Sponsors Need Vendors’ Metrics to Select the Best

An issue causing growing frustration among clinical trial executives are vendors unable or unwilling to share metrics with sponsors.

While careful vendor selection is more critical than ever because of ICH E6, sponsors are increasingly frustrated with a lack of metrics to help gauge how likely it is that an operational problem may arise with a vendor.

“You need information to be able to help you understand what has happened in the past, how often it happened, how bad the impact is when it does happen,” says Linda Sullivan, co-founder and executive director of Metrics Champion Consortium (MCC).

Preparing for the Unexpected is a Team Effort

By Ashley Hay

SAN DIEGO – How effectively a sponsor, CRO or site responds to a trial-disrupting emergency all depends on the planning they do long before disaster strikes.

Don’t wait to prepare, Jennifer Sheller, Merck’s North American regional head of global clinical trial operations, advised attendees at the Drug Information Association conference last week.

Sheller shared lessons Merck has learned from helping its trial sites through hurricanes and other difficult situations. Common issues that hinder a site in emergency conditions include inability of patients to get to their scheduled visits or site staff to show up on time for their shifts. Supplies may be lost or inaccessible, electricity and phone lines may be down.

Establishing what Merck calls an incident management team (IMT) requires the participation of several different functions, including human resources, quality, clinical supply and data management. The response plan should include a chart that outlines all team members’ roles and lines of communication, as well as a list of all team members' and trial staff in positions of risk.

Create an IMT that can hit the ground running, Sheller said, stating that her current team can pull together within 30 minutes, fully able to meet and prepare for what lies ahead.

Problems with certain types of vendors can be more critical than others, according to Jill Petro, a trial manager at Janssen R&D.

”I think where people run into problems is when they don’t share enough information with the vendors about what’s going to happen in their program,” says Sullivan. “Often, problems in the design of the study could be avoided if vendors were brought in earlier.”

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Industry Briefs

**Pharma to FDA: Limit or Spell Out Use of Covariates in Randomized Trials**

The FDA should limit or at least spell out the different kinds of covariates allowed in randomized trials, a pair of drug industry giants told the agency.

In comments on the FDA's April draft guidance on adjusting for covariates in randomized trials, AstraZeneca and LabCorp urged the agency to consider just how much might be too much when using complicated covariation analysis to help determine statistical significances or to help sharpen estimates of how well a treatment might work.

AstraZeneca said it worries that too many prognostic factors could result in overfitting, which could lead to faulty conclusions.

LabCorp urged "caution" when thinking about covariates in small sample sizes, for similar reasons that AstraZeneca cited. The network also suggested that regulators include a discussion on what's to be done when covariates are missing data.

Read the draft guidance and the four comments here: https://bit.ly/2Fyn8Bh.

**FDA Seeks Comment on ICH Safety Data, Bioanalytical Validation Guidances**

The FDA is inviting public comment on two International Council for Harmonisation draft guidance documents, one designed to help move clinical trials along more quickly, the other designed to make sure that researchers are getting the best possible data before trials can get started.

In ICH E19 — Optimization of Safety Data Collection, the ICH asks whether some safety data can be trimmed from trials in order give patients a break from near-endless record-keeping. The council is interested in learning how some safety data could be cut out of trials.

Separately, in ICH M10 — Bioanalytical Method Validation, the council has issued draft guidelines on how researchers can validate their bioanalytical assays in nonclinical trials.

Comments on both draft guidances are due by Sept. 25.
Read the M10 guidance here: https://bit.ly/2KH3zuL.

**FDA Considers How Heart Patients Feel, Function, in New Draft Guidance**

Endpoints for heart failure drug trials could be based on improvements in subjects' symptoms and/or daily life, not just their survival, under a new draft guidance the FDA released last week.

“A drug that improves symptoms or function when added to standard of care would be valuable even if it did not improve survival or hospitalization,” the 10-page draft guidance says. “Moreover, it is possible that if a drug provided substantial and persistent improvement in symptoms or function … some decrease in survival would be acceptable.”

If sponsors want to take the quality-over-mortality path, the agency would consider such factors as:
- The mortality and other safety findings for similar drugs;
- The amount of time patients will be exposed to a candidate drug, such as a treatment of fewer than 10 days, which carries no requirement for long-term mortality data; and
- Mortality and safety data on the candidate drug for a closely related population.

Read the draft guidance here: https://bit.ly/2XBpNnZ.

**FDA to Require Clinical Data for High-Risk Tissue Ablation Systems**

Sponsors of certain high-risk prostate tissue ablation systems would have to collect additional clinical data to support their applications for FDA clearance under a draft guidance issued by the agency last week.

High-intensity ultrasound tissue ablations systems are considered “significant risk” devices, the draft guidance says, a classification that imposes additional requirements for clinical testing to document the device's adverse event profile and provide evidence of efficacy.

“Prostate tissue ablation devices addressed by this guidance document are significant risk devices subject to all requirements of the Investigational Device Exemptions (IDE) regulation,” the guidance says. Sponsors of such devices also would be required to follow clinical trial regulations governing IRB review and informed consent.

Recommended safety and efficacy endpoints should include determination that the device:
- Does not damage tissue outside the target range; and
- Does ablate tissue within the target range.

The guidance also would allow, in some cases, real-world data to support energy output changes to a device that already has obtained 510(k) clearance.

Comments on the draft guidance are due Aug. 26.
Read the draft guidance here: https://bit.ly/2Xg0h8r.

continues on next page»
FDA Issues Guidance on Developing Drugs to Treat Epidermolysis Bullosa

Sponsors of drugs to treat or prevent serious flare-ups of certain skin disorders are allowed to use endpoints based on symptom relief under a final guidance from the FDA.

There is insufficient clinical experience to establish definitive endpoints for treatment of epidermolysis bullosa, the guidance says, but trials may collect data on effects on symptoms such as itching, pain, blister prevention, and wound healing.

Before beginning a trial, the agency recommends sponsors discuss with the review division the choice of the primary efficacy endpoints and the time point for evaluation.

The guidance notes that recruitment and retention of patients with certain types of EB is challenging because trial procedures can exacerbate skin damage. Special considerations for this may include telemedicine and other avenues to reduce the need for patient travel.

Read the full guidance here: https://bit.ly/2J7KcrC.

FDA Plans 2019 Draft Guidances on Trial Designs, Gene Therapies

The FDA's Center for Biologics Evaluation and Research has released its guidance agenda for the second half of 2019, including planned draft guidances on trial designs and several gene therapies.

In its guidance agenda for the remainder of the year, CBER lists a draft guidance for sponsors on working with the FDA to design complex and innovative trials for drug and biologic products.

The list also includes plans for draft guidances on the study of human gene therapies for hemophilia, retinal disorders and rare diseases.

The guidance agenda does not guarantee that CBER will address all topics on the list and does not preclude the center from developing guidance documents on subjects not on the list.


FDA Rethinking Trial Data Transparency Pilot

The FDA is turning to the public to help decide whether it should continue its languishing program to share trial data on approved drugs.

Launched in 2018, the agency’s plan was to enroll nine drug sponsors in a pilot program to test the feasibility of releasing sponsor-generated summaries of trial methods and results. In March 2018 the pilot produced a single data summary report and has shown no activity since then (CenterWatch, January 21, 2019).

In a Federal Register notice last week, the FDA invited drug companies and other interested parties to weigh in on the future of the pilot program. The agency said it wants to hear from drug companies about their concerns and suggestions for improving the program enough to attract more participants.

At the same time, it asks for comments on whether to scrap the pilot and focus on a new review template for drug sponsors. The template proposed would summarize expert views on a drug’s safety and efficacy instead of having reviewers comment individually.

Comments are due by Aug. 26.

Read the notice here: https://bit.ly/2ZORsiT.

AbbVie to Acquire Allergan in Seismic $63 Billion Deal

AbbVie sent shockwaves through the drug industry last week, announcing that it had reached a deal to acquire fellow drug giant Allergan for approximately $63 billion.

The deal will bring Allergan and its blockbuster Botox under AbbVie’s roof, giving AbbVie some security as the exclusivity for rheumatoid arthritis blockbuster Humira nears its 2023 expiration. Humira earned global sales of almost $20 billion in 2018, while Botox earned $3.6 billion.

The deal is subject to federal review, but it's roughly half of what was on offer three years ago, when Pfizer walked away from a proposed $160 billion takeover of Allergan.

Allergan President and CEO Brett Sanders will join AbbVie’s board under the terms of the transaction.
**Up and Coming**

*This feature highlights changes in clinical research organizations’ personnel.*

**Pfizer**

Former FDA Commissioner Scott Gottlieb has joined the board of directors at Pfizer. Gottlieb will serve on two different board-level committees, the Regulatory and Compliance Committee and the Science and Technology Committee.

**Zelluna**

Zelluna Immunotherapy has announced the appointment of Jens-Peter Marschner as chief medical officer. Marschner was previously Abbvie’s oncology medical lead for Western Europe and Canada.

**Cambrex**

Cambrex Corporation has announced three senior appointments. Dottie Donnelly-Brienza has been named senior vice president and chief human resources officer; Bruno Biscaro has been appointed president, drug products; and Joe Nettleton has been named senior vice president, drug substance. Brienza most recently served as chief human resources officer at Cantel Medical. Biscaro was previously president, North America at Famar. Nettleton previously held the position of vice president, U.S. operations with Cambrex.

**Ambys Medicines**

Deidre Roniger has been appointed senior vice president, corporate development and Amanda Valentino as chief people officer at Ambys Medicines. Roniger was previously managing partner at DNA Ink. Valentino was most recently the senior director of talent acquisition and strategy at Genentech.

**TB Alliance**

TB Alliance has named Eugene Sun to the position of senior vice president for research and development. Sun was previously the senior advisor to the HHS Biomedical Advanced Research and Development Authority.

**STADA**

Eelco Ockers has been appointed executive vice president, Germany at STADA. Ockers was most recently regional director DACH & Nordics at Reckitt Benckiser.

**eXthera**

eXthera Pharmaceuticals has named Michael Kurz as vice president of translational medicine and medical affairs at the clinical-stage biotechnology company. Kurz previously served as executive director and head of translational medicine and medical affairs at Edge Therapeutics.

**SmartPharm**

José Trevejo has been named chief executive officer at SmartPharm Therapeutics. Trevejo, a co-founder of SmartPharm, was most recently vice president, clinical development at Cycle- rion Therapeutics.

**DBV Technologies**

DBV Technologies has appointed Pharis Mohideen as chief medical officer of DBV Technologies, effective July 22. Hugh Sampson, who assumed the role of interim CMO in early 2019, will continue with the company as chief scientific officer. Mohideen most recently served as chief medical officer with Millendo Therapeutics.

**Paratek**

Evan Loh has been promoted to chief executive officer at Paratek Pharmaceuticals. Loh has served as chief operating officer at Paratek since January 2017 and as president and chief medical officer since June 2014. Michael Bigham, who had served as the chairman and CEO since 2014, will remain with the company in the newly created role of executive chairman.

**Parata**

Parata Systems has announced the appointment of Rocco Volpe as chief operating officer. Volpe was previously vice president, global operations at Cognex Corporation.

**Abeona**

Abeona Therapeutics Inc. has announced the appointment of Victor Paulus as senior vice president, regulatory affairs, and Jodie Gillon as vice president of patient advocacy and clinical affairs. Paulus was previously vice president and global head of regulatory affairs at clinical-stage immunotherapy company Hookipa Pharma. Gillon previously spent more than a decade with Pfizer as the global medical lead for patient engagement within the rare diseases unit and the director of medical communications within the chief medical office.

**Impel**

John Leaman has been named chief financial officer at Impel NeuroPharma. Leaman was formerly the chief financial officer and head of corporate development at Selecta Biosciences.

**EVERSANA**

Bhaskar Sambasivan has been named president, patient services and chief strategy officer at EVERSANA. Sambasivan was most recently the senior vice president and global head, life sciences at Cognizant.

**RevoluGen**

Stefano Giolito has been appointed chief marketing officer at RevoluGen. Giolito was previously the marketing global vice president of Unilever.
Sponsors Need Vendors’ Metrics continued from page 1

Although translation, laboratory and interactive voice/web response vendors comprise a small portion of the overall clinical research enterprise, mistakes in those areas can cause critical delays, Petro says, so it’s important to be particularly vigilant.

“It’s easy to say you’re trying to pick for the best quality,” she says, “but there are a lot of things that feed into quality.” Petro recommends using a checklist to make sure all considerations are covered.

For translation vendors specifically, Petro advises asking what portion of the staff is full-time (to gauge the likelihood of high turnover), and about the minimum training requirements for staff (to gauge the likelihood of errors).

Another important component is the vendor’s internal quality standards, such as requiring double-checks for each document, and whether those additional quality checks come at an extra charge. Finally, it’s best to ask about the vendor’s policy on a rush and whether those additional quality checks later down the line.

For central laboratories, Petro recommends asking about such factors as the lab’s ability to perform all of the tests the trial requires, how long it takes to ship kits to sites and how quickly it can deliver results. She also advises asking about the company’s ability to transfer data to the sponsor and whether there is an additional charge for doing so.

Finally, for interactive voice services, sponsors should be aware of the vendor’s experience with the type of trial being conducted, such as a randomization v. stratification trial design. Like the other vendors, the vendor should be able to transfer data and should be comfortable with the various countries/languages included in the study.

“It all comes back to that risk base and oversight” outlined in ICH E6, Petro says. “Every company is looking for technology solutions [to] be able to tell FDA inspectors that they are doing their oversight.”
Preparing for the Unexpected
continued from page 1

“To ensure your sites are ready to handle unexpected events, revisit your emergency preparedness plan often. Having site staff sign and acknowledge standards of practice only goes so far.”

— Ray Policare, global monitoring partner lead, Merck

Emergency response for clinical trials means more than assisting patients and site staff, however. Documents should be protected as well. A preparedness plan should direct sites to regularly secure and backup all their data, and the response team should maintain a high level of detail in its documentation of the relief effort, recording in the trial master file such information as the number of sites impacted, issues with patient access to the trial drug, and changes in scheduled monitoring visits.

To ensure your sites are ready to handle unexpected events, revisit your emergency preparedness plan often. Having site staff sign and acknowledge standards of practice only goes so far, Policare said. Implementing mandatory annual training along with running mock-disasters can help increase everyone’s readiness.

He said Merck’s response team in the past has had trouble keeping up with developments on the ground — weather changes, etc. — and so has included links to helpful resources such as NOAA, the National Weather Service, CalFire and Ready.gov in the company’s preparedness plan.

Safety when in a dangerous environment. A check-in system should be a priority. Sheller suggested the use of a geospatial tracking tool to monitor the locations of team members, site staff and patients. Phone trees, maps and lists of staff in positions of risk all can be helpful.

The IMT also should be able to pack essential items and evacuate quickly, Policare said, if the situation becomes dangerous, a lesson he learned personally when his home in California was threatened by a wildfire.

Communication also is essential to Merck’s plan, and not just among team members. Policare encouraged the use of line managers to communicate information regarding staff safety all the way up to the CEO.

Communication insights: Learn inside techniques to attaining smooth cooperative relationships with your sites, as well as maintaining a high standard of due diligence through dozens of communications takeaways.

High index of suspicion: Develop a sharp eye for potential problems and errors that can threaten the integrity of clinical trials and know when to “communicate and escalate” in a timely fashion to prevent protocol or GCP violations.

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**High index of suspicion:** Develop a sharp eye for potential problems and errors that can threaten the integrity of clinical trials and know when to “communicate and escalate” in a timely fashion to prevent protocol or GCP violations.

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## Drug & Device Pipeline News

<table>
<thead>
<tr>
<th>Company</th>
<th>Drug/Device</th>
<th>Medical Condition</th>
<th>Status</th>
<th>Sponsor Contact</th>
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<tbody>
<tr>
<td>Cyxone</td>
<td>T20K</td>
<td>multiple sclerosis (MS)</td>
<td>Phase I trial initiated enrolling healthy male volunteers in the Netherlands</td>
<td>cyxone.com</td>
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<td>NantKwest Inc.</td>
<td>PD-L1 t-haNK</td>
<td>solid tumors</td>
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<td>Pepscan</td>
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<td>cancer</td>
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<td>pepscan.com</td>
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<td>I-Mab Biopharma</td>
<td>TJC4</td>
<td>advanced malignant tumors</td>
<td>Phase I trial initiated</td>
<td>i-mabbiopharma.com</td>
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<td>Asieris Pharmaceuticals</td>
<td>APL-1202 in combination with BCG (Bacillus Calmette Guerin)</td>
<td>non-muscle invasive bladder cancer (NMIBC)</td>
<td>Phase Ib trial initiated enrolling subjects in China</td>
<td>asieris.cn</td>
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<tr>
<td>Precigen, Inc.</td>
<td>PRGN-3006 UltraCAR-T</td>
<td>relapsed or refractory acute myeloid leukemia (AML) or higher risk myelodysplastic syndrome (MDS)</td>
<td>Phase I/II trial initiated enrolling seven subjects</td>
<td>precigen.com</td>
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<tr>
<td>Syntrix Pharmaceuticals</td>
<td>SX-682 in combination with KEYTRUDA (pembrolizumab)</td>
<td>metastatic melanoma</td>
<td>Phase I/II trial initiated enrolling 77 subjects at Massachusetts General Hospital and Dana Farber Cancer Institute</td>
<td>syntrixbio.com</td>
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<tr>
<td>Minovia Therapeutics</td>
<td>Mitochondrial Augmentation Therapy (MAT)</td>
<td>Pearson syndrome</td>
<td>Phase II trial initiated enrolling 12 subjects with PBH</td>
<td>minovia.com</td>
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<tr>
<td>Xeris Pharmaceuticals, Inc.</td>
<td>developmental ready-to-use glucagon</td>
<td>Post-bariatric hypoglycemia (PBH) following bariatric surgery</td>
<td>Phase II trial initiated enrolling 12 subjects with PBH</td>
<td>xerispharma.com</td>
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<td>iLiAD Biotechnologies</td>
<td>BPZE1</td>
<td>pertussis</td>
<td>Phase IIb trial initiated</td>
<td>iliadbio.com</td>
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<td>X4 Pharmaceuticals, Inc.</td>
<td>mavorixafor (X4P-001)</td>
<td>WHIM (Warts, Hypogammaglobulinemia, Infections and Myelokathexis)</td>
<td>Phase III trial initiated enrolling 28 subjects in 20 countries</td>
<td>x4pharma.com</td>
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<tr>
<td>XW Laboratories Inc.</td>
<td>XWL-008</td>
<td>narcolepsy</td>
<td>Orphan Drug designation granted by the FDA</td>
<td>xwlabs.com</td>
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<tr>
<td>Aridis Pharmaceuticals, Inc.</td>
<td>AR-501</td>
<td>lung infection associated with cystic fibrosis</td>
<td>Orphan Drug designation granted by the FDA</td>
<td>aridispharma.com</td>
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<td>LifeMax Laboratories, Inc.</td>
<td>LM-030</td>
<td>Netherton Syndrome</td>
<td>Orphan Drug designation granted by the FDA</td>
<td>lifemaxlabs.com</td>
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<td>Boehringer-Ingelheim Eli Lilly and Company</td>
<td>emapogliflozin</td>
<td>chronic heart failure</td>
<td>Fast Track designation granted by the FDA</td>
<td>boehringer-ingelheim.com lilly.com</td>
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<tr>
<td>Arrowhead Pharmaceuticals Inc.</td>
<td>ARO-AAT</td>
<td>alpha-1 liver disease</td>
<td>Fast Track designation granted by the FDA</td>
<td>arrowheadpharma.com</td>
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<td>ANI Pharmaceuticals, Inc.</td>
<td>Vancomycin Hydrochloride for Oral Solution USP, 250 mg/5 ml</td>
<td>enterocolitis caused by <em>Staphylococcus aureus</em> (including meticillin-resistant strains) and antibiotic-associated pseudomembranous colitis caused by C. difficile</td>
<td>Approval granted by the FDA</td>
<td>anipharmaceuticals.com</td>
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<td>Regeneron Pharmaceuticals, Inc.</td>
<td>Dupixent (dupilumab)</td>
<td>chronic rhinosinusitis with nasal polyposis (CRSwNP)</td>
<td>Approval granted by the FDA</td>
<td>regeneron.com</td>
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<td>Dignitana AB</td>
<td>DigniCap Delta</td>
<td>chemotherapy-induced hair loss</td>
<td>Approval granted by the FDA</td>
<td>dignitana.com</td>
</tr>
</tbody>
</table>
Upcoming Event Highlights

**Conferences**

**SEPTEMBER 4-5, 2019**
**Clinical Trial Risk & Performance Management Summit**
Philadelphia, PA
Discover the secrets to implementing a successful metrics program by choosing one of two tracks, vendor oversight or risk-based quality management.

**SEPTEMBER 27-29, 2019**
**Society of Clinical Research Associates 2019 Annual Conference**
San Antonio, TX
For the 28th year, SOCRA will welcome clinical research professionals from across the world. This three-day conference will offer current information and tools, best practices and training to assure that you’re up-to-date and compliant in your clinical research practice.

**OCTOBER 23-25, 2019**
**FDA Inspections Summit**
Bethesda, MD
Over the past 13 years thousands of industry professionals have attended the FDA Inspections Summit and benefited from the unmatched presentations and panel discussions led by FDA officials and industry experts.

**OCTOBER 27-30, 2019**
**MAGI Clinical Research Conference 2019 West**
Las Vegas, NV
The conference includes 100+ sessions and workshops in six tracks that offer practical information on clinical operations & project management, site management, contracts, budgets & billing, regulatory compliance and special topics. Earn 23.5+ CME, CNE, CLE, CCB and other credits.

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**Jobs via Kelly Services**

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<tr>
<th>Position</th>
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<tr>
<td>Clinical Supply Planning Manager</td>
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<tr>
<td>Clinical Supply Chain Specialist</td>
<td>Santa Ana, CA</td>
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<td>Schedule Coordinator</td>
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<tr>
<td>Clinical Research Scientist</td>
<td>Summit, NJ</td>
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<tr>
<td>Clinical Director</td>
<td>Palo Alto, CA</td>
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<td>Laboratory Technician (Molecular)</td>
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<td>Quality Assurance Manager</td>
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<td>Laboratory Supervisor (Molecular)</td>
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**More Jobs**

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<td>Clinical Research Specialist</td>
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<td>Clinical Research Principal Investigator</td>
<td>Care Plus NJ, Paramus, NJ</td>
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<td>Contract Analyst</td>
<td>WIRB-Copernicus Group (WCG), Cary, NC</td>
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<td>Clinical Research Nurse Coordinator</td>
<td>Minnesota Epilepsy Group PA, Saint Paul, MN</td>
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<tr>
<td>Principal Clinical Data Analyst</td>
<td>WIRB-Copernicus Group (WCG), Wayland, MA</td>
</tr>
<tr>
<td>Sr. Clinical Research Associate</td>
<td>Camras Vision, Research Triangle Park, NC</td>
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</table>

**Academic Programs**

- Boston College
  - **Clinical Research Certificate Program**
    Chestnut Hill Campus, Newton, MA

- Drexel University College of Medicine
  - **Master’s/Certificate Programs in Clinical Research Organization and Management**
    Online

- University of North Carolina at Wilmington
  - **MS Clinical Research and Product Development**
    Online

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