

Emphasis on Patients and Data Will Transform Clinical Trials Industry, Says Getz

By Suz Redfearn

Clinical research is poised on the verge of a huge transformation driven by three factors: the patient engagement movement, rich data and analytics and the learning health system model.

That's the future according to Ken Getz, industry veteran and long-time watcher of the space who spoke at the Association for Clinical Research Professionals (ACRP) annual conference last week.

The drug development industry will continue to see success rates decline unless it finds operating models that offer a better chance at a successful outcome, said Getz, director of sponsored programs and research associate professor at Tufts University

School of Medicine's Center for the Study of Drug Development, and founder and chairman of the Center for Information & Study on Clinical Research Participation (CISCRP).

Getz added that each of the three movements — patient engagement, data and analytics and the learning health system model — could be critical for optimizing development performance, especially when interacting simultaneously.

The patient engagement movement, driven by the desire to ensure that trials are relevant to patients and that patient input is considered, has already streamlined feasibility and made the patient feel like they have more skin in the game.

see **Patients and Data** on page 3 >>

IRB Requirements for Individual Patient-Expanded Access IND – GCP Questions, FDA Answers

The FDA's Office of Good Clinical Practices (OGCP) is an important resource for clinical trial professionals who cannot find the answers they need in the agency's multitude of regulations, guidelines and policies.

OGCP answers questions submitted via email to gcp.questions@fda.hhs.gov, interpreting the FDA's position, offering advice on how to proceed and pointing out key documents and resources that provide more in-depth guidance. The following questions address IRB requirements for individual patient-expanded access.

Waiver of IRB Requirements for Individual Patient Expanded Access IND

I have reviewed the recently updated FDA guidance documents, "Waiver of IRB Requirements for Drug and Biological Product Studies" and "Expanded Access to Investigational Drugs for Treatment Use — Questions and Answers" as well as updated FDA Form 3926 and am seeking clarification related to FDA's expectation for IRB review, or what is termed "concurrency", in the guidance.

Specifically:

- ▶ FDA guidance "Expanded Access to Investigational Drugs for Treatment Use — Questions and Answers" Q6 states, "Is institutional review board (IRB) review and approval required for all expanded access categories?"

see **IRB Requirements** on page 4 >>

In this issue

Industry Briefs...2

Three Questions...5

Jeff Lee, President, eCOA of Patient Engagement, Bracket

Drug & Device Pipeline News...6

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

Trial Results...7

CenterWatch reports on results for four drugs.

JobWatch...8

Job listings, networking events and educational programs.




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Industry Briefs

CTTI Planning Recommendations on Investigators, Decentralized Trials and Mobile Technologies

The Clinical Trials Transformation Initiative is developing several new sets of recommendations relating to clinical trials — on the qualification of investigators, the potential legal and regulatory hurdles to decentralized trials and obstacles to incorporating mobile technology, according to its 2017 annual report. In the report marking the organizations 10th anniversary, CTTI also aims to develop toolkits personalized to stakeholders to help with adoption of its recommendations and says it will share case studies with the clinical research community to show how the resources can be applied to improve processes and outcomes. The initiative issued five new sets of recommendations last year including: developing novel endpoints generated by mobile technology; making registries into reusable platforms for conducting clinical trials; providing for pregnancy testing in clinical trials; strengthening pediatric trials in antibacterial drug development; and strengthening the investigator site community. Read the CTTI annual report here: <https://www.ctti-clinicaltrials.org/news/ctti-releases-2017-annual-report-one-decade-impact-one-vision-ahead>.

More Women Needed In Heart Disease Clinical Trials, Study Finds

Women are underrepresented in clinical trials for heart diseases when considering their prevalence within each disease population, according to study findings reported in the Journal of the American College of Cardiology. To determine the percentage of women enrolled, researchers looked at 36 approvals for 35 drugs for diseases such as acute coronary syndrome/myocardial infarction, coronary artery disease, heart failure, atrial fibrillation and hypertension, to determine the percentage of women enrolled.

Researchers found that just 34 percent were women. The researchers concluded that factors prior to screening, such as the ability of a candidate to participate and the identification of potential trial participants, may be the reasons behind the low number of women, as the data in this latest study shows that the low number of enrolled women reflects the lower number of women referred for pre-trial participation screening.

Clinical Trial Participation Brings Hefty Travel Burden, Study Finds

A study published in The Oncologist found that patients who enroll in clinical trials for treatment experience a heavy travel burden. The study analyzed the data of 1,600 patients who enrolled in clinical trials between 1993 and 2014, measuring the distance they traveled from their home to the site of the study and finding that, overall, patients traveled a median distance of 25.8 miles. Patients in NIH-sponsored studies had to go even greater distances, incurring 39.4 miles on average, and patients in phase 1 studies had to travel farther than any other type, navigating a median of 41.2 miles to participate in them, the study said.

Academic Institutions Slow With Clinical Trial Transparency Requirements, Study Finds

Academic institutions have been slow to get on track with stricter requirements released by the HHS and NIH for clinical trial registration and reporting, according to a study by the Johns Hopkins Bloomberg School of

Public Health. The study, published May 2 in the BMC Medicine journal, looked at survey data from over 350 U.S. academic institutions that conduct clinical trials. The researchers found that relatively few had enough staff or necessary policies in place to comply with the new requirements. Before the stricter requirements came into effect, the researchers conducted an online survey of academic institutions registered on ClinicalTrials.gov to determine how prepared they were for the new requirements. Of the 783 eligible accounts contacted, they received responses from 366. Only 43 percent of the accounts had a policy for clinical trial registration, and only 35 percent had a policy on reporting trial results. Survey respondents frequently reported devoting almost no staff time to the website's registration and reporting requirements, with a median full-time staff equivalent of 0.08, or just a few hours per week devoted to regulatory compliance.

CSDR Partners With Non-Profits to Expand Data-Sharing to Academic Clinical Trial Data

Online clinical trial data resource Clinical Study Data Request (CSDR) has launched data-sharing collaborations with four nonprofits to expand the services it offers to researchers. CSDR will partner with the Wellcome Trust, the Medical Research Council, Cancer Research UK and the Bill & Melinda Gates Foundation. The groups will help CSDR broaden its offerings to include academic-led clinical trial data on top of the patient-level clinical data it already offers.



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Patients and Data (continued from page 1)

It's about "making our trials more convenient, making them easier for our patients to participate, to stay in these studies, and to create a level of transparency, where they feel they are a partner and they're part of this process from the outset all the way through to completion of the study and, ultimately, to the development and the commercialization of the program itself," said Getz.

And one of the key messages that patients are communicating via this movement is that they're not particularly interested in coming to an investigator site for all visits.

"They want to be able to participate wherever they can most easily join [a study], and that may not necessarily be at a physical location, but instead really has to be a place where the patient is either participating at the point of care, or perhaps at their home, or using some type of remote technology or application," said Getz.

Add to that movement the now widespread use of big data and analytics, said Getz. He highlighted the efforts of sponsors and CROs to look at all data that they now collect, with an eye toward mining it to glean much more meaningful insights than what's currently extracted.

"How can we analyze that data to predict performance? How can we analyze that information to understand patterns in disease?" said Getz. "That's a very, very important area with electronic and medical health records at its core."

Getz says the industry is now seeing organizations experimenting with much larger data sets to influence protocol design and overall development planning using data from EMR and other sources. They're also using it to try to improve the site identification process and enhance their ability to locate and recruit ever more difficult-to-find patients wherever they might be. He added that the field is also moving toward predictive analytics and machine learning to automate how it interprets and uses this data.

Put the patient-centric and data analytics

"We've spent the last 30 or 40 years thinking about the clinical trial as a process to be managed, and now the data is actually changing our entire orientation."

—Ken Getz, director of sponsored programs and research associate professor, Tufts CSDD

movements together, said Getz, and you start to see the role that the patient will play at the core of all this data — data that is increasingly being automated and analyzed to guide management decisions and operating activity.

"We've spent the last 30 or 40 years thinking about the clinical trial as a process to be managed, and now the data is actually changing our entire orientation," said Getz. "It's the patients' data and it's the patients' engagement that really defines where we will meet them, where we will collect the data and how we will interact with them over time."

The third big movement in the mix is the learning health system model. Explained Getz, this involves analyzing every response a patient might have to an investigational drug or a drug that is already commercially available, and using that information for more targeted trials and, eventually, marketing.

"Every time we learn something, if we're able to capture and archive that data and analyze that data, we can anticipate what these patterns will suggest in terms of which patients will be most receptive to, and might best respond to, a given therapy," he said.

And these responses will change over time as a patient's reactions to a drug may change with age or with disease progression, or as they encounter co-morbidities.

"All of this together suggests that we're moving away from this process-oriented approach to supporting clinical research and

more to a data-oriented approach with the patient at the core," said Getz.


So what now? Getz predicts that trials will migrate away from private physicians' practices and into larger health settings and research centers, where there's more data and more flexibility when it comes to managing trials where data is being collected in a more customizable manner (ePRO, at-home visits, telemedicine, etc). And now that NIH funding is flat, large health centers will show more interest in industry-funded trials, and in time these trials will become more of a mission-critical revenue source for them, he predicted.

He also predicted that traditional recruitment advertising and promotion practices will erode, replaced by EMR and the patient's own motivation targeted through the use of data platforms. In addition, Getz said he thinks the appeal of multi-specialty environments as sites will diminish as sponsors and CROs become more attracted to doctors who have familiarity with a specific disease. And many of these doctors will never have participated in a trial before.

But even that will constitute just a portion of how each trial is run, he said.

"We have been in an environment where clinical research really resides within very physical parameters — dedicated facilities or areas within a clinical practice, but we're now shifting into a much more fluid and flexible environment," said Getz. "So many of the models we hear about may be viable as just part of the way a trial is conducted. We may engage a few physical facilities, we may use wearable devices, we may use telemedicine and home nursing networks, with all of these different models interacting together."

What does that mean for the former traditional investigative site?

"It suggests that you have to be much more open to and adept at managing a more flexible model so that you can remain attractive to organizations as they move in this direction," said Getz. "We have to be able to accommodate that level of customization in every trial." 

IRB Requirements (continued from page 1)

A6: Except for emergency expanded access use (see Q8) when there is not sufficient time to secure prospective IRB review, an investigator treating a patient with an investigational drug under expanded access is responsible for obtaining IRB review and approval consistent with 21 CFR part 56 before treatment with the investigational drug may begin, regardless of whether the protocol is submitted in a new IND or to an existing IND (21 CFR 312.305(c)(4)). In the case of emergency expanded access use, FDA authorization is still required (§312.310(d)), but it is not necessary to wait for IRB approval to begin treatment.

...

- ▶ FDA guidance "Waiver of IRB Requirements for Drug and Biological Product Studies" Section VIII states, "A physician submitting an individual patient-expanded access IND using Form FDA 39268 may select the appropriate box on that form to request a waiver under §56.105 of the requirements in §56.108(c), which relate to IRB review and approval at a convened IRB meeting at which a majority of the members are present. FDA concludes that such a waiver is appropriate for individual patient expanded access INDs when the physician obtains concurrence by the IRB chairperson or another designated IRB member before treatment use begins (no separate IRB approval process or notification to the IRB would be needed)." *It is noted that this implies that "concurrence" is NOT IRB approval.*
- ▶ Form FDA 3926 states, "10.b. Request for Authorization to Use Alternative IRB Review Procedures

I request authorization to obtain concurrence by the Institutional Review Board (IRB) chairperson or by a designated IRB member, before the treatment use begins, in order to comply with FDA's requirements for IRB review and approval. This concurrence would be in lieu of review and approval at a convened IRB meeting at which a majority of the members are present. *It is noted that this does not state "...in lieu of review and approval" but is specific to convened IRB review.*

Related to these documents, I had the following questions:

1. It is unclear if it is FDA's expectation that the "concurrence" by IRB Chair (or designated reviewer) is done via an expedited review mechanism (which would technically constitute IRB approval) or if it can be done by an administrative process that documents the concurrence when a waiver is requested (and therefore the "designated IRB member" doesn't necessarily have to be a designee of the IRB Chair for purposes of expedited review as concurrence is not technically IRB approval). It is noted that the term "concurrence" is used rather than "approval" but there is reference to "designated IRB member" which is often used in the context of expedited review.
2. In addition, my interpretation is that informed consent is still required under 21 CFR 50 for expanded access, including individual patient, so would the review of these requirements be addressed via the concurrence?


A The IRB chairperson (or designated IRB member) would consider the same

information that the full IRB would consider to determine whether to approve the treatment when reviewing and concurring for individual patient-expanded access use.

Informed consent is required for expanded access uses. Review of the informed consent would be part of the IRB review and concurrence process for individual patient-expanded access use.

Q Just to further clarify the actual review pathway that is allowed, when the IRB chairperson (or designated IRB member) reviews an individual patient-expanded access use request, would the IRB chairperson document their review and concurrence as being done via expedited review (under 21 CFR 56.110) or done via an "administrative" (non-IRB review) concurrence action?

Specifically, for those institutions that use electronic IRB systems to track and manage IRB reviews, we are trying to figure out if we must route these individual patient-expanded access use requests (when a waiver is requested) via an expedited review pathway or if they can have a separate administrative review pathway.

A I think you are asking which regulatory IRB review pathway this type of review fits into, full board or expedited or if it would be in a different review pathway. Generally, review of individual patient-expanded access use by an IRB chairperson (or designated IRB member) would follow a different review pathway, that is, one in which the IRB chair or designee reviews the relevant documents (as determined by the IRB) and then his or her decision to concur or not (and/or any questions and responses) is documented. 

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Three Questions

Jeff Lee, Bracket

CWWeekly presents this feature as a spotlight on issues faced by executives in clinical research. This week we hear from Jeff Lee, President, eCOA of Patient Engagement, Bracket. Jeff joined Bracket in 2017, following the acquisition of his company, mProve Health, which he founded 2010. As CEO of mProve Health, a leading provider mobile technologies for patient recruitment, engagement, and data collection in clinical research studies, Jeff grew the company globally.

Q Do you think the clinical trial industry is ready to use a Bring Your Own Device (BYOD) model for ePRO on any study?



A The bring your own device approach is gaining momentum in the industry as the FDA continues to push for greater use of ePRO in clinical trials. As the possibilities of BYOD drive forward, it is becoming more feasible to use this type of approach on any study. However, many sponsors are understandably wary of jumping all in. There is conservative preference to await formal FDA guidance on this topic, as well as few examples of the successful BYOD on regulatory approved studies. While the industry may not be at the point where it is ready to use BYOD exclusively, the model is here to stay and fundamental to the future of clinical trials. Today's patients are more tech savvy than ever before and are ready to accept BYOD. It's up to the clinical trial industry to embrace this readiness and make the shift.

Q What is happening in the industry that is affecting perspectives about BYOD?

A The growth in smartphone penetration has brought increased opportunities

for BYOD. However, the movement has been stalled for years at a "BYOD stalemate": the FDA cannot issue any statements on the validity of data sourced from personal devices without seeing drug studies that are using this type of approach. Conversely, pharma companies are reluctant to risk the success of their clinical trials on a data collection method that the FDA hasn't formally blessed. At Bracket Global we are working to break this deadlock and demonstrate how personal devices can be used more widely on studies.

mProve Health, a Bracket Company teamed up with ICON and Medidata in 2016 to conduct a comprehensive survey to better

"While the industry may not be at the point where it is ready to use BYOD exclusively, the model is here to stay and fundamental to the future of clinical trials."

understand industry attitudes toward collecting data on personal devices. This survey polled clinical trial and outcomes research specialists on potential hurdles such as: "subjects may lose or change their device", or that the "data collected may not be private", "that site staff would be burdened" or "that the patient would delete or corrupt the app", etc. Overall, most respondents were "unconcerned" or only "a little concerned."


Given the industry's considerable debate over modality equivalence and validated data, one might expect eCOA leaders to be extremely concerned about the equivalence of surveys completed across different devices. On the contrary, over half of the respondents to the survey neither agreed nor strongly agreed that "testing was required on all possible devices"; and over half agreed or strongly agreed that "demonstrating equivalence on a single device was acceptable if all subjects could be guaranteed to use a device of a minimum screen resolution and size."

Q What's the Choose Your Own Device (CYOD) model? And how does the CYOD methodology support greater flexibility for sponsors and patients?

A Choose Your Own Device, allows patients to choose to use their personal device or a provisioned solution. By providing a choice, patients benefit from increased flexibility and optionality.

Non-smartphone owners or patients who prefer not to use their personal device for the study can select to use a provisioned device, while patients who prefer to centralize study commitments and personal needs on a single device can choose to use their own.

Under the CYOD model, patients can decide what works best for them. The patient centricity movement has gained traction throughout the industry, so giving patients the ability to choose how they participate in an ePRO study only makes sense. Partial provisioning — usually anywhere from 25-75% — offers a middle route that can avoid the hurdles of requiring 100% BYOD and the inconvenience of full provisioning. Offering choice over which device patients use will flatten the learning curve going into the study. It will also make the study more convenient for the patient in the long-term, whether that means not being committed to expensive personal smartphone ownership or the freedom from carrying multiple devices. Removing device frustration will eliminate a big obstacle for the tech-wary or the dropout-prone. For clinical research teams and investigative sites, the use of patients' own devices also removes the need to deliver training or supply hardware.

As the industry pushes forward in navigating its journey towards 100% BYOD, CYOD is proving to be an ideal stopover point. 

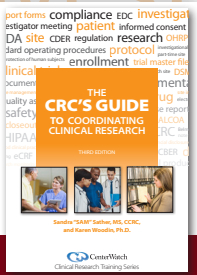
Drug & Device Pipeline News

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Company	Drug/Device	Medical Condition	Status	Sponsor Contact
Ocular Therapeutix	OTX-TIC (travoprost intracameral implant)	glaucoma and ocular hypertension	Phase I trial initiated	ocutx.com
Galapagos NV and MorphoSys AG	MOR106	moderate-to-severe atopic dermatitis (AD)	Phase II trial initiated evaluating 180 subjects	glpg.com morphosys.com
ThromboGenics NV	THR-317 administered in combination with ranibizumab (Lucentis, Novartis)	Diabetic Macular Edema (DME)	Phase II trial initiated enrolling 70 subjects	thrombogenics.com
Wize Pharma, Inc.	LO2A	Symptomatic treatment of dry eye syndrome (DES) in patients with Sjögren's syndrome	Phase IV trial initiated enrolling 60 subjects in the Israel	wizepharma.com
Immusoft Corporation	Immune System Programming	MPS I (Mucopolysaccharidosis type I)	Orphan Drug Designation granted by the FDA	immusoft.com
Stealth Biotherapeutics	elamipretide	Leber's hereditary optic neuropathy (LHON)	Orphan Drug Designation granted by the FDA	stealthbt.com
Conavi TM Medical Inc.	Novasight Hybrid System	simultaneous imaging of coronary arteries with both intravascular ultrasound (VUS) and Optical Coherence Tomography (OCT)	510(k) clearance granted by the FDA	conavi.com
Jazz Pharmaceuticals	Xyrem (sodium oxybate) oral solution	cataplexy and Excessive Daytime Sleepiness (EDS) in pediatric narcolepsy patients	sNDA filed with the FDA	jazzpharmaceuticals.com
Acceleron Pharma Inc.	ACE-083	Facioscapulohumeral muscular dystrophy (FSHD) treatment	Fast Track Designation granted by the FDA	acceleronpharma.com
SCYNEXIS, Inc.	Oral SCY-078	vulvovaginal candidiasis (VVC) and for the prevention of recurrent VVC	Fast Track Designation and Qualified Infectious Disease Product (QIDP) granted by the FDA	scynexis.com

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Trial Results

New Phase IV Trial Data Showed that Epiduo Forte Decreased Acne Lesions

Galderma announced positive results from OSCAR, a Phase IV trial, multicenter, randomized, investigator-blinded, vehicle-controlled, intra-individual comparison study (right/left half-face). The purpose of OSCAR was to evaluate the efficacy of Epiduo Forte (adapalene and benzoyl peroxide) Gel, 0.3 percent/2.5 percent in the treatment of moderate-to-severe acne and to understand if, by decreasing active acne lesions, Epiduo Forte Gel could thereby decrease the risk of atrophic (depressed) acne scars. Results demonstrated Epiduo Forte Gel significantly decreased acne lesions, as measured over a period of 24 weeks vs. vehicle ($P < .0001$), with acne lesion reduction as early as week one. Subjects received 24 weeks of treatment with Epiduo Forte Gel or vehicle (half-face) and full-face skin care. At 24 weeks, based on satisfactory investigator-assessed efficacy and subject agreement, subjects could be treated with once-daily Epiduo Forte Gel on the full face for up to 24 additional weeks with two additional visits at weeks 36 and 48. According to a patient satisfaction survey, overall, 90.1 percent were satisfied to very satisfied with Epiduo Forte Gel vs. 59 percent with vehicle.

Allergan Announces Positive Phase III Clinical Trial for Ubrogepant

Allergan announced positive results from ACHIEVE II (UBR-MD-02), the second of two


pivotal Phase III clinical trials evaluating the efficacy, safety and tolerability of orally administered ubrogepant 25 mg and ubrogepant 50 mg compared to placebo in a single migraine attack in adults. The ACHIEVE II study included 1,686 U.S. adult patients randomized (1:1:1) to placebo, ubrogepant 25 mg and 50 mg respectively, to treat a single migraine attack of moderate-to-severe headache intensity. In the modified ITT (mITT) population of 1,355 patients, 18 to 75 years of age with a history of migraine, both doses showed a statistically significant greater percentage of ubrogepant patients achieving pain freedom at two hours after the initial dose as compared to placebo patients (25 mg vs placebo, $p=0.0285$, 50 mg vs placebo, $p=0.0129$). The ACHIEVE II trial is a Phase III, multicenter, randomized, double-blind, placebo-controlled, parallel group study to evaluate the efficacy, safety and tolerability of two doses of ubrogepant (25 mg and 50 mg) compared to placebo for the treatment of a single migraine attack.

Rigel Pharmaceuticals Presents Phase III Data of TAVALISSE

Rigel Pharmaceuticals announced positive results from the Fostamatinib in Thrombocytopenia (FIT) Phase III clinical program of TAVALISSE (fostamatinib disodium hexahydrate) for the treatment of adults with chronic immune thrombocytopenia (ITP). FIT-1 and FIT-2 were randomized, double-blind, placebo-controlled Phase III trials evaluating TAVALISSE, an oral spleen tyrosine kinase (SYK) inhibitor, in comparison with placebo in

a total of 150 adult patients with persistent or (predominantly) chronic ITP. The studies were designed in accordance with FDA guidance and the efficacy endpoints were based on an objective laboratory assessment of platelet count. Patients who completed the 24-week study treatment in either FIT-1 or FIT-2 could enroll in the long-term, open-label extension study (FIT-3). These Phase III studies were the first to evaluate second- or third-line treatment for ITP in the current era of widespread use of TPO-RA and rituximab.

Galapagos and MorphoSys Announce Initiation Phase II Clinical Trial

Galapagos and MorphoSys announced that the first patient has been screened in IGUANA, a Phase II study with MOR106, an investigational antibody directed against IL-17C, in atopic dermatitis patients. At least 180 patients with moderate-to-severe atopic dermatitis (AD) are planned to be treated over a 12-week period with one of three different doses of MOR106 (1, 3 or 10 mg/kg) or placebo using two different dosing regimens in this Phase II trial in multiple centers across Europe. The placebo-controlled, double-blind study will evaluate the efficacy, safety and pharmacokinetics (PK) of MOR106. Dosing at two- or four-week intervals will be evaluated over the 12-week treatment period, followed by a 16-week observation period. The primary objective will be assessed by the percentage change from baseline in Eczema Area and Severity Index (EASI) score at week 12. 

Medical Device SOP



SOP for Good Clinical Practice by Sponsors of Medical Device Clinical Trials reflects best practices, and addresses FDA Guidance and device regulations to minimize regulatory exposure and comply with industry standards.

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JUNE 5-6, 2018
FDA Data Integrity: For Device and Pharma Firms, and Their Suppliers
Philadelphia, PA

JUNE 7-8, 2018
SOPs and Policies for the 21st Century
Philadelphia, PA

JUNE 13-14, 2018
Ensuring The Quality Connection with your CMO
Philadelphia, PA

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JUNE 1-31, 2018
Program Phlebotomy Training—Two Day Training
Various locations

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Webinars

MAY 22, 2018
Managing Safety Reporting for Advanced Therapies
Angela Pitwood, VP-Pharmacovigilance at Vigilare International, a WIRB Copernicus Group (WCG) subsidiary will be heading the webinar.

JUNE 14, 2018
Setting and Measuring Quality Objectives for Medical Devices
The rules and procedures are technical, involving both FDA rules and ISO 13485:2016. Dan O'Leary will walk you through the process and give you compliance tools to make warning letters a thing of the past.

[[VIEW ALL WEBINARS](#)]