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CenterWatch Weekly

November 18, 2019

Mayo's Startup Acceleration Project Cuts Timelines Dramatically

By Colin Stoecker

Mayo Clinic has cut its study start up times by two-thirds, thanks to administrative restructuring, staff education and new technology.

Through its Transforming the Activation of Clinical Trials (TACT) project, the clinic was able to bring study startup times down from 183 days in 2015 to an average 65 days in 2019.

And TACT is paying off in sponsor satisfaction. Thanks to the initiative, 82 percent of industry sponsors said they were either satisfied or highly satisfied with study startup times.

"We are being viewed very favorably from sponsors and CROS, and they have expressed gratitude," said Julie Watters, senior project manager at Mayo Clinic.

In 2015, when the project began, "We were recognizing that it was taking too long to activate clinical trials," said Watters. "And after our leaders identified this, we realized that over time the process for activating clinical trials had become more complex."

Mayo's newly formed Office of Clinical Trials, headed by medical director Adil Bharucha, restructured the study startup process to get financial, contractual and regulatory work done at the same time rather than sequentially.

Getting principal investigators (PI) involved early in the process was critical. But the office also added five new associate project managers to serve as quarterbacks for study startups.

see **Mayo's Startup Acceleration** on page 6 »

Ask the Expert: Examining and Reporting Safety Information

This monthly feature presents a variety of questions from clinical trial professionals with answers from WCG Clinical's expert staff. This month features two WCG pharmacovigilance experts, WCG Vigilare Vice President Angela Pittwood and Jim Bannon, president of the scientific and regulatory review division of WCG Clinical.

Question:

How, and how frequently, should I look at aggregate data to ensure patient safety?

Answer:

Pittwood: I believe that it's important to be looking at the data all the time. Even with small clinical trials, I think it's important to know what's happening. The first part of any kind of risk management is the safety physician who sees these safety reports coming in.

As the individual cases are being processed, that's your first line of defense, so to speak. And then, as you work through the protocol and as you work through the different studies, I think it's important to start to look at any kind of adverse events of special interest — anything that is in the protocol or in the class of product that you might want to make sure is being addressed as it happens. Maybe there are certain events that may occur that you want to make sure are not happening on a frequent basis.

Looking at the data as it comes in is one thing, but then looking at it as it accumulates each month, each quarter leads into your aggregate reports or your study reports. That's when you're going to be looking at that data more clearly and look-

see **Ask the Expert** on page 7 »

Industry Briefs

Final Guidance on Smallpox Development Using the Animal Rule

In preparation for a potential smallpox outbreak or bioterrorism attack, a final FDA guidance provides recommendations for testing vaccines in animals.

Under the FDA's Animal Rule, drugmakers can test live viruses on animals in lieu of endangering human subjects. The FDA guidance requires data from at least two lethal animal studies to show efficacy of the vaccine because "no single animal model is known to be the best predictor of human responses to smallpox."

The guidance directs sponsors conducting such animal studies to prepare designs for one or more clinical trials in the event of a public emergency involving smallpox.

"The design of these animal studies should be based on the general principles of human clinical trial design," says the guidance.

Google Data Partnership Under HHS Scrutiny

A data-sharing partnership between Google and a 21-state private health network is under scrutiny by the Department of Health and Human Services over whether the effort is HIPAA-compliant.

Launched last week, Google's Project Nightingale gives the tech giant the ability to analyze the personal health information from the Ascension Catholic hospital system, using artificial intelligence (AI) tools to help Ascension devise personalized medical treatments.

The hospital system claims that Google's G-Suite is HIPAA-compliant and builds on its robust data and security protection protocols. Google said that it would answer HHS's questions as part of the probe but believes that it has maintained HIPAA compliance.

Mayo Clinic entered into a similar agreement with Google earlier this year to store its data in their cloud and use its AI toolset to analyze the information. Mayo Clinic, however, specified that the information held by Google would be de-identified to remove any danger of individual patients being recognized.

IMDRF Updates Guidelines for Clinical Investigations of New Devices

Three updated international guidelines on medical devices released last week define what clinical evidence is needed for marketing approval of a new device.

In an effort to keep current with industry developments, the International Medical Device Regulators Forum's (IMDRF) guidelines for investigational devices define when a devicemaker must conduct a clinical trial and when it may rely on existing evidence gathered from published literature.

Devicemakers must conduct their own clinical trials when they cannot find evidence of safety and effectiveness in previously conducted trials, according to the guideline on clinical investigations.

The guideline on clinical evaluation specifies that "data relevant to the clinical evaluation may be held by the manufacturer or a third party, or be available in the scientific literature, for the device in question or for comparable devices." The guideline also says that real-world evidence is acceptable.

The third guideline contains terms and definitions related to clinical evaluation and clinical investigation.

Read the clinical investigation guideline here: https://bit.ly/34WCDxi.

Read the clinical evaluation guideline here: https://bit.ly/371g1xp.

Read the definitions guideline here: https://bit.ly/2XdZTEs.

Study Points to a Decade of Underreporting Clinical Trials

Trial results entered in Clinicaltrials.gov in the past decade show a poor quality of reporting from both industry sponsors and academic medical centers, according to a new report published in the *New England Journal of Medicine*.

Of the 36,000 trials completed since the database launched in September 2008, only 66 percent, have complied with a federal mandate to report final data within one year of completion, researchers found.

Industry-sponsored trials showed a higher rate of compliance — 77 percent reported — than nonindustry trials, only 63 percent of which have reported their results.

"We have observed that industry sponsors tend to be well-staffed and have a centralized process for supporting the submission of results, whereas nonindustry sponsors tend to rely on individual investigators with minimal centralized support," says the report.

Trial transparency advocate TranspariMED also found in a March 2019 study that one-third of universities failed to report their trials within the one-year time limit. Similar problems exist in European trials, TranspariMED noted in an April 2019 study. Only about half of trials had complied with the mandate to report results to the EU Clinical Trials Register (*CenterWatch Weekly*, May 6, 2019).

Authors of the ClinicalTrials.gov study concluded that contributing data throughout

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Beth Belton Editorial Director
Colin Stoecker Reporter
Stephanie Akers Production
Russell Titsch Business Development Director

wcg CenterWatch

CenterWatch Main and Editorial Offices
300 N. Washington St., Suite 200, Falls Church, VA 22046
editorial@centerwatch.com / sales@centerwatch.com

Permission requests can be emailed to editorial@centerwatch.com.

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Industry Briefs (continued from page 2)

a trial using electronic data capture and other digital tools would improve the reporting rate and quality of the data.

The study was conducted with the support of the Intramural Research Program of the National Library of Medicine, which administers ClinicalTrials.gov.

Adverse Event Brings Solid Biosciences DMD Gene Therapy Trial to Halt

Another Duchenne muscular dystrophy gene therapy trial has been held up by the FDA following a serious adverse event in one patient. The agency halted Solid Biosciences' trial of SGT-001 twice before due to reported serious adverse events.

The patient is in recovery and the five other patients treated in the study are "all doing well," the company said.

Pfizer and Sarepta Therapeutics are also developing DMD gene therapies. Pfizer reported similar serious adverse events in a single patient in June but the other five patients in the trial showed immune responses as expected.

Sarepta has not reported any serious adverse events for its DMD gene therapy. In August, the firm contested an FDA adverse event reporting system (FAERS) submission on a patient enrolled in its microdystrophin trial for DMD (*CenterWatch Weekly*, Aug. 12, 2019). The company called the submission "erroneous," and the study's drug safety monitoring board recommended that the trial continue.

CenterWatch Reveals Sponsor and CRO Results from 2019 Global Site Survey

Well-trained CRAs are the most important aspect of a site's relationship with a sponsor or CRO, according to CenterWatch's 2019 Global Site Relationship Benchmark Survey.

More than 4,000 sites responded to the survey this year, rating the most desirable traits in a sponsor or CRO. Most sites, 66 percent, said they value professional and knowledgeable CRAs. Attributes also appearing in the top 10 include organization and preparation, accessible staff, timely drug availability, and open communication.

The survey shows sites' dissatisfaction with sponsors' handling of protocols, with only about 40 percent of sponsors receiving high marks in this area. CROs handling of budgets and payments also was scored low, with only about 37 percent receiving high marks.

Click here to purchase a copy of the report: https://bit.ly/32N1Ada.

Three Observational Studies to Use Apple Watch and iPhone

Three new observational studies will test the ability of the Apple Watch and iPhone to provide warning signals for irregular heartbeat and other physiological symptoms that may indicate the need for medical intervention.

Apple will partner with the National Institutes of Health, the American Heart Association and several academic research centers to gather data that will help develop algorithms for predicting certain irregularities.

The Apple Heart and Movement Study aims to enroll 500,000 people over the next five years. The Apple Women's Health Study wants 1 million people to sign up over the next 10 years, and subjects will be asked to track their menstrual cycle and respond to regular surveys about it. And the Apple Hearing Study aims to enroll 150,000 people over the next two years with subjects completing hearing tests while their phones detect and measure loud noises in their environment.

Participants, who must be over age 18, will be able to control which types of information they share and can delete data within 24 hours of its collection. Apple has said it will not sell data collected from the studies.

Apple's first foray into observational research was a heart study with the Stanford Medicine system completed last week that used the Apple Watch to monitor 419,000 participants' heart rates and provided ECG patches to the .5 percent of participants whose watches notified them of irregularities.

Alzheimer's Biomarker Repository Provides Data and Tools for Clinical Trials

The nonprofit UsAgainstAlzheimer's has launched the first searchable database for Alzheimer's biomarkers.

The database will contain information on amyloids, brain iron levels, cell signaling, genetic variations from DNA, eye movement, inflammation, neuronal damage, Tau, oxidative stress and vasculature to measure the onset of the disease.

Intended for use by researchers, policymakers, patients and caregivers, the database can be edited and updated by qualified researchers and scientists.

New Trial Will Test PTSD-Specific Therapies

A new trial funded by the U.S. Army will test what could become the first treatments developed specifically for posttraumatic stress disorder (PTSD).

The adaptive clinical trial, which will be conducted by Cohen Veterans Bioscience (CVB), will use precision gene therapy to study how the disorder affects brain physiology.

The three-and-a-half-year trial will start in the fall of 2020, with the goal of advancing to phase 3 of testing by 2022.

The trial will be overseen by a committee representing the Veterans Health Administration, the National Institute of Mental Health, the National Institute of Alcohol Abuse and Alcoholism, the FDA and the Defense Health Agency's Psychological Health Center of Excellence.

WCG Acquires Waife & Associates

WCG Clinical has acquired clinical trial management consultancy Waife & Associates (W&A).

W&A has provided management consulting services for biopharmaceutical clinical research companies for more than 25 years, serving more than 200 clients worldwide. W&A's founder Ronald S. Waife will become WCG's chief management consulting officer.

Up and Coming

This feature highlights changes in clinical research organizations' personnel.

ADC Therapeutics

ADC Therapeutics SA has named **Jennifer Herron** its first chief commercial officer. Herron recently served as executive vice president and CCO at Immunogen.

Altasciences

Altasciences has named **Martin Poirier** senior director of bioanalytical sciences. Poirier was formerly scientific director for laboratory sciences at Charles River Laboratories.

Assembly Biosciences

Assembly Biosciences has appointed **Luisa Stamm** chief medical officer. Stamm last served as a senior member of the HCV and HIV clinical research teams with responsibility for scientific and clinical development activities and overall research strategy at Gilead.

Aytu BioScience

Matthew Phillips has been appointed executive vice president of commercial operations at Aytu BioScience. Phillips was formerly chief commercial officer for Cerecor, Inc.

AZTherapies

AZTherapies has named **Ernest Penachio** vice president of manufacturing operations and CMC. Penachio was most recently vice president of manufacturing operations and facilities with Acorda Therapeutics.

BeyondSpring

BeyondSpring Inc. has named **Gregg Russo** senior vice president of human resources. Russo previously served as head of human resources at Chugai Pharma USA, a Roche company.

Equillium

Bruce Steel has been named chief executive officer and **Krishna Polu** executive vice president of research and development and chief operating officer at Eqillium, Inc. Steel previously served as president and chief business officer; Polu was most recently chief medical officer at the company.

Evoke

Evoke has named **Karsten Risch** chief medical officer. Risch was most recently CMO at Havas Health & You.

Flagship Pioneering

Flagship Pioneering has appointed **Prakash Raman** to the newly created role of chief business development officer. Raman was most recently vice president and global head of business development and licensing at Novartis Institutes for BioMedical Research.

Gynesonics

Kelly Petrucci has been named vice president of healthcare economics and market access at Gynesonics. Petrucci was previously director of payer relations and value based offers with Boston Scientific.

Holon Solutions

Jon Zimmerman has been named chief executive officer at Holon Solutions. Zimmerman was previously president of Virence Health.

IDEAYA Biosciences

IDEAYA Biosciences, Inc. has appointed **Paul Barsanti** vice president and head of drug discovery. Barsanti was most recently an executive in residence at 5AM Ventures.

Kaleido Biosciences

Kaleido Biosciences, Inc. has expanded its leadership team with the addition of **William Duke** as chief financial officer. Duke previously served as CFO of Pulmatrix, Inc.

Lifescience Dynamics

Alfred Reszka has been appointed chief business officer at Lifescience Dynamics. Reszka previously held the position of executive director and head of strategic business intelligence at Merck & Co.

Neovasc

Bill Little has been appointed chief operating officer at Neovasc Inc. Little was most recently global head of customer and new market insights and divisional vice president of global marketing with Abbott.

Neurana Pharmaceuticals

Neurana Pharmaceuticals Inc. has named **Randall Kaye** chief medical officer. Kaye was most recently CMO of Click Therapeutics.

Newronika

Newronika, a neurological research center spinoff from the University of Milan, has named **Oleg Svanidze** chief medical officer. Svanidze most recently was CMO at Swiss-based Xeltis AG.

Noxopharm

Alexander Hunter has been named chief commercial officer at Noxopharm. Hunter's most recent appointment was chief financial officer at Elk Petroleum.

Obsidian Therapeutics

Shyam Subramanian was named vice president and head of technical operations, **Parnian Zia-Amirhosseini** vice president and head of regulatory affairs and quality assurance, and **Melanie Call** vice president and head of program development at Obisidian Therapeutics. Subramanian previously held the position of head of cell therapy development and manufacturing at Casebia Therapeutics. Zia-Amirhosseini most recently served executive director of regulatory affairs at Sarepta Therapeutics. Call previously led the accelerating center at the cell and gene therapy center at IQVIA.

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Up and Coming

(continued from page 4)

OneQor Pharmaceutical

Joseph Fortunak has been named chief scientific officer at OneQor Pharmaceutical. Fortunak is currently a professor of chemistry and pharmaceutical sciences at Howard University.

Partner Therapeutics

Partner Therapeutics, Inc. has appointed **John McManus** chief business officer. McManus was most recently chief executive officer at Aeolus Pharmaceuticals.

Rakuten Medical

Brenton Keath has been appointed chief financial officer and **Dana Johnson** as general counsel and corporate secretary at Rakuten Medical. Keath previously served as head of finance for Rakuten Commerce in the U.S. Johnson most recently served as vice president and head of legal affairs and corporate compliance for Gritstone Oncology.

Relay Therapeutics

Relay Therapeutics has expanded its senior management team with the appointment of **Andy Porter** as executive vice president and chief people experience officer. Porter was most recently chief people officer at the Broad Institute of MIT and Harvard.

Rubius Therapeutics

Rubius Therapeutics, Inc. has named **Maiken Keson-Brookes** chief legal officer and corporate secretary. Keson-Brookes was most recently general counsel at Synlogic, Inc.

RubrYc Therapeutics

Rakesh Verma has been appointed senior vice president of discovery and development at RubrYc Therapeutics, Inc. Prior to the appointment at RubrYc, Verma was site head of ARMO Biosciences.

T1D Exchange

T1D Exchange has named **David Walton** chief executive officer. Walton was previously chief commercial officer at QuiO.

Teva

Teva Pharmaceutical Industries Ltd. named **Eli Kalif** as executive vice president and chief financial officer. Kalif was most recently senior vice president of finance at Flex Ltd.

Vericel

Vericel Corporation has named **Sean Flynn** vice president and general counsel. Flynn formerly served as vice president and general counsel at Verastem, Inc.

Features

Mayo's Startup Acceleration

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"During the study startup, the associate project manager is the coordinating point," said Watters. "There are many people involved, and the associate project manager is the focal point to ensure the schedule and remove barriers."

"We make sure that we have a good blend of skills and knowledge" in project managers, said Watters. "We ensure variation throughout cross training, for example with early cancer vs. Car-T or other therapeutic areas. It's a close-knit team that shares knowledge."

"We do offer study coordination resources that can assist our study teams," said Watters. "We also have research protocol specialists available to assist with study startup."

According to Watters, it is crucial to have an operational owner once a project launches. In Mayo's case, the Office of Clinical Trials became the owner of study startups and has successfully sustained gains for the past four years.

"We are being viewed very favorably from sponsors and CROS."

—Julie Watters, senior project manager, Mayo Clinic

Mayo developed a dashboard to help staff streamline and track required startup tasks. The dashboard shows days allocated for certain primary tasks, days remaining and delayed items in red for legal, regulatory and financial tasks.

"Some advantages of the dashboard are that it makes people accountable, and by tracking metrics we can tell if any specific area needs adjustment," said Watters.

The study startup teams also have a weekly phone call, which ensures that issues arising in the beginning of the startup process are dealt with before they become part of an ongoing protocol.

Another key advantage of using technology is a phone app created for communication with one of Mayo Clinic's four centralized IRBs.

"Not only is it timely, but also very user-friendly," said Bharucha. "As part of TACT, the IRB pre-screens protocols before they are submitted and walks study teams through the process." The app is critical to get busy PIs to submit items even when out of town without a computer.

Features

Ask the Expert

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ing to see what assessments you've been making along the way. There definitely are more formal ways of doing this, but I think the first part of that is let me just take a look every month and see what's coming in, from a safety physician perspective.

Bannon: Signal detection does begin with the individual case, and having the same medical reviewer look at all the data is a key step in understanding the safety profile that is developing.

Question:

Do you have any tips on getting PIs to comply with best practices in reporting safety problems? Without regulations, some can be difficult to persuade.

Answer:

Pittwood: Well, I think it boils down to education and training when the protocol starts. Those investigator kickoff meetings are very important so that the sponsor can go over the expectations and what it is that we need the investigators to do and be responsible for.

The investigators need to be informed about what is needed. When you're starting a study you need to know what your institution requires you to do and how often the IRBs and the ethics committees need you to forward these reports to them as well. It's really about being informed.

A lot of site coordinators can do a lot to help in that regard. Basically, they're mostly the eyes and ears of the investigator, who sometimes might need some reminding: "This is something you need to look at" or "This is something you need to know." I think it's about having good communication on a regular basis, not only within the site, but also between the sponsor and the investigators, to make sure that they are performing the task for which they've been recruited.

Bannon: A principal investigator has clear responsibilities, but if we don't really interact and communicate in the best and most efficient way with the investigator, we're creating a burden at that level that could sometimes be perceived as noncompliance, when it's really just not organizing the communication properly and not organizing that through the appropriate use of the properly trained people.

The interactions that I think go best at the site level, at the investigator level, are those that are completed by healthcare practitioners — nurses, pharmacists, physicians, etc. — who have a clear understanding of what it's like to be in practice, a clear understanding of what it means and what the right questions are to ask, and then in addition to that, to have drug safety experience. I think having that as criteria for the individuals speaking to the sites and organizing the questions, to make sure that the most informative information to help delineate the case is collected up front, is appropriate, is really an important aspect of compliance.

Drug & Device Pipeline News

Company	Drug/Device	Medical Condition	Status	Sponsor Contact
Triple-Gene LLC	INXN-4001	heart failure	Phase 1 trial initiated enrolling 12 stable subjects with implanted Left Ventricular Assist Device (LVAD)	3GTx.com
Cerveau Technologies Inc.	[F18]MK-6240	neurodegenerative diseases	Phase 1 trial initiated enrolling healthy volunteers and subjects with Mild Cognitive Impairment (MCI) and with Alzheimer's Disease (AD) at Kobe City Medical Center General Hospital in Japan	cerveautechnologies.com
Aravive, Inc. AstraZeneca	AVB-500 in combination with durvalumab	platinum-resistant, recurrent epithelial ovarian cancer	Phase 1/2 trial initiated	aravive.com astrazeneca.com
Turning Point Therapeutics, Inc.	TPX-0046	advanced solid tumors	Phase 1/2 trial initiated enrolling 350 TKI-treatment naïve and -pretreated subjects with RET-altered non-small-cell lung, thyroid and other advanced cancers	tptherapeutics.com
Dragonfly Therapeutics, Inc.	DF1001	advanced solid tumors	Phase 1/2 trial initiated enrolling subjects with locally advanced or metastatic solid tumors who express HER2	dragonflytx.com
Turning Point Therapeutics, Inc.	repotrectinib	solid tumors	Phase 1/2 trial initiated enrolling 75 pediatric patients with ALK-, NTRK- and ROS1-positive solid tumors	tptherapeutics.com
VBI Vaccines Brii Biosciences	BRII-179 (VBI-2601)	chronic hepatitis B virus (HBV) infection	Phase 1b/2a trial initiated enrolling 65 subjects	vbivaccines.com briibio.com
xBiotech USA, Inc.	bermekimab	severe Atopic Dermatitis (AD)	Phase 2 trial initiated	xbiotech.com
AVEO Oncology Biodesix, Inc.	ficlatuzumab in combination with high-dose cytarabine	relapsed and refractory acute myeloid leukemia (AML)	Phase 2 trial initiated enrolling 60 adult subjects with AML who failed induction chemotherapy or who achieved a complete response, but relapsed within one year	aveooncology.com biodesix.com
Aptinyx Inc.	NYX-2925	painful diabetic peripheral neuropathy (DPN)	Phase 2 trial initiated enrolling 200 subjects with advanced DPN	aptinyx.com
Aptinyx Inc.	NYX-2925	fibromyalgia	Phase 2 trial initiated enrolling 300 subjects	aptinyx.com
Viracta Therapeutics, Inc.	nanatinostat in combination with valganciclovir	relapsed/refractory Epstein-Barr virus (EBV)-positive lymphoid malignancies	Fast Track designation granted by the FDA	viracta.com
X4 Pharmaceuticals, Inc.	mavorixafor (X4P-001)	WHIM (Warts, Hypogammaglobulinemia, Infections and Myelokathexis) syndrome	Breakthrough Therapy Designation granted by the FDA	x4pharma.com
Celgene Corporation	Reblozyl (luspatercept–aamt)	anemia in adult patients with beta thalassemia who require regular red blood cell (RBC) transfusions	Approval granted by the FDA	celgene.com

JobWatch

The Source for Clinical Research Jobs and Career Resources

Twice monthly, *CWWeekly* provides featured listings of clinical research job openings, upcoming industry conferences and educational programs from **JobWatch**, CenterWatch's online recruitment website for both clinical research employers and professionals.

For conferences, webinars, training programs and job postings,
Join the LinkedIn JobWatch group!

Jobs via Kelly Services

Clinical Study Associate I
Jacksonville, FL

Rave Clinical Programmer
South San Francisco, CA

Clinical Trial Specialist
Raynham, MA

Sr. Clinical Trial Specialist
Blue Ash, OH

Clinical Data Coordinator II
North Chicago, IL

Clinical Data Analyst
New York, NY

Clinical Data Coordinator
South San Francisco, CA

Clinical Compliance Assistant
Santa Ana, CA

Customer Service Representative
Franklin, TN

CI10 - Utilization Management Rep I
Albany, NY

Laboratory Technician (Molecular)
San Diego, CA

Administrative Assistant
Titusville, NJ

Clinical Laboratory Scientist I
Horsham, PA

Production Technician
Gaithersburg, MD

[VIEW ALL KELLY SERVICES JOBS]

More Jobs

Senior Regulatory Specialist - Cancer Center (Clinical Trials Office)
University of Illinois Cancer Center
Chicago, IL

Clinical Customer Success Specialist
Castor
Hoboken, NJ

Project Specialist
ACI Clinical
Bala Cynwyd, PA

Financial Data and Analysis Manager
WIRB-Copernicus Group Inc
Princeton, NJ

Director, Human Capital Management
WIRB-Copernicus Group Inc
Hamilton, NJ

Project Manager - Clinical Research
Analgesic Solutions, LLC
Wayland, MA

Clinical Research Analyst
PharmaSeek
Madison, WI

Collection Specialist
Western Inst. Review Board
Puyallup, WA

[VIEW ALL JOB LISTINGS]

Upcoming Event Highlights

Webinars

NOVEMBER 19, 2019

ICH E8 Developments: Are You Sure You're Up to Date?

1:30 p.m. - 3:00 p.m. EST

With ICH E8(R1) set to be adopted in June 2020, your planning, design and conduct of clinical trials will look different than they do today. Make sure you're ready to implement the new guidelines. This webinar clarifies how.

Webinar Takeaways:

- The purpose of the ICH E8 guideline and its relationship to other ICH Efficacy guidelines, including ICH E6(R2) (Good Clinical Practice [GCP]) and ICH E9 (Statistical Principles for Clinical Trials)
- The impact to current research practices that could influence your SOPs, procedures, processes and documentation pertaining to ICH guidance
- And more…

NOVEMBER 26, 2019

Increase Compliance, Reduce Risk with Integrated Digital Solutions: Create a Connected System and Streamline Your Operations

1:30 p.m. - 3:00 p.m. EST

First to market: A coveted spot you aspire to reach in the crowded life sciences arena. You have multiple SOPs in place to improve efficiency and ease of use, in an effort to minimize wasted time and win that sought-after place. But you are far more likely to be first to market when your SOPs and digital solutions are integrated, ensuring nothing falls through the cracks. After all, if you don't know there's a problem, you can't address it.

[VIEW ALL WEBINARS]