiated enrolling 250 subjects at 50 sites in the U.S. and Europe</td>
<td>biohavenpharma.com</td>
</tr>
<tr>
<td>AZTherapies, Inc.</td>
<td>ALZT-OP1</td>
<td>early Alzheimer’s disease</td>
<td>Phase 3 trial initiated enrolling 620 subjects with early stage Alzheimer’s disease, ages 55-79</td>
<td>aztherapies.com</td>
</tr>
<tr>
<td>Nektar Therapeutics</td>
<td>bempegaldesleukin</td>
<td>subjects with previously untreated unresectable or metastatic melanoma</td>
<td>Breakthrough Therapy designation granted by the FDA</td>
<td>nektar.com</td>
</tr>
<tr>
<td>Bristol-Myers Squibb</td>
<td>PROPEL mini steroid</td>
<td>frontal and ethmoid sinus surgery</td>
<td>Approval granted by the FDA</td>
<td>bms.com</td>
</tr>
<tr>
<td>Endotronix, Inc.</td>
<td>Cordella Pulmonary Artery (PA) Pressure Sensor System</td>
<td>chronic heart failure</td>
<td>IDE approval granted by the FDA</td>
<td>endotronix.com</td>
</tr>
<tr>
<td>Intersect ENT</td>
<td>PROPEL</td>
<td>frontal and ethmoid sinus surgery</td>
<td>Approval granted by the FDA</td>
<td>intersectent.com</td>
</tr>
<tr>
<td>Retrophin, Inc.</td>
<td>THIOLA EC (tiopronin)</td>
<td>cystinuria</td>
<td>Approval granted by the FDA</td>
<td>retrophin.com</td>
</tr>
<tr>
<td>Merck</td>
<td>KEYTRUDA (pembrolizumab)</td>
<td>subjects with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (Combined Positive Score [CPS] ≥10) with disease progression after one or more prior lines of systemic therapy</td>
<td>Approval granted by the FDA</td>
<td>merck.com</td>
</tr>
<tr>
<td>Bayer</td>
<td>Nubeqa (darolutamide)</td>
<td>non-metastatic castration-resistant prostate cancer (nmCRPC)</td>
<td>Approval granted by the FDA</td>
<td>bayer.com</td>
</tr>
</tbody>
</table>

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Jobs via Kelly Services

<table>
<thead>
<tr>
<th>Position</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Director</td>
<td>Palo Alto, CA</td>
</tr>
<tr>
<td>Medical Receptionist</td>
<td>Evansville, IN</td>
</tr>
<tr>
<td>Research Associate - qPCR</td>
<td>Carlsbad, CA</td>
</tr>
<tr>
<td>Associate Scientist</td>
<td>South San Francisco, CA</td>
</tr>
<tr>
<td>Genetic Associate Lab Technologist</td>
<td>Pittsburgh, PA</td>
</tr>
<tr>
<td>Assistant Manager of Donor Services</td>
<td>Knoxville, TN</td>
</tr>
<tr>
<td>Clinical Support Coordinator</td>
<td>San Diego, CA</td>
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<tr>
<td>Certified Pharmacy Technician</td>
<td>Oakwood, OH</td>
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More Jobs

<table>
<thead>
<tr>
<th>Position</th>
<th>Location</th>
</tr>
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<tbody>
<tr>
<td>Manager, Clinical Programming</td>
<td>Bala Cynwyd, PA</td>
</tr>
<tr>
<td>Clinical Research Coordinator</td>
<td>Scottsdale, AZ</td>
</tr>
<tr>
<td>Drug Industry Daily Reporter</td>
<td>Falls Church, VA</td>
</tr>
<tr>
<td>Administrative Assistant, Patient Outreach and Marketing</td>
<td>WIRB-Copernicus Group (WCG)</td>
</tr>
<tr>
<td>Associate Data Manager</td>
<td>WIRB-Copernicus Group (WCG)</td>
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<tr>
<td>Contracts Administrator</td>
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<td>Genetic Associate Lab Technologist</td>
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Academic Programs

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<th>Institution</th>
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<tr>
<td>Boston College</td>
<td>Clinical Research Certificate Program</td>
</tr>
<tr>
<td>Drexel University College of Medicine</td>
<td>Master’s/Certificate Programs in Clinical Research Organization and Management Online</td>
</tr>
<tr>
<td>University of North Carolina at Wilmington</td>
<td>MS Clinical Research and Product Development Online</td>
</tr>
</tbody>
</table>

Upcoming Event Highlights

Conferences

- **SEPTEMBER 4-5, 2019**
  - Clinical Trial Risk & Performance Management Summit
  - Philadelphia, PA
- **SEPTEMBER 27-29, 2019**
  - Society of Clinical Research Associates 2019 Annual Conference
  - San Antonio, TX
- **OCTOBER 23-25, 2019**
  - FDA Inspections Summit
  - Bethesda, MD
- **OCTOBER 27-30, 2019**
  - MAGi Clinical Research Conference 2019 West
  - Las Vegas, NV

Webinar

- **AUGUST 15, 2019**
  - Real World Evidence and Data: A Tufts Study of 30 Pharma Companies
  - 1:30 p.m. – 3:00 p.m. EDT
  - Based on their knowledge, and using several recent case studies, Dr. Mary Jo Lambert — associate director of sponsored research at the CSDD — and Francis Kendall — senior director at Cytel — will share valuable information on:
    - Types of technology used to access or collect RWD and evidence and partnerships that support usage
    - Significant challenges to using RWD as well as strategies and practices that impact return on investment or performance
    - The key drivers for change and the adoption of RWE
    - And more