Ethics of Pay-to-Play Trials: SACHRP Recommendations

By Colin Stoeker

Recognizing that some trials must ask patients to share the cost of expensive investigational drugs, supplies or tests, the Secretary’s Advisory Committee on Human Research Protections (SACHRP) has developed recommendations to help sponsors stay on the right side of that ethical line.

The recent growth of the “pay to play” concept has led to a number of fraudulent trials — especially in the area of stem cell therapies — that draw patients into paying high costs for medically unsound treatments.

According to SACHRP, sponsors should only charge to cover the cost of a study, not to turn a profit, and should have to justify charges to their IRBs. The committee recommends a series of questions to guide sponsors in developing the justification:

- Does the study meet relevant thresholds of scientific quality?
- Is the risk-benefit balance justifiable?
- Why are traditional research funding sources not used?
- Will requiring payment influence equitable subject selection?
- Is requiring payment likely to interfere with the patient’s decision-making process?

In justifying charges, sponsors must be open and honest with their IRBs, says one compliance expert.

“At the heart of this debate is transparency,” says David Borasky, vice president of SACHRP.

Virtual Trial vs. Personal Touch: Is There a Happy Medium?

By Colin Stoeker

The clinical trials industry is divided on the value of virtual trials, with some thought leaders extolling their benefits and others decrying the loss of personal contact between patient and trial.

Relying on digital solutions for data-gathering and communication, sponsors and research organizations can reach patients that might otherwise not be able to participate and can save money by cutting the trial site out of the equation.

“Conducting trials virtually has a compelling economic reason — to cut the site out completely — but patients don’t want to participate in a trial in a vacuum,” says Ken Getz, director of the Tufts Center for the Study of Drug Development.

“They still want to feel that they are in a relationship with professionals that will help guide them,” Getz says.

While a completely virtual and “site-less” approach may be feasible for running some late-phase trials that deal with less life-threatening indications, early-phase and investigational cancer trials might require a physical site visit to conduct an MRI or intravenously administer a medicine with more medical oversight.

The question to be considered is, do patients value the convenience of virtual trials more than the relationship aspect of site-based trials?

Virtual trials might be too abrupt or impersonal, says Getz. One of the benefits patients see Virtual Trial vs. Personal Touch on page 6 »
EC Releases New Advanced Therapy Guidelines, Site Suitability Template

The European Commission has finalized guidelines for trials of cell- and tissue-based therapies as part of the transition to its new clinical trials regulations expected in 2020.

The guidelines, designed to supplement the more general ICH E6 good clinical practices guideline, make recommendations for handling, storage and use of human tissues and cells, which the EC refers to as advanced therapy medicinal products (ATMP).

They also present recommendations for tracing ATMPs from the donor through delivery to the trial site and ultimately to the recipient.

Additional safeguards should be applied for children and pregnant women, or in the case where a subject has an immediate need for the life-saving therapy, the guidelines say. They also recommend patient follow-up after the end of a trial and staff training on the process of taking biopsies/extracting cells before manufacturing or administering the investigational product.

The guidelines also say control groups receiving placebo only should not be subjected to a procedure if it presents more than minimal risk and minimal burden. Any invasive procedures should be outlined in the protocol or investigator’s brochure if they are part of the trial.

The EC also released a new Site Suitability Template for sponsors of all trials to use in their applications. The template, which must be completed for all sites in a trial, describes the site, facilities, equipment and trial procedures.

The new clinical trials regulation took effect in May 2016, but the EC has allowed trials to follow guidelines of the former clinical trials directive until the commission develops or revises all compliance documents. The commission still is working on guidelines on the content of the trial master file and a question-and-answer document on the new regulations.


McKesson and Aetion Build RWE Platform for Cancer Trials

McKesson and Aetion have entered into a collaboration to use real-world evidence to support clinical trials in oncology, targeting tumors, breast, lung and melanoma cancers.

The collaboration combines Aetion’s evidence platform with data from McKesson’s IKnowMed electronic health record system.

The platform will be available to researchers at Brigham and Women’s Hospital in Boston, which is leading the FDA’s RWE pilot project RCT Duplicate (CenterWatch Weekly, April 15, 2019).

The two companies are both members of the Friends of Cancer Research RWE pilot project. The project focuses on assessing frontline treatments in patients with advanced non-small cell lung cancer.

NSF International Acquires CRO AMAREX

NSF International has acquired a majority interest in Amarex Clinical Research, taking over the CRO’s current phase 1 trials and adding trial management to its suite of life science consulting services.

Maryland-based CRO Amarex will be absorbed by NSF’s global health and science consulting business and will be called Amarex Clinical Research. It will retain its chief executive officer, Kazem Kezempour.

The merger will allow NSF to add clinical trial management and operations expertise, biostatistics, data management, pharmacovigilance and data safety monitoring committee capabilities to its medical writing and consulting services.

Amarex will gain access to NSF’s international expert network. Financial terms were not disclosed.

Real-World Data Only Partially Valid, Study Shows

The ability of real-world data (RWD) to fully replicate clinical trial results is limited, a new study says, but RWD can be used to support some of a trial’s data needs.

In a study published in the Journal of the American Medical Association, a group of university researchers examined the data from 220 clinical trials conducted in the U.S. in 2017, matching them to information gleaned from electronic health records, insurance claims, disease registries and patient-reported data.

Only 15 percent of the trials’ data could be fully replicated using the RWD. In 72 percent of cases examined, however, conclusions reached using RWD matched at least one aspect of a trial’s data, such as inclusion/exclusion criteria or primary endpoints.

“Although the increasing use of real-world evidence in medical research presents opportunities to supplement or even replace some clinical trials,” the researchers conclude, “observational methods are not likely to obviate the need for traditional clinical trials.”
Up and Coming

This feature highlights changes in clinical research organizations’ personnel.

**Alexion Pharmaceuticals**
Alexion Pharmaceuticals has named Tanisha Carino chief corporate affairs officer. Carino was most recently executive director at FasterCures.

**Aarios Therapeutics**
Aarios Therapeutics has named Brad Adams as the first vice president of commercial. Adams was most recently vice president of sales at Acell.

**Avricore Health**
Hector Bremner has been appointed chief executive officer and Bob Rai has been named president of Avricore Health. Bremner was previously executive vice president of Avricore’s branding, strategic communications and public affairs. Rai previously held the position of CEO at the company.

**AzurRX BioPharma**
James Sapirstein has been appointed chief executive officer at AzurRX BioPharma. Sapirstein was CEO for ContraVir Pharmaceuticals, formally known as Hepion.

**BiomX**
Merv Bassan has been named chief development officer at BiomX. Bassan is a former vice president of translational sciences at Teva Pharmaceutical Industries.

**BioSpecifics Technologies**
Kevin Buchi was named chief executive officer at BioSpecifics Technologies. Buchi recently served as president and CEO of TetraLogic Pharmaceuticals.

**Checkmate Pharmaceuticals**
Checkmate Pharmaceuticals has named James Woolridge chief medical officer and Steven Hamburger vice president of regulatory affairs. Woolridge was previously affiliated with Aeglea BioTherapeutics where he was CMO; Hamburger was recently vice president of regulatory affairs and quality assurance at Tarveda Therapeutics.

**Covance**
Covance has appointed Paul Kirchgraber chief executive officer. Kirchgraber last served as senior vice president and head of Covance’s clinical trials testing solutions.

**CytomX Therapeutics**
CytomX Therapeutics has named Amy Peterson chief development officer. Peterson most recently served as chief medical officer of BeiGene.

**Enzyvant Sciences**
Jeb Ledell has been named chief operating officer at Enzyvant Sciences. Ledell was formerly COO at Compass Therapeutics.

**Galera Therapeutics**
Galera Therapeutics has appointed Christopher Degnan chief financial officer. Degnan was most recently with Verrica Pharmaceuticals as CFO.

**Gilead Sciences**
Gilead Sciences has named Andrew Dickinson chief financial officer. Dickinson served as chief strategy officer at the company prior to his promotion.

**Hepion Pharmaceuticals**
Stephen Harrison has been named consultant medical director. Harrison is currently a visiting professor of Hepatology at the Radcliffe department of medicine at the University of Oxford, the medical director for Pinnacle Clinical Research and the president of Summit Clinical Research.

**LabCorp Diagnostics**
John Ratliff has been named chief executive officer and Judi Seltz chief human resources officer at LabCorp Diagnostics. Ratliff was previously CEO of Covance. Seltz formerly served as vice president of human resources for the global human health division at Merck.

**Lyra Therapeutics**
Dana Washburn has been appointed chief medical officer at Lyra Therapeutics. Washburn was corporate vice president and head of global medical services for Parexel International.

**Mundipharma Pharmaceuticals**
Mundipharma Pharmaceuticals has added to its leadership with Matthew Homent named Ireland country manager. Homent previously served as director of commercial operations at Napp Pharmaceuticals Limited in the UK.

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Up and Coming (continued from page 3)

Oncology Pharma
Oncology Pharma has named Vijay Mahant chief scientific officer and chief operating officer. Mahant served as founder and chief executive officer of MediLite Diagnostika.

Orchestra BioMed
Orchestra BioMed named Juan Lorenzo vice president of product development for focal therapies and Paul Goode vice president of product development for bioelectronic therapies. Lorenzo was recently director of research and development at CERENOVUS, a Johnson & Johnson company. Goode was vice president of research and development and chief technology officer for GERD.

Palladio Biosciences
Marella Thorell has been appointed chief financial officer at Palladio Biosciences. Thorell previously served as CFO and chief operating officer and an executive director at Realm Therapeutics.

Pharm-Olam
Pharma-Olam named Robert Davie chief executive officer. Davie was formerly vice president and general manager of global clinical development at Covance.

Poseida Therapeutics
Kerry Ingalls has been named chief operating officer at Poseida Therapeutics. Ingalls previously oversaw clinical and commercial manufacturing at Amgen.

Pyxis Oncology
Ronald Herbst has been appointed chief scientific officer at Pyxis Oncology. Herbst was vice president of research and development and head of oncology research at MedImmune.

Revance Therapeutics
Mark Foley was named president and chief executive officer at Revance Therapeutics. Previously, Foley was CEO of Zeltiq Aesthetics.

Seelos Therapeutics
Seelos Therapeutics has appointed Scott Applebaum as strategic regulatory consultant. Applebaum was most recently president of Context Therapeutics.

Vaccibody AS
Vaccibody AS has named Siri Torhaug chief medical officer. Before joining Vaccibody, Torhaug served as the medical team lead for oncology at AstraZeneca.
Ethics of Pay-to-Play Trials
continued from page 1

for IRB compliance at WCG Clinical, who co-chaired the October SACHRP meeting at which the recommendations were developed. “Be transparent with the IRB about the need to charge, the costs to participants and telling the subjects about costs, research and the difference between medical care and clinical trials,” Borasky says. “Otherwise it’s hard to come up with specific guidelines.”

Because pay-to-play trials offer plenty of ethical pitfalls, they become a balancing act between the FDA, the IRB, the investigator and sponsor, and ultimately affect the patient, according to Borasky.

Some pay-to-play proposals he has seen clearly have been trying to circumvent the system. Submitting an investigational new drug (IND) application to the FDA should have been the first step. “The submitters of those studies generally have withdrawn their application at that point,” he says. “They are trying to avoid FDA entanglements.”

The IRB’s role is to question the motivation for charging in the first place, Borasky says, adding that he always defers to the FDA.

“When studies come in with this type of framework, we look at them critically, look at the consent process and FDA regulations,” and call them out if they aren’t compliant. Companies that aren’t forthcoming about why they haven’t gone through the appropriate FDA channels get special scrutiny, Borasky says.

“There is concern that these are not the most scientifically robust studies,” he says. “We ask if they have an IND with the FDA and is this documented appropriately as an investigational new drug study. If they hedge us or don’t engage with the FDA, then it’s a red flag.”

Another area of concern when dealing with pay-to-play trials is the patient’s inability to discern between clinical care from a doctor and that of scientific research. This therapeutic misconception could be worsened by bringing a cost factor into the study, Borasky says. Paying to participate in a clinical trial isn’t the same as paying for an approved treatment. More clinical trials fail than succeed, he points out.

There is also concern that pay-to-play trials will attract more affluent subjects who can afford the higher cost or give those subjects the wrong motivations to participate in the first place, causing them to base their expectations on monetary value.

At the other extreme, poor patients or those under undue influence, like prisoners, might be more susceptible to these types of trials. “Historically, what IRBs have been worried about is exploitation,” says Borasky. There are concerns that clinical research studies are attractive to individuals with financial limitations because they may not have access to any other kind of healthcare.

“Research is not meant to exploit low economic status people, and this flips that on its head and asks ‘Should we worry if only people with lots of money can afford to pay extra to be able to get the treatment?’”

As far as cost goes, there is no hard and fast rule for sponsors on how much or how little to charge to cover the costs of a study, Borasky says.

“The IRBs are left to make a lot of decisions without concrete guidelines,” he says. “Researchers should be expected to make reasonable efforts to offset those concerns.”

“There is concern that these are not the most scientifically robust studies.”

—David Borasky, Vice President of IRB Compliance, WCG Clinical

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- New FDA guidances, including new data integrity expectations
- The impact of risk-based monitoring
Virtual Trial vs. Personal Touch
continued from page 1

get from trials is access to professionals or experts that can give them special attention. “For select trials, this may actually make sense. But as an across-the-board solution for all trials, it’s hard to see [virtual] being viable.”

Pfizer made the first attempt at a virtual trial in 2011 with its REMOTE study, an entirely home-based clinical trial for overactive bladder disease. For that study, informed consent was obtained online and documented by electronic signature, and the study drug was delivered directly to subjects’ homes. Adverse event reports and efficacy outcomes were recorded using mobile devices and web-based tools. But the study ultimately failed to recruit enough patients.

Since then, FDA interest in virtual trials — which the agency refers to as decentralized trials — has increased as it seeks out new and innovative approaches to drug development.

The FDA has created a working group that is reviewing the concept of virtual trials, which will likely lead to a guidance on the subject. There is no date set for releasing a draft guidance.

In the meantime, the industry is developing different approaches to the concept of virtual trials.

A hybrid model, which mixes remote data collection with clinical site visits, can reduce the burden on study participants while maintaining the personal connection, according to Lindsay McNair, chief medical officer with WCG Clinical.

One example of the hybrid model is VirTrial’s trial management platform, which combines video, text and email communication to help clinical trial sites address specific patient or study needs. The platform can be customized to meet both patients’ and sites’ needs.

“We are not trying to replace sites,” says Amanda Rangel, vice president of business development at VirTrial. “Our trials are not 100 percent virtual trials. Our approach is to focus on the human element.”

“As we get better at integrating solutions, we may create a more customized approach.”

—Ken Getz, Director, Tufts Center for the Study of Drug Development

VirTrial hopes to replace 25 percent to 40 percent of standard trials with its hybrid approach, which combines in-person visits with digital interaction to make the clinical trial process as accessible and easy as possible for patients.

VirTrial’s platform, which claims to be best used with Phase 3 and 4 studies, aims to help patients communicate with doctors and trial staff using their mobile devices, getting answers to questions as simple as, “Am I allowed to take Tylenol?” And VirTrial’s matrix of trial staff contacts means someone is always available to answer those questions.

“We know that if something is not easy to use, the patients and sites won’t use it,” Rangel says. Enhancing communication between patients and sites keeps the patient engaged, she says.

Transparency Life Sciences (TLS) is taking a fully virtual approach and has tested its first all-virtual trial concept. By simulating all the procedures required for a pulmonary function trial, TLS has built a foundation for future virtual trials.

“We are the first enterprise that was built entirely on the hypothesis that clinical trials will go virtual eventually,” says Tomasz Sablinski, TLS founder and chief executive officer.

Participants in the TLS Virtual Siteless Technology Open Research (VISITOR) project were able to record data commonly collected in clinical trials — blood pressure, heart rate, body weight, for example — and use a single-lead EKG to monitor pulmonary function, uploading it digitally to the study hub from their homes or offices.

“This creates a template or scaffolding, says Sablinski. “We can build off that and do studies which follow those considerations.”

Striking a middle ground between the VirTrial and TLS models, IQVIA takes a more flexible approach to the balance between virtual and personal.

When IQVIA starts looking at a study, says Josh Rose, vice president and global head of strategy, first it examines the protocol and determines where traditional aspects of the trial can be replaced with virtual ones.

“We look at patient burden and we look at the study with five or six visits and what [aspects] of those visits can be moved to the patient’s home,” Rose says. “Sometimes it can be the entire study. But it’s not black and white.”

As sponsors continue to show more interest, creating virtual trials becomes more of a balancing act for combining technology and scientific research. But just because there are numerous technological tools available now for virtual trials, McNair says, that does not make them complete solutions for study conduct.

There is a misconception that virtual trials are all about putting technology and a study on an app, but nothing could be further from the truth, Rose says. “Phase 3 and 4 studies are complex. There are lots of safety precautions and measurements. It’s sending the wrong message.”

Sablinski says that 25 percent of current studies could be done entirely virtually but the concept still is only a blip on the industry’s radar.

“As we get better at integrating solutions, we may create a more customized approach,” says Getz. “That relationship between the patient and investigator is important and so are the ways to continue to reinforce that relationship.”

Researchers in the future will need experience in thinking about the unique design, conduct and ethical challenges of virtual clinical trials, McNair says, as more of them move toward this model of research.
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**Drug & Device Pipeline News**

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<th>Company</th>
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<td>NeuLara</td>
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<td>Phase 1 trial initiated enrolling 200 healthy subjects</td>
<td>neuclone.com</td>
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<td>Alder BioPharmaceuticals, Inc.</td>
<td>ALD1910</td>
<td>Migraine</td>
<td>Phase 1 trial initiated enrolling 100 healthy subjects between the ages of 18 and 55</td>
<td>alderbio.com</td>
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<td>Amphivena Therapeutics, Inc.</td>
<td>AMV564</td>
<td>Tumors</td>
<td>Phase 1 trial initiated enrolling subjects in San Antonio, TX, MD Anderson Cancer Center and Peninsula Cancer Institute in Newport News, VA</td>
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<td>Nektar Therapeutics</td>
<td>NKTR-255</td>
<td>relapsed or refractory non-Hodgkin lymphoma (NHL) or multiple myeloma (MM)</td>
<td>Phase 1 trial initiated enrolling 40 subjects</td>
<td>nektar.com</td>
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<td>DiaMedica Therapeutics Inc.</td>
<td>DM199</td>
<td>Chronic kidney disease</td>
<td>Phase 2 trial initiated enrolling 60 African American subjects with CKD caused by IgA nephropathy (IgAN) and hypertensive with CKD at 10 sites in the U.S.</td>
<td>diamedica.com</td>
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<td>PhaseBio Pharmaceuticals</td>
<td>PB2452 with low-dose aspirin</td>
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<td>Phase 2b trial initiated enrolling 200 elderly subjects aged 50-80</td>
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<td>Diamyd Medical</td>
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<td>Latent Autoimmune Diabetes in Adults (LADA)</td>
<td>Phase 2 trial initiated enrolling 15 subjects newly diagnosed with LADA not yet on insulin therapy at the Norwegian University of Science and Technology in Trondheim</td>
<td>diamyd.com</td>
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<td>Can-Fite BioPharma Ltd.</td>
<td>Namodenoson</td>
<td>Nonalcoholic steatohepatitis (NASH)/nonalcoholic fatty liver disease (NAFLD)</td>
<td>Phase 2 trial initiated enrolling 60 subjects with NAFLD with or without NASH</td>
<td>can-fite.com</td>
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<td>Denovo Bipharma LLC</td>
<td>DB102</td>
<td>glioblastoma (GBM) in combination with radiation and temozolomide</td>
<td>Phase 2b trial initiated enrolling 200 patients with newly-diagnosed GBM</td>
<td>denovobiopharma.com</td>
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<td>Boehringer Ingelheim</td>
<td>BI 1265162</td>
<td>cystic fibrosis</td>
<td>Phase 2 trial initiated enrolling subjects with relapsed or refractory lymphoma at sites in the U.S. and Europe</td>
<td>boehringer-ingelheim.us</td>
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<td>Hope Biosciences</td>
<td>HB-adMSCs</td>
<td>Traumatic Brain Injury and Hypoxic-Ischemic Encephalopathy</td>
<td>Phase 1/2 trial initiated enrolling 24 subjects</td>
<td>hope.bio</td>
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<td>Imbrium Therapeutics</td>
<td>IMB-115</td>
<td>insomnia associated with alcohol cessation (IAAC)</td>
<td>Phase 2 trial initiated enrolling adults with moderate or severe alcohol use disorder (AUD) experiencing IAAC</td>
<td>imbriumthera.com</td>
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<td>Diffusion Pharmaceuticals</td>
<td>TSC</td>
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<td>Phase 2 trial initiated enrolling 160 subjects at 23 hospitals in the Virginia and Los Angeles County</td>
<td>diffusionpharma.com</td>
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### Drug & Device Pipeline News (continued from page 8)

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<td>NanoFlu</td>
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<td>Axsome Therapeutics, Inc.</td>
<td>AXS-05</td>
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<td>SurgiMab</td>
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<td>AstraZeneca</td>
<td>DS-8201</td>
<td>breast cancer</td>
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<td>astrazeneca-us.com</td>
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<td>Akorn, Inc.</td>
<td>betamethasone dipropionate lotion USP (augmented)</td>
<td>inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses</td>
<td>ANDA approval granted by the FDA</td>
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<td>Subtle Medical</td>
<td>SubtleMR</td>
<td>image processing to improve medical imaging</td>
<td>510(k) clearance granted by the FDA</td>
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<td>subtlemedical.com</td>
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<td>Cleveland Diagnostics, Inc.</td>
<td>IsoPSA</td>
<td>prostate cancer diagnostic test</td>
<td>Breakthrough device designation granted by the FDA</td>
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<td>cleveland-diagnostics.com</td>
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<td>Genentech, Inc.</td>
<td>Xofluza</td>
<td>influenza complications</td>
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</table>
Upcoming Event Highlights

Conferences

- **OCTOBER 23, 2019**
  - WCG’s Fall 2019 Patient Advocacy Forum
  - Washington, DC

- **OCTOBER 23-25, 2019**
  - 14th Annual DA Inspections Summit
  - Bethesda, MD

- **OCTOBER 27-30, 2019**
  - MAGI Clinical Research Conference 2019 West
  - Las Vegas, NV

- **OCTOBER 31-NOVEMBER 3, 2019**
  - CNS Summit 2019
  - Boca Raton, FL

- **NOVEMBER 13-15, 2019**
  - ICH E6 GCP Interactive Workshops
  - Philadelphia, PA

Webinars

- **OCTOBER 30, 2019**
  - EDC vs eSource: Is it Time to Move?
  - Sponsored by Cmed Technology
  - 11:00 a.m. - 12:00 p.m. EDT

- **NOVEMBER 14, 2019**
  - The National Patient-Centered Clinical Research Network (PCORnet)
  - 11:00 a.m. - 12:30 p.m. EST

- **NOVEMBER 19, 2019**
  - ICH E8 Developments: Are You Sure You’re Up to Date?
  - 1:30 p.m. - 3:00 p.m. EST

Jobs via Kelly Services

- **Clinical Trial Leader**
  - South San Francisco, CA

- **Medical Office Assistant**
  - Owatonna, MN

- **Upstream Manufacturing Associate**
  - Gaithersburg, MD

- **Laboratory Technician**
  - Indianapolis, IN

- **Scientific Program Manager (Regulatory) - NIH**
  - Gaithersburg, MD

- **Sr. Regulatory Affairs Labeling Specialist**
  - Orange, CA

- **Clinical Director**
  - Palo Alto, CA

- **Clinical Project Manager I (Non-MD)**
  - North Chicago, IL

- **Clinical Contracts Associate**
  - Foster City, CA

- **Clinical Data Coordinator**
  - Scottsdale, AZ

- **Clinical Studies Specialist III**
  - North Chicago, IL

- **Clinical Project Associate**
  - Foster City, CA

- **Safety Science Associate Medical Director**
  - San Francisco, CA

- **Laboratory Technician (Molecular)**
  - San Diego, CA

More Jobs

- **Clinical Research Nurse**
  - Battelle
  - Baltimore, MD

- **Clinical Scientist, eCOA**
  - MedAvante-ProPhase
  - Myrtle Point, OR

- **Clinical Research Associate I / II**
  - Covance
  - Work Remotely

- **Data Manager - Clinical Research**
  - ACI Clinical
  - Bala Cynwyd, PA

- **Project Manager - Clinical Research**
  - MedAvante-ProPhase
  - Hamilton, NJ

- **Sr. Systems Engineer**
  - WIRB-Copernicus Group (WCG)
  - Hamilton, NJ

- **Project Manager, Scale Management**
  - MedAvante-ProPhase
  - Hamilton, NJ

- **Clinical Data Analyst**
  - Analgesic Solutions, LLC
  - Wayland, MA

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