FDA Adds Questions and Answers to Coronavirus Clinical Trial Guidance

By James Miessler

The FDA has updated its guidance on conducting clinical trials during the COVID-19 pandemic with an extensive Q&A section, including a long list of factors to consider when deciding the status of ongoing trials and ones soon to be initiated, as well as how to obtain informed consent remotely.

Patient safety is the most important factor to consider when deciding whether to suspend or continue a trial already in progress or to initiate a study during the national health emergency, the FDA said. In the newly added Q&A section, the agency recommends certain assessments sponsors should make in such a decision, including:

- Assessing whether limitations created by the pandemic on protocol implementation pose new safety risks to participants and whether the risk can be practically mitigated by amending study processes and/or procedures;
- Weighing whether the clinical investigator/sub-investigators will be continually available to oversee the trial and assess/handle safety issues that arise;
- Determining if there will be enough trial support staff on hand and adequate equipment and materials available to them;
- Considering whether clinical investigator sites will remain open to participants for required in-person assessments.

Consider Data Needs Carefully When Altering Trial Protocols in Response to COVID-19

By Brandon May

To get through the COVID-19 crisis with their trials intact, sponsors and sites should take a new look at their data and data collection methods, including evaluating whether a trial will have enough reliable data to support a positive decision, finding ways to collect more data or using data monitoring committees (DMCs) to help assess and modify studies.

Different types of trials need different solutions, says Jonathan Seltzer, chief scientific officer of WCG Clinical. Some trials may have enough data to close out the study early, others will have to decide whether data still to be collected is important enough to be worth putting people at risk or find other ways to get needed data, Seltzer says.

“The DMCs may have some really good input about what data can be collected during this time,” he said at a WCG Clinical webinar last week on coping with the pandemic, “but you should really consult with the DMCs to discuss the safety of the participants and the maintenance of the trial’s integrity.”

Seltzer also said that DMCs and Data Safety Monitoring Boards (DSMBs) can play a role in amending protocols to mitigate the risk of adverse events (AEs) and serious adverse events (SAEs) related to the virus. Typically, DMCS/DSMBs are unblinded and they may have already reviewed efficacy data. See Consider Data Needs on page 7 >>
COVID-19 Drug Research Roundup

Below is a roundup of research activity on COVID-19 vaccines and treatments. It is an update of a weekly column that we will be featuring. To see last week’s column, click here.

COVID-19 vaccines:
- Johnson & Johnson has identified a vaccine candidate frontrunner for COVID-19. The drugmaker said it has also ramped up its manufacturing capabilities, including the establishment of U.S. vaccine manufacturing operations, with the goal of supplying more than 1 billion doses of a vaccine globally. J&J said it plans to begin testing the vaccine candidate in humans no later than September.
- Additionally, Johnson & Johnson announced that it has paired up with HHS’ Biomedical Advanced Research and Development Authority on vaccine development efforts. Together, they have contributed more than $1 billion toward novel coronavirus vaccine research, the company said.
- The World Health Organization’s (WHO) Solidarity multi-arm trial has enrolled its first patients in Norway and Spain. WHO said the trial, which is evaluating the safety and effectiveness of four drugs or drug combos against COVID-19, is a "historic trial that will dramatically cut the time needed to generate robust evidence." The organization predicted a vaccine is still 12 to 18 months away.
- Sanofi and Translate Bio are collaborating on the development of a novel mRNA vaccine candidate for novel coronavirus. Translate Bio will leverage its mRNA research platform to identify and develop vaccine candidates, while Sanofi will lend its support for any hopeful prototypes.
- Scientists with the University of Pittsburgh School of Medicine announced they have developed a potential vaccine for COVID-19. Testing in mice showed that the vaccine creates enough antibodies specific to SARS-CoV-2 to potentially neutralize the virus. The vaccine uses lab-made pieces of viral protein to build immunity the same way current flu shots function. When tested in mice, the vaccine, delivered through a fingertip-sized patch, produces antibodies specific to SARS-CoV-2 at quantities thought to be sufficient for neutralizing the virus.

COVID-19 treatments:
- Sanofi and Regeneron said they have dosed the first patient in their global Phase 2/3 COVID-19 trial of the human monoclonal antibody Kevzara (sarilumab). The clinical program has initiated in Canada, France, Germany, Italy, Russia and Spain, and is enrolling patients. The drug inhibits IL-6, which could help control acute respiratory-distress syndrome caused by severe COVID-19 infection.
- Gilead has announced the initiation of two phase 3 randomized studies in the UK that will look into the safety and efficacy of its antiviral remdesivir in treating moderate to severe COVID-19. The studies, which received the government’s urgent public health research designation, will initially use 15 centers.
- Synairgen has dosed the first patient in its clinical trial of the antiviral SNG001. The phase 2 trial is being held to see if the inhaled formulation of interferon-beta-1a is safe and effective in treating COVID-19. In two phase 2 clinical trials of SNG001 in asthmatic patients, the drug activated antiviral pathways in the lung and improved lung function in patients with respiratory viral infections.
- Fujifilm is offering to provide its influenza antiviral to interested countries and regulators. The company suggested the drug could potentially have an antiviral effect on the coronavirus. Fujifilm warned that while the drug received Japanese approval in 2014 for treating influenza, it’s never seen market distribution and isn’t available in hospitals or pharmacies.
- Mylan has waived exclusivity rights for its generic version of AbbVie’s HIV antiviral Kaletra (lopinavir/ritonavir) to enable other drugmakers to supply the potential COVID-19 treatment. The generic is tentatively approved by the FDA and would receive 180-day exclusivity after AbbVie’s patents expire in November 2021 and May 2022. Chinese researchers running a trial of lopinavir/ritonavir in hospitalized patients with severe COVID-19 said earlier this month that the data did not show a benefit beyond the standard of care.

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Industry Briefs

**WCG COVID-19 Resource Center Gives Trial Participants Key Information**

WCG Clinical has launched a new COVID-19 online patient resource center to help trial participants understand how the pandemic may affect their trials and to help prospective participants match to clinical trials via CenterWatch iConnect.

WCG Senior Director of Patient Advocacy Lori Abrams says it’s crucial to keep patients in the loop about trial developments during the crisis. Sponsors and sites need to understand that patients are worried and unsure about the future of their treatments, including if study visits will continue and whether they will still receive their drugs, and if so, how, Abrams says.

Sponsors can provide sites with details of trial modifications so sites can update participants via phone and video. Patients also deserve regular communication from trusted sources like patient advocacy groups (PAGs), Abrams says, noting that many drugmakers and CROs have started to provide PAGs with prompt information on clinical trial pauses, on-time and delayed study visits, and temporary study changes made in response to the crisis.

She also recommends creating a buddy system for participants so they can share their experiences with one another and said that PAGs can help facilitate that.

Here’s a link to WCG’s patient resource center: https://bit.ly/2JOkk4Z.

**Sponsors Begin to Settle on Trial Adjustments During Pandemic**

While some sponsors are pulling back on enrollment and site activation, others are expressing confidence that they can continue their trial activities with adjustments to avoid the risk of COVID-19 exposure.

**Akero Therapeutics** still hopes to report topline data from its fatty liver disease trial in the second quarter but is unsure how long it will take to collect biopsies from the remaining half of its 50-patient cohort. Biopsies of the remaining 25 patients could be conducted in locations less affected by COVID-19, the company says. Akero will delay the portion of the AKR-001 trial that involves patients with compensated cirrhosis.

**Alligator Bioscience** reports it will pause recruitment for its phase 1 trials of metastatic cancer drugs ATOR-1015 and ATOR-1017.

**Amgen** is optimistic about its pipeline, especially its trial for lung cancer drug AMG 510, which is currently in phase 2 and fully enrolled. Phase 3 trials for its tezepelumab asthma drug and the omecamtiv mecarbil heart failure study also are fully enrolled. The company says it does not anticipate any “significant delays” for these trials.

**AM-Pharma** says it will go ahead with its phase 3 trial of recAP, an anti-inflammatory enzyme, although it will push initiation from this summer to the fall. The company says the severity of the condition recAP is intended to treat, sepsis-associated acute kidney injury, contributed to the decision to stick to the original trial timeline as closely as possible.

**AVRbio** is continuing patient identification activities for its trials in the U.S., Canada and Australia. The Boston-based gene therapy company is pursuing a phase 2 global trial of its drug AVR- RD-01 to treat Fabry disease, which already has dosed four patients, and a phase 1 investigator-led trial of the same drug that is fully enrolled. Other trials include phase 1/2 studies of treatments for cystinosis and Gaucher disease.

**CRISPR Therapeutics** has halted dosing of patients in its trials of products to treat severe hemoglobinopathies and immuno-oncology due to expected shortages of hospital beds and other resources in locations affected by COVID-19. The company, as of its last report, was still enrolling patients in an early safety trial started last summer.

**Dynavax Technologies** reports its HEPLISAV-B postmarketing observational studies are continuing in California. Its dialysis trial of the same drug is continuing to enroll, the company says, because the state classifies dialysis as essential medical treatment. Interim analysis data should be reported later this month.

**Eiger Biopharmaceuticals** is switching to remote patient visits, local lab testing and home delivery of investigational drugs for its rare and ultra-rare disease trials in 20 countries, including its phase 3 D-LIVR trial. The company expects enrollment for the trial will not be completed until 2021. Other trial adjustments Eiger is making include extending screening windows and delaying remaining site activations.

**Genfit** is going ahead with plans to unblind data from its phase 3 nonalcoholic steatohepatitis (NASH) treatment as soon as the FDA has provided feedback on the study. The company has paused its phase 1 trials of its NASH drug elafibranor and stopped enrollment in its phase 2 liver fat study. A phase 2 NASH trial and a phase 3 trial on primary biliary cholangitis are on hold.

**GlaxoSmithKline** has issued guidance on continuing non-COVID-19 studies during the pandemic, including recommending that investigators ensure the appropriate monitoring and follow-up of currently enrolled subjects before considering recruitment of new patients. Studies involving healthy volunteers should not be initiated, and the company will delay trials that have not reached the point of first-patient-first-visit.

**Mithra** will continue its phase 3 studies of Donesta in 2,200 menopausal women in North America, South America, Europe...
This feature highlights changes in clinical trial organizations’ personnel.

**Alimera Sciences**
Steven Gill has been appointed to the newly created role of vice president of thought leader engagement at Alimera Sciences. Most recently, Gill was the associate director, thought leader liaison at Novartis U.S.

**Bone Therapeutics**
Stefanos Theoharis has been named chief business officer of Belgian biotech Bone Therapeutics. Previously, Theoharis served as senior vice president at Cell Medica.

**BrainStorm Cell Therapeutics**
BrainStorm Cell Therapeutics has announced the appointment of David Setboun to the role of executive vice president and chief operating officer. Setboun was most recently the vice president of corporate development of strategy and business at Life Biosciences.

**Cambrex**
Troy Player has been named president of early-stage development and testing at Cambrex. Player arrived at Cambrex after serving as vice president and general manager of the contract manufacturing business unit at West Pharmaceuticals.

**ChroniSense Medical**
ChroniSense Medical has tapped Bridget Ross to lead the company in the role of CEO. Previously, Ross was president of the global medical group at Henry Schein.

**Cognition Therapeutics**
Lisa Ricciardi has stepped down from her previous position on the board of directors at Cognition Therapeutics to assume the position of acting CEO. The role was left vacant after Kenneth Moch stepped down to assume an advisory position.

**Cybrexa Therapeutics**
Arthur DeCillis has joined Cybrexa Therapeutics as the company’s acting chief medical officer. DeCillis will continue serving as president of his own consulting company, DeCillis Consulting.

**CytomX**
Carlos Campoy has been recruited by CytomX to assume the roles of senior vice president and chief financial officer. Campoy was most recently chief financial officer of Alder BioPharmaceuticals.

**Cytovance**
Cytovance has announced the promotion of Jesse McCool to CEO. Previously, McCool held the position of chief technology officer.

**I-Mab**
Gigi Feng has been selected to be I-Mab’s new vice president and global head of corporate communications. Feng was recently global communications head at Sanofi. Fernando Sallés has been appointed to the newly created role of senior vice president and head of U.S. and E.U. business development. Prior to this role, Sallés was a business development executive at Pteropsida Ventures.

**Immune Regulation**
Jonathan Rigby has been named CEO of clinical-stage biotech company Immune Regulation. Rigby was most recently president and CEO of SteadyMed Therapeutics.

**Menlo Therapeutics**
Menlo Therapeutics has named Andrew Saik the organization’s chief financial officer and treasurer. Previously, Saik was chief financial officer of PDS Biotechnology.

**Mereo BioPharma**
Michael Wyzga has taken on the role of interim chief financial officer following the departure of Richard Jones. Wyzga previously held the positions of president and CEO of Radius Health.

**Midatech Pharma**
Stephen Stamp, chief financial officer of Midatech Pharma, now holds the combined roles of CEO and chief financial officer, following the departure of prior CEO Craig Cook.

**Plus Therapeutics**
Gregory Stein has been named head of clinical development of Plus Therapeutics. Stein is co-founder and most recently CEO of Curtana Pharmaceuticals.

**PRISYM ID**
PRISYM ID has announced that Richard Adams will join the company as its CEO. Previously, Adams was the divisional director of healthcare at Wilmington. The company’s chief financial officer role will be assumed by Lauren Patterson, who was most recently chief financial officer at Revium Group.

**Promethera Biosciences**
William Macias has assumed the position of interim chief medical officer at Promethera Biosciences, immediately following Etienne Sokal’s transition from the role to become the company’s senior scientific and medical adviser.

**Q BioMed**
Geoff Fatzinger has been appointed to the role of global head of regulatory affairs at Q BioMed. Fatzinger’s regulatory expertise spans 20 years across all phases of product development.

**Recursion**
Recursion has tapped Michael Secora as its chief financial officer. Prior to taking this position, Secora was managing director.
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and Russia but will pause recruitment for some sites.

Moderna has halted new enrollment and site initiation for its current rare disease trials. The company is collaborating with the NIH on trials of a COVID-19 vaccine, mRNA-1273.

Relmada Therapeutics reports it will stop its trials involving patients with pulmonary arterial hypertension and pause enrollment in the phase 3 FALCON study of bardoxolone in patients with autosomal dominant polycystic kidney disease, but will continue the second year of its phase 3 bardoxolone trial in patients with chronic kidney disease caused by Alport syndrome.

The UK’s Medicines and Healthcare products Regulatory Agency says all sponsors of phase 1 trials under its jurisdiction should have conducted an assessment of risk to trial participants by now and made the decision to pause, terminate or continue trials based on public and patient safety.

Belgium Accelerates Clinical Trial Approval Process

Applications for clinical trials in Belgium can now receive the go-ahead from the government within four days rather than the two to four weeks sponsors previously had to wait.

Citing the COVID-19 crisis as the impetus behind the move, the Federal Agency for Medicinal Drugs and Health Products decided to shorten the trial approval process to get new vaccines and drugs in general to the public more quickly.

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and head of capital markets and venture of Laurion Capital.

Relmada Therapeutics

Relmada Therapeutics has appointed Marc de Somer to the role of senior vice president of clinical development and safety. Most recently, de Somer was chief medical officer of Prilenia Therapeutics.

Rhythm Pharmaceuticals

Hunter Smith, chief financial officer of Rhythm Pharmaceuticals, will now act as the company’s interim CEO.

Santen Pharmaceutical

Tatsuya Kaihara has been appointed to the role of corporate officer and head of North America business of Santen Pharmaceutical as well as CEO of its subsidiary Santen. Kaihara previously served as chief strategy officer and deputy chief executive and financial officer of Santen.

Seneca Biopharma

Seneca Biopharma has hired Matthew Kalnik to take on the roles of president and chief operating officer. Kalnik is the founder and previous CEO of Antidote Therapeutics. Dane Saglio has also been hired to the role of chief financial officer at Seneca. Most recently, Saglio was chief financial officer of RegeneRx Biopharmaceuticals. Seneca has promoted Thomas Hazel, who has held senior positions within the company for 17 years, to the role of senior vice president of research and development.

StrideBio

Maritza McIntyre has been named chief development officer of StrideBio. McIntyre was most recently the president of Advanced Therapy Partners.

Vaccibody

Clinical-stage biopharmaceutical company Vaccibody has appointed Gunnstein Norheim, who most recently served as vaccine science director at CEPI, to lead the company’s infectious disease research and development strategy.

Vertex Pharmaceuticals

Vertex’s former chief medical officer, Reshma Kewalramani, has stepped into the CEO spot left open by Jeffrey Leiden’s move up to executive chairman. Kewalramani, who has a background in R&D, is only the second woman to head up a big pharma company, joining GSK’s Emma Walmsley.

ViralClear Pharmaceuticals

Jerome Zeldis has joined ViralClear Pharmaceuticals, a new division of BioSig Technologies, as executive chair. Most recently, Zeldis was CEO of Celgene Global Health and chief medical officer of Celgene.

The CRA Trainer

An Interactive Companion to The CRA’s Guide to Monitoring Clinical Research.

Learn more at www.centerwatch.com/cratrainer

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FDA Adds Questions and Answers
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assessments or whether the investigator has the ability to give required in-person assessments at an alternative location(s) or whether the assessments can be done virtually;
▶ Evaluating the continued availability of trial supplies and continued operations of vendors, especially related to the investigational product and supplies essential to maintaining safety monitoring and other key trial procedures;
▶ Assessing if IRB, Independent Ethics Committee (IEC) and Data Monitoring Committee staff will continue to operate, and if there will be adequate communication with them to support trial needs;
▶ Weighing public health measures that may be in place by federal and state authorities for the coronavirus, and if they could impact the trial.

“Given the evolving situation, with likely increasing impacts on investigators, staff and supply chains, sponsors should carefully consider the ability to effectively mitigate risks such that patient safety and trial integrity are assured,” the FDA said.

The agency noted that the risks and benefits of keeping a trial going are likely different than those involved in initiating trials other than ones evaluating COVID-19 treatments and vaccines.

While the agency’s added recommendation to use electronic methods if the technology is available for informed consent is helpful, it doesn’t address all the current difficulties in the consent process, such as obtaining consent from legally authorized representatives (LARs), according to WCG Chief Compliance Officer David Forster.

“One issue that quickly arose is that when a potential COVID-19 research subject lacks the capacity to consent, and the consent of their LAR is required, the LAR is often in quarantine and cannot readily provide a signed consent form,” he said.

The agency advises sponsors to follow certain steps if informed consent cannot be obtained electronically. They should use a healthcare worker to deliver the form to the patient, but if direct communication is unsafe, sponsors can arrange a three-way call or video conference with the patient, an impartial witness and additional participants if requested by the patient, such as next of kin. This should be done using a standard approach that identifies the people on the call, reviews the informed consent with the patient by the investigator, answers any patient questions and confirms various issues, such as the participant’s willingness to participate in the trial.

David Borasky, WCG’s vice president of IRB compliance, said that although IRBs have approved remote consent and data collection for numerous studies, “it’s too soon to tell what the challenges will be when it comes to implementation.”

Right now, it is important to have ongoing dialogue between sponsors, research sites and IRBs, with sponsors considering how they can implement scientifically valid and compliant with regulations, he said. Borasky also advised that IRBs be prepared to handle a flood of changes in research spurred by the developing health crisis.

“IRBs should be concerned with managing what is likely an unprecedented influx of changes in research that are necessary to keep research moving forward in a reasonable manner, as well as the review and approval of new research,” he said.

Forster said that the guidance supports increased IRB flexibility during this time — allowing sponsors to bundle amendments and institute changes to deal with apparent immediate hazards or threats to patient safety — but doesn’t explain how sponsors should streamline IRB reporting.

“At this point, I believe most IRBs will be satisfied with receiving notices of protocol deviations or changes in research that are made to eliminate immediate hazards in any format, such as email or letter,” he said. "The IRB’s main concern at this point is to ensure that subject and research staff safety is enhanced as much as possible given the pandemic."

The Q&A section also expands on how sponsors should manage protocol deviations and amendments made to trials in response to the pandemic. For example, if visits are to be conducted by telephone or video contact rather than at the investigational site as originally specified in a study’s protocol, the agency said it would be acceptable if the sponsor created documentation listing all study visits (study reference number, patient ID and date of visit) that deviated from the protocol.

The agency acknowledged that there will most likely be delays in on-site monitoring of clinical trials during the pandemic and advised sponsors to find alternative ways to maintain trial participant safety and data quality/integrity, such as by enhancing central monitoring, contacting sites by telephone to review study procedures, participant status and study progress, or remotely monitoring individual participants when viable.

In addition, the Q&A section in the guidance touches on home delivery and infusion of investigational products in certain situations, among other topics.

Consider Data Needs
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Guidance from the FDA allows for consultation with DMCs/DSMBs about study modification. Guidance from the European Medical Association recommends using DMCs/DSMBs to help:

- Re-start usual trial operations and additional measures when completing the trial after the pandemic (e.g., validation of outcomes that were measured differently);
- Determine the need to adjust the trial sample size and additional analyses to investigate the treatment effect of the pandemic before, during and after the trial; and
- Deal with any identified potential sources of bias, such as missing values, newly identified intercurrent events or other unforeseeable required changes to trial elements.

Sponsors may consider forming DMCs/DSMBs if their trial doesn’t already have one, said Janet Wittes, founder and president of WCG Statistics Collaborative. The DMCs/DSMBs may help sponsors clearly define AEs of special interest and help identify whether the trial should continue. In terms of COVID-19, the DMCs/DSMBs may also be able to help sponsors define the impact of the pandemic on the trial itself.

But, Wittes warned, sponsors should avoid giving DMCs/DSMBs too many responsibilities, which could compromise the integrity of the trial and may ultimately render its data invalid. “While it may be tempting to go to them to seek recommendations on what to do with a trial,” she added, “an open-ended question like that can affect the validity of the trial.”

When capturing data on COVID-19-related AEs, “Let’s think about the most important safety information,” Seltzer said on navigating trials during the pandemic. AEs can be classified as severe, serious and of special interest and Seltzer offered guidelines for how to classify COVID-19-related AEs when reporting them to sponsors and regulators.

He provided the following classifications:

- AEs – A trial participant who becomes infected with the virus but is asymptomatic.
- SAEs – A patient who is hospitalized with COVID-19 and/or dies, including patients treated in non-hospital environments used to handle the overflow of COVID-19 patients.
- AEs of special interest – events specific to a certain trial, patient or COVID-19 that might otherwise not be considered reportable.

Wittes also cautioned webinar attendees about making protocol adjustments to a trial that has an FDA-approved Special Protocol Assessment (SPA) plan. To protect the integrity of the SPA, Wittes recommended:

- Writing a supplement to the trial’s statistical analysis plan;
- Considering carefully whether a change in primary outcome or primary method of analysis will impact the SPA; and
- Clearly documenting and justifying changes or additions being made.

In addition to working with DMCs/DSMBs to guide protocol changes and AE reporting, Wittes said sponsors of trials that are not directly studying COVID-19 should think about whether their trial offers enough clinically meaningful benefit to warrant continuation. Additionally, she suggested studies in their early phases should hit the pause button. “If your trial is still in the design phase or in the screening phase,” she said, “my advice would be to halt recruiting and take this time to make sure your protocol, case report forms and databases are clean before you can start up your trial.”

If trials are in the phase where the last visit has occurred and it’s time to collect the queries, Wittes suggests sponsors should think a little harder about how to collect those queries. “Remember that the [sites] are going to be extremely busy with COVID-19 cases,” she said, “so some of the queries that really aren’t essential to the analysis of the data or interpretation of the study don’t necessarily need to be collected.” She emphasized the importance of only collecting those data that are central to the interpretation of the trial. These data include important safety and efficacy endpoints as well as the primary outcome and important secondary outcomes.

Seltzer added that the possible silver lining of this pandemic will be that the industry will develop some best practices for clinical trials that will help prevent possible future infections. These best practices will probably be developed in relation to remote assessments and virtual visits. “We all know that the reason people don’t enroll in clinical trials is the burden of coming in,” he added, “so we may be able to improve the entire process [with virtual trials] and potentially protect the safety of our patients by keeping them out of hotbeds of infection.”

The COVID-19 crisis may also help the industry learn how to perform trials in a simpler way that’s less visit- and data-intensive, Wittes added. “The clinical trials community should do a real self-reflection about whether we are collecting too much data and if we are demanding too much of our participants,” she said. In addition, Wittes said she hopes that this unprecedented time may inspire sponsors to consider thinking about other pandemics or natural disasters when writing future protocols. “We should consider putting in a section in the protocol on what centers should do when these things happen,” she said, “so a combination of protocols that identify that these things may happen and what centers should do will be really important.”

To listen to a recording of the webinar, click here: https://bit.ly/2X2l0KC.
Achieve enrollment timelines with a customized, end-to-end recruitment plan from WCG Patient Engagement services. Backed by proven methods, a knowledge base of industry site enrollment performance, and our on-the-ground site support, we partner with you to enable your sites to achieve recruitment milestones on or ahead of schedule. These efficiencies could amount to you saving two months in patient screening time, or 4,838,400 seconds.
## Drug & Device Pipeline News

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<td>taletrectinib</td>
<td>first-and second-line Non-Small Cell Lung Cancer (NSCLC) patients with ROS1 mutations and locally advanced or metastatic solid tumors with NTRK mutations</td>
<td>IND clearance and Clinical Trial Authorization granted from Chinese drug evaluation agency (CDE)</td>
<td>anhearttherapeutics.com</td>
</tr>
</tbody>
</table>

continues on next page »
Drug & Device Pipeline News (continued from page 9)

<table>
<thead>
<tr>
<th>Company</th>
<th>Drug/Device</th>
<th>Medical Condition</th>
<th>Status</th>
<th>Sponsor Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intellia Therapeutics</td>
<td>CRISPR/Cas9-based engineered cell therapy</td>
<td>sickle cell disease</td>
<td>IND approved by FDA</td>
<td>intelliax.com/novartis.com</td>
</tr>
<tr>
<td>Novartis</td>
<td>CS12192</td>
<td>autoimmune diseases and other related diseases</td>
<td>IND approved by Center for Drug Evaluation, National Medical Products Administration of China</td>
<td></td>
</tr>
<tr>
<td>AstraZeneca</td>
<td>Imfinzi (durvalumab)</td>
<td>first-line treatment for adult patients with extensive-stage small cell lung cancer in combination with standard-of-care chemotherapies, etoposide and either carboplatin or cisplatin (platinum-etoposide)</td>
<td>approved by the FDA</td>
<td>astrazeneca.com</td>
</tr>
<tr>
<td>Eli Lilly</td>
<td>Taltz (ixekizumab) injection</td>
<td>pediatric patients (ages 6 to under 18) with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy</td>
<td>approved by the FDA for expanded indication</td>
<td>lilly.com</td>
</tr>
<tr>
<td>Rockwell Medical</td>
<td>intravenous formulation of Triferic (Triferic AVNU)</td>
<td>adult patients with hemodialysis-dependent chronic kidney disease</td>
<td>approved by the FDA</td>
<td>rockwellmed.com</td>
</tr>
<tr>
<td>Zoll Medical</td>
<td>second-generation TherOx System (SuperSaturated Oxygen SSO2) Therapy</td>
<td>reduction of heart muscle damage in &quot;widowmaker&quot; heart attack patients</td>
<td>approved by the FDA</td>
<td>zoll.com</td>
</tr>
</tbody>
</table>

In-depth analytical reports on key trends offering insights for your strategies and practices
Key regulatory updates to keep organizations informed of the latest FDA initiatives, changes and requirements
Subscriptions start at $399
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.

### Jobs via Kelly Services

<table>
<thead>
<tr>
<th>Role</th>
<th>Location</th>
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</thead>
<tbody>
<tr>
<td>Clinical Contracts Associate</td>
<td>Foster City, CA</td>
</tr>
<tr>
<td>Operations Planner II</td>
<td>Lansdale, PA</td>
</tr>
<tr>
<td>Laboratory Technician</td>
<td>Commerce City, CO</td>
</tr>
<tr>
<td>Associate Scientist</td>
<td>Somerset, NJ</td>
</tr>
<tr>
<td>Manufacturing Technician 2</td>
<td>Pleasanton, CA</td>
</tr>
<tr>
<td>Laboratory Technician</td>
<td>Commerce City, CO</td>
</tr>
<tr>
<td>Research Associate</td>
<td>Morrisville, NC</td>
</tr>
<tr>
<td>Medical Director - Oncology</td>
<td>Cambridge, MA</td>
</tr>
<tr>
<td>Clinical Lab Data Manager</td>
<td>San Francisco, CA</td>
</tr>
<tr>
<td>Clinical Project Associate</td>
<td>Foster City, CA</td>
</tr>
<tr>
<td>Scientist I</td>
<td>South San Francisco, CA</td>
</tr>
<tr>
<td>Clinical Project Coordinator</td>
<td>Raynham, MA</td>
</tr>
</tbody>
</table>

[ VIEW ALL KELLY SERVICES JOBS ]

### More Jobs

<table>
<thead>
<tr>
<th>Role</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Research Coordinators/Assistants</td>
<td>Orange County Research Center, Tustin, CA</td>
</tr>
<tr>
<td>Support Team Member</td>
<td>IRBNet, Cambridge, MA</td>
</tr>
<tr>
<td>Senior Clinical Data Scientist Programmer</td>
<td>MedAvante-ProPhase, Hamilton, NJ</td>
</tr>
<tr>
<td>Clinical Data Manager</td>
<td>MedAvante-ProPhase, Hamilton, NJ</td>
</tr>
<tr>
<td>Project Manager - Patient Recruitment</td>
<td>ThreeWire, New York, NY</td>
</tr>
<tr>
<td>Senior Project Manager</td>
<td>Analgesic Solutions, LLC, Wayland, MA</td>
</tr>
<tr>
<td>Associate Site Coordinator Russia</td>
<td>ThreeWire, Frankfurt Am Main, Hessen DE</td>
</tr>
<tr>
<td>QA Analyst</td>
<td>MedAvante-ProPhase, Hamilton, NJ</td>
</tr>
</tbody>
</table>

[ VIEW ALL JOB LISTINGS ]

### Academic Programs

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

[ VIEW ACADEMIC PROGRAM DETAILS ]

### Upcoming Event Highlights

#### Conferences

**SEPTEMBER 9 – SEPTEMBER 10, 2020**  
**CLINICAL TRIAL RISK AND PERFORMANCE MANAGEMENT SUMMIT**  
Philadelphia, PA

**Call for Abstracts**  
Is your organization interested in sharing a case study about using MCC metrics and/or quality tools? Contact Linda Sullivan, MCC Executive Director, or Keith Dorrcott, MCC Ambassador, to learn how your organization can be a part of the 2020 MCC Clinical Trial Risk and Performance Management Summit.

**OCTOBER 7 – OCTOBER 9, 2020**  
**15TH ANNUAL FDA INSPECTIONS SUMMIT**  
Washington, DC

#### Webinars

**APRIL 8, 2020**  
**BILLING FOR CLINICAL TRIALS: TIPS ON OPTIMIZING REIMBURSEMENT AND STAYING COMPLIANT**  
1:30 p.m. – 3:00 p.m. EDT

**APRIL 8, 2020**  
**PART 4: CLINICAL TRIALS IN THE ERA OF COVID-19 - THE CHANGES YOU NEED TO MAKE NOW**  
2:00 p.m. – 3:00 p.m. EDT

**APRIL 22, 2020**  
**EU CLINICAL TRIALS PRIVACY**  
1:30 p.m. – 2:30 p.m. EDT

**MAY 5, 2020**  
**GET READY FOR ICH E6(R3): HOW TO PREPARE WHEN YOU’RE STILL STRUGGLING TO ADOPT ICH E6(R2)**  
11:00 a.m. – 12:00 p.m. EDT

[ VIEW ALL EVENTS ]