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CenterWatch Weekly

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Voluntary Remote Records Reviews Will Not Replace Formal On-Site Inspections

By Charlie Passut

The FDA is conducting clinical trial oversight through informal remote review of site, sponsor and CRO records while the COVID-19 pandemic is limiting the agency's ability to conduct traditional on-site inspections. But the agency stresses that these reviews are not taking the place of formal inspections and possible enforcement actions.

In March, because of COVID, the FDA stopped doing on-site inspections. In July, the agency said it had resumed mission-critical on-site investigations although they have been few and far between. To make sure trial oversight was still being addressed, the FDA has been doing voluntary and informal remote records reviews. Experts say they are similar to on-site inspections, but the FDA says they do not replace a legally binding inspection.

"It is important to note these are voluntary assessments and are not inspections conducted under FDA's authority," an agency spokesperson said. To date, the agency says it has conducted 33 remote records review since April, nine for trials in the U.S. and 24 abroad.

Based on discussions with "very senior FDA officials," the voluntary remote records reviews are helping the FDA keep on top of what trials are doing for the agency's internal assessment purposes, says David Chesney, who served the FDA for 23 years as investigator, supervisory investigator,

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Adoption of Electronic Data Management Systems Accelerating During COVID-19

By Leslie Ramsey

COVID-19 has given the clinical trials industry the push it needed to go paperless, with 84 percent of sites, CROs and sponsors already doing so or poised to make the switch to electronic data management (EDM) systems.

The industry is approaching the apex of what Nathan Levens, director of virtual solutions and technology for RealTime, calls the bell curve of e-source adoption, with about 50 percent of the industry already using e-source and another 34 percent of organizations preparing to transition, Levens told the Society for Clinical Research Sites (SCRS) annual conference last week. But about 16 percent of trial organizations will be "laggards," he predicted.

Late adopters are usually those who waited for the product to be perfect, Levens said, while early adopters are those who "see the vision and want to ride the wave of that new technology."

He encouraged hesitant sites to think about what they need now. "If you can find a system that solves at least 90 percent of your pain points," he said, "it's worth it to pull the trigger."

One site that proves Levens' point is Pinnacle Clinical Research in Texas, which has been able to weather the pandemic with the help of e-source, according to CEO Gail Hinkson. At the start of 2020, Pinnacle was conducting 40 trials and enrolling up to 20 new subjects per month, which meant it

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COVID-19 Update

COVID-19 Drug Research Roundup

COVID-19 Vaccines:

Gamaleya Institute's COVID-19 neutralizing antibody vaccine, Sputnik V, is now under phase 3 investigation in the United Arab Emirates. Late-stage trials of the Russian vaccine are currently under way in Russia, Saudi Arabia, Belarus and the Philippines. There are also plans to investigate Sputnik V in Venezuela and India.

Russia has also announced that it has approved EpiVacCorona, a COVID-19 vaccine developed by the **Vector Institute**. This marks the second COVID-19 vaccine approved in the country, behind Sputnik V, that occurred ahead of a planned late-stage 30,000-participant trial.

Novavax is leading an effort to develop a single vaccine effective against both influenza and COVID-19, but work on the vaccine likely won't start until after the pandemic. Currently, the company is seeking FDA approval for NanoFlu, an influenza vaccine, based on positive findings from a late-stage study. Additionally, the company is in the process of developing its own separate COVID-19 vaccine, NVX-CoV2373, which is set to undergo phase 3 testing in late November. Efficacy data for Novavax's COVID-19 vaccine candidate is expected in March 2021.

Trials studying COVID-19 vaccine candidates have largely left out children and adolescents. **Pfizer** is leading the U.S. by being the first company to enroll children as young as 12 in its global phase 3 COVID-19 vaccine trial of its vaccine candidate BNT162b2.

The **University of Exeter** in the UK is studying the tuberculosis Bacillus Calmette-Guerin (BCG) vaccine against COVID-19 in the new BCG vaccination to reduce the impact of COVID-19 in healthcare workers' (BRACE) trial. A total of 10,000 healthcare staff at risk of COVID-19 transmission across centers in the UK, Australia, the Netherlands, Spain and Brazil will participate in this randomized, placebo-controlled trial. Global expansion of the BRACE trial is being made possible by $10 million in funding from the Bill and Melinda Gates Foundation.

Bharat Biotech won't be able to move on to a 28,500-participant phase 3 study of its COVID-19 vaccine candidate Covaxin until complete safety and immunogenicity data from an ongoing phase 2 trial is submitted to the Drugs Controller General of India (DCGI). An application to conduct the phase 3 study has already been submitted to DCGI. The phase 2 trial is still ongoing, however, and some volunteers in this trial have yet to receive their second dose.

An unexplained illness in one patient participating in **Johnson & Johnson's** COVID-19 vaccine study has caused the pharma company to pause its COVID-19 vaccine studies until an independent data safety monitoring board can review the safety event. The 60,000-patient trial has closed its online participant-enrolling system and has also paused all vaccine dosing.

A Taiwan government subsidy has been granted to **Medigen** and **Dynavax** to test a combination of their COVID-19 vaccine candidates in an open-label phase 1 trial in Taiwan. The total amount of the subsidy will reach up to $16.4 million, which will be released at agreed-upon milestones. A total of 45 healthy subjects between the ages of 20 and 50 will be enrolled in the trial. The first participant has been dosed with the combined vaccine product at the National Taiwan University Hospital.

Vaxart has dosed its first participant in an early-phase, dose-ranging study of oral VXA-CoV2-1, the company's own COVID-19 vaccine candidate. The phase 1 trial is seeking to determine the safety and immunogenicity of low and high doses of the oral tablet in adults between 18 and 54 years of age. Preclinical data have already shown that the vaccine can produce immune responses and strong mucosal immune responses against SARS-CoV-2.

COVID-19 Therapies:

The **National Institute of Allergy and Infectious Diseases** (NIAID) has paused enrollment in its phase 3 trial evaluating Eli Lilly's COVID-19 antibody treatment candidate at the recommendation of its independent data safety monitoring board. The company, which had just filed an application for Emergency Use Authorization for the treatment, did not share any details about the event that led to the pause.

The first participants have been enrolled in the National Heart, Lung and Blood Institute's multicenter phase 2 study investigating fostamatinib, an oral spleen tyrosine kinase inhibitor from **Rigel Pharmaceuticals**, as a treatment for COVID-19.

Eli Lilly's rheumatoid arthritis drug baricitinib in conjunction with **Gilead Sciences'** antiviral remdesivir was associated with a 12.5 percent reduction in COVID-19 patient recovery time compared with remdesivir alone, according to new data

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COVID-19 Update (continued from page 2)

from the Adaptive COVID-19 Treatment Trial (ACTT-2). The dual-therapy approach reduced time to recovery from eight to seven days. Based on the data from the ACTT-2, Eli Lilly is discussing with the FDA the possibility of an Emergency Use Authorization for baricitinib to treat hospitalized patients with COVID-19.

Additionally, **Gilead Sciences** released final results from a phase 3 remdesivir trial showing it helped patients improve in multiple areas compared to placebo and worked a day faster than previous results showed. The results, which come from the National Institute of Allergy and Infectious Diseases' 1,062-patient phase 3 trial, showed that remdesivir plus standard of care shortened recovery time by four days, meeting its primary endpoint. According to the final day-29 results, patients given remdesivir achieved clinical recovery five days faster than placebo patients, with a median recovery time of 10 days for remdesivir and 15 days for placebo, a day faster than earlier results indicated.

AstraZeneca plans to test its experimental long-acting antibody combination AZD7442 in two new phase 3 clinical trials within the next few weeks. One trial will examine the efficacy and safety of AZD7442 for preventing infection for 12 months in 5,000 participants. The other study will investigate the potential of AZD7442 in preventing infection after exposure in 1,100 participants. Additional studies will test the combination therapy as a COVID-19 treatment in 4,000 adults with SARS-CoV-2 infections. Development and large-scale manufacturing of the combination therapy will be supported by a $486 million grant from the Biomedical Advance Research and Development Authority.

Biopharmaceutical company **Apogenix** has enrolled its first patient in a multicenter, open-label phase 2 ASUNCTIS trial. The study will evaluate the safety and efficacy of asunercept plus standard of care vs. standard of care alone in 400 patients with severe COVID-19. Regulatory approval for the trial has been granted in Spain and Russia.

Data from an open-label prospective study from **Relief Therapeutics** and **NeuroRx** show that treatment with RLF-100 (aviptadil) was associated with an 81 percent survival beyond 60 days in 45 patients with respiratory failure and severe COVID-19. In contrast, approximately 17 percent of patients who received the drug survived beyond 60 days. Overall, treatment with aviptadil was associated with a nine-fold increased probability of survival and respiratory failure recovery. **Bachem Americas** has agreed to manufacture the treatment, upon approval, in quantities that will treat 1 million patients.

Clinical-stage specialty pharmaceutical company **TLC** has enrolled its first participant in a phase 1 trial of TLC19, an inhalable treatment or prophylactic therapy for COVID-19. The company's treatment is a proprietary liposomal formulation consisting of a small amount of hydroxychloroquine. The trial will evaluate the tolerability, safety and pharmacokinetics of single ascending doses of the inhaled therapy in 30 healthy volunteers.

Tevogen Bio has submitted an Investigational New Drug application to the FDA to develop a T-cell treatment for COVID-19. The company will evaluate its proprietary antigen-specific T-cell technology for treating hospitalized patients with COVID-19 in future clinical trials.

Treatment with **Recipharm's** proprietary molecule Erdosteine improved health-related quality of life parameters and dyspnea in a trial of 20 patients with COVID-19 and severe respiratory failure. The study was conducted in Italy. Plans are under way to begin additional studies of Erdosteine.

Sorrento Therapeutics has received authorization by the Brazilian Health Regulatory Agency to conduct a phase 2 trial of abivertinib in patients with mild, moderate and severe COVID-19. The study will be conducted in Brazil and will enroll 400 patients. Treatment will be given for only seven days, compared with the 14-day protocol in a U.S. trial.

Grifols has started a phase 3 trial for its anti-coronavirus hyperimmune globulin, a treatment derived from the plasma of recovered COVID-19 patients. The trial is being conducted in collaboration with HHS' Biomedical Advance Research Development Authority, the National Institute of Allergy and Infectious Diseases, and the FDA to see if the treatment can strengthen antibody response and reduce the risk of serious illness or death if taken when initial symptoms arise. The trial will enroll 500 patients in 18 countries, and the participants will be given either a combination of the convalescent plasma treatment and remdesivir or placebo and remdesivir.

Industry Briefs

WCG Announces IRB Consolidation and New Review Submission Platform

WCG Clinical last week announced it has unified its five separate IRBs under a single WCG IRB banner and launched a new IRB submission platform.

The five IRBs — formerly known as Western IRB (WIRB), Copernicus Group IRB, Midlands IRB, New England IRB and Aspire IRB — will now work as a single entity using the same processes and principles.

"This is just one further example of our commitment to positively transform the clinical trial process while keeping patient safety as our highest priority," said Donald A. Deieso, WCG Clinical's CEO.

The new Connexus platform, WCG IRB says, provides easier and more secure document submission for clients and allows them to track the status of their review through a process that is fully transparent. Through Connexus, WCG's goal is "to improve the submission process, eliminate and reduce errors, and thereby achieve the highest ethical standards in the board review process," says David Forster, WCG Clinical's chief compliance officer.

WCG's flagship IRB is celebrating its 52nd anniversary this year. Two more IRBs that WCG acquired were established in the 1980s, Midlands IRB in 1981 and New England IRB in 1989. Copernicus Group followed in 1996 and Aspire IRB in 2004. Together, the five IRBs represent more than 160 years of experience in ethical review and more than 200 review board members.

The newly unified WCG IRB will serve more than 3,100 institutions, including 150 academic medical centers.

Information on using Connexus is available at: https://bit.ly/345GGcR.

NIH Studying Approved and Investigational Therapies for Use Against COVID-19

The National Institute of Allergy and Infectious Diseases (NIAID) has begun a phase 2 study of the potential of approved therapies and late-stage investigational drugs for hospitalized COVID-19 patients.

The study, termed the ACTIV-5 Big Effect Trial (ACTIV-5/BET), is enrolling adults with COVID-19 at up to 40 sites in the U.S. It is being conducted in partnership with the National Institutes of Health's Accelerating COVID-19 Therapeutic Innovations and Vaccines (ACTIV) program.

In the randomized ACTIV-5/BET trial, licensed drugs and investigational therapies that show promise against COVID-19 compared with controls will be propelled into larger COVID-19 trials. Around 100 hospitalized patients will be randomly assigned to each study arm. No more than three investigational therapies will be tested at once.

The first candidate to be tested in the trial includes monoclonal antibody risankizumab from Boehringer Ingelheim and AbbVie. This drug is currently FDA-approved for severe plaque psoriasis, but ACTIV-5/BET will test it in combination with remdesivir vs. placebo.

ACTIV-5/BET will also test lenzilumab, Humanigen's late-stage investigational drug for the prevention and treatment of cytokine storm, in combination with remdesivir.

Japan Publishes COVID-19 Vaccine Trial Principles

In newly released guidelines, Japan's Pharmaceuticals and Medical Devices Agency (PMDA) recommends using confirmed SARS-CoV-2 infection, arterial oxygen saturation, requirement of oxygen therapy and death as key study endpoints for clinical trials evaluating COVID-19 vaccines.

The recommendations from the PMDA are similar to those released by the FDA and other regulatory agencies across the world. For the evaluation of COVID-19 vaccine safety, the PMDA advises clinical trial sponsors to collect all adverse events for at least 28 days following vaccine administration.

The PMDA guidelines also asks sponsors to follow trial participants for at least one year to determine long-term safety and efficacy of a COVID-19 vaccine.

The PMDA states in its guideline principles that longer follow-up periods for safety and efficacy assessment may be necessary but will depend on characteristics of the vaccine candidate.

Despite mandating long-term follow-up of these vaccines, the PMDA says it may also allow COVID-19 vaccines to come to market based on preclinical efficacy evidence and immunogenicity data that connect an immunogenic marker to a vaccine's ability to prevent COVID-19.

The full PMDA principles can be found here: https://bit.ly/345h5AP.

Survey: Most Trial Sites Reducing In-Person Visits to Quell Patient Fears During Pandemic

Approximately 51 percent of patients in clinical trials are concerned about coming into contact with other participants who may have COVID-19, prompting nearly 83 percent of U.S. sites to adjust patient scheduling to limit the number of participants in the office at the same time, according to a survey of 268 U.S. clinical trial sites.

The survey, conducted by SubjectWell and Reify Health, also found that approximately 85 percent of sites in the U.S. are offering phone screenings before in-person visits to reduce the number of participants coming into the office. Almost 93 percent and 91 percent of sites have implemented protocols to keep infected staff and patients out of the office, respectively.

Nearly all sites (96 percent) have also said they have increased sanitation procedures during the COVID-19 pandemic. Additionally, almost 90 percent of surveyed sites reported increasing their supply of personal protective equipment for in-office staff. Around 88 percent of site respondents also said they are using in-office temperature screenings.

Up and Coming

This feature highlights changes in clinical trial organizations' personnel.

Achilles Therapeutics

Achilles Therapeutics has appointed **Karl Peggs** to the role of chief medical officer. Peggs is currently the professor of transplant science and cancer immunotherapy at the UCL Cancer Institute.

Atlantic Healthcare

Nermeen Varawalla has been named chief medical officer and head of clinical development of Atlantic Healthcare. Formerly, Varawalla was senior vice president and head of clinical development at BTG International.

Bavarian Nordic

Bavarian Nordic has appointed **Anu Kerns** to the role of executive vice president of people and organizations. Kerns was most recently the global change and transformation lead at Novo Nordisk.

Dewpoint Therapeutics

Ameet Nathwani has been appointed CEO of Dewpoint Therapeutics. His most recent appointments were chief medical officer, chief digital officer and executive committee member at Sanofi.

e-therapeutics

Ali Mortazavi, former CEO of Silence Therapeutics, has taken the helm of e-therapeutics as its newest CEO.

Flagship Pioneering

Tuyen Ong, former senior vice president and head of the ophthalmology franchise at Biogen, has been named CEO-partner of Flagship Pioneering. Ong will also hold a concurrent role of CEO at Ring Therapeutics.

Frazier Healthcare

Don Frail and **Michael Varney** have been added as senior advisers on the life sciences team at Frazier Healthcare. Most recently, Frail was senior vice president of R&D at Allergan, and Varney previously held the position of executive vice president and head of Genentech's research and early development.

hyperCORE

hyperCORE, a clinical study site network, has appointed **Karri Venn** as its new CEO. Venn is also currently the president of research at LMC Healthcare.

Inozyme Pharma

Inozyme Pharma has named **Yves Sabbagh** senior vice president and chief scientific officer. Sabbagh was most recently head of rare renal and musculoskeletal diseases research at Sanofi.

Inversago Pharma

Michael Harvey, who recently served as vice president of drug development and Montreal site head at Ipsen, has been named senior vice president of drug development at Inversago Pharma.

Jaguar Health

Melissa Yeager has been appointed senior vice president of regulatory affairs and quality assurance at Jaguar Health and its wholly owned subsidiary Napo Pharmaceuticals. Previously, Yeager was senior vice president of Alder BioPharmaceuticals.

Kedrion Biopharma

Val Romberg, former executive vice president of operations for CSL Behring, has been named CEO of Kedrion Biopharma.

MaxCyte

MaxCyte has hired **Sarah Meeks** to fill the role of vice president of business development and **Steve Nardi** to vice president of manufacturing and engineering operations. Meeks was most recently vice president of business development at Synpromics. Nardi joins MaxCyte from Iradimed, where he served as vice president of worldwide manufacturing. In addition, MaxCyte has promoted **Brad Calvin** from executive vice president of global commercial operations to the role of chief commercial officer.

Maze Therapeutics

Sarah Noonberg has been tapped by Maze Therapeutics to take the role of chief medical officer. Previously, Noonberg was chief medical officer of Nohla Therapeutics.

Medeor Therapeutics

Daniel Brennan has been appointed to the role of chief medical officer of Medeor Therapeutics. Brennan will continue to serve in his current roles of inaugural medical director at the Comprehensive Transplant Center at Johns Hopkins Hospital and professor of nephrology at the Johns Hopkins Division of Renal Medicine.

Meissa Vaccines

Meissa Vaccines has named former senior vice president of business development at Portola Pharmaceuticals, **William Daly**, to the role of chief business officer. Meissa has also appointed **Keith Wells** to chief manufacturing officer. Wells was most recently a scientific and technical adviser to the Biomedical Advance Research and Development Authority.

Micron Medical

Micron Medical has appointed former MiMedx executive vice president and chief strategy officer, **Mark Landy**, to CEO.

Novavax

Novavax has promoted **Russell Wilson** to executive vice president and NanoFlu™ general manager. Wilson's most recent role was senior vice president of business development, which he has held at Novavax since 2011.

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Up and Coming (continued from page 5)

OncoSec Medical

Sandra Aung has been named senior vice president and chief clinical development officer of OncoSec Medical. Aung most recently served as the senior director of clinical development at Nektar Therapeutics.

Recce Pharmaceuticals

Michele Dilizia has been named chief scientific officer of Recce Pharmaceuticals. Previously, Dilizia was the executive director of microbiology and regulatory affairs at Recce.

Sanofi

Frank Nestle has been named global head of research and chief scientific officer of Sanofi. Nestle was the former global head of immunology and inflammation, and chief scientific officer of North America at Sanofi.

SpectraWave

Cardiology-focused startup SpectraWave has appointed **Eman Namati** to CEO. Previously, Namati was CEO of NinePoint Medical.

SPI Pharma

Scott Thomson has been named CEO of SPI Pharma. Most recently, Thomson was senior vice president of the care chemicals division of North America at BASF.

Trevi Therapeutics

Trevi Therapeutics has made several new key appointments, including **Shashank Rohatagi** to vice president of pharmacology and clinical pharmacokinetics, **Farrell Simon** to vice president and head of U.S. marketing and **Katherine Takaki** to vice president of global regulatory affairs. Rohatagi was recently senior principal scientist for clinical pharmacology at Metrum Research Group, and Simon previously held the position of chief of staff to the group president of biopharma at Pfizer. Also, Takaki previously served as vice president of global regulatory affairs at Iterum Therapeutics.

Features

Voluntary Remote Records

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director of investigations and ultimately director of the San Francisco district office.

The remote records reviews are one way for the FDA to continue its oversight function in the absence of on-site inspections. However, "if they conduct an assessment remotely and they tell the site — in this case, clinical trial sites — that this a voluntary, consensual participation that they're entering into, then it's not technically an inspection," he told *CenterWatch Weekly*.

And Chesney acknowledges the remote records review process is no substitute for a formal inspection. "They don't call them 'remote inspections' on purpose because [the FDA has] very clear and longstanding defined authority to conduct inspections, and that's not what they're doing," said Chesney, general manager for DL Chesney Consulting. "Frankly, they don't want anybody litigating this and then end up with an adverse precedent on the books. So, they're taking great pains not to use the word 'inspection.'"

Chesney said the scope of documentation and questions the FDA could pose during a remote regulatory assessment are the same as outlined in the agency's inspection instructions: informed consent forms, source records, case report forms, electronic records, monitoring plans and reports, and any other study-related records.

"You'll see most of it could be done remotely just as easily as on-site," Chesney said. "Logistically, it may be a little more complicated because you have to figure out the best way to transmit documents."

Despite the clear differences between an on-site inspection and an informal records review, Chesney said the agency is gathering much of the same information. "From a practical standpoint, is it really all that different? No, they're doing pretty much the same things," Chesney explains. Findings that would normally be presented on a Form 483 after an inspection are instead conveyed orally during a discussion with the site at the conclusion of the assessment.

"They don't call them 'remote inspections' on purpose because [the FDA has] very clear and longstanding defined authority to conduct inspections, and that's not what they're doing."

—David Chesney, General Manager, DL Chesney Consulting

But another key difference between an inspection and a remote records review: sites are not automatically given a copy of the final report; they can request one through FOIA. Although FOIA requests can take several weeks to process, getting the final report would be a way for sites and sponsors to document what has happened.

In a traditional inspection, which begins with FDA investigators presenting an official Form 482 — Notice of Inspection, any deviations or violations found would be listed on a Form 483 — Inspectional Observations, and the agency would determine whether enforcement action — such as warning letters, trial suspensions, seizures or even criminal charges — is necessary.

But under the FDA's remote regulatory assessment model, the agency is reaching out to sites for their voluntarily participation in a records review without issuing the Form 482 that gives it the statutory authority to inspect and enforce, according to Chesney.

Chesney warns that a formal inspection could be a consequence of a remote records review if serious issues are uncovered. The FDA concurs. According to an FDA spokesperson, "Follow-up inspections will be conducted as deemed necessary based upon the information obtained during these assessments. In some case, no follow-up inspection will be necessary. Also, a remote regulatory assessment may be ended early if significant concerns are raised during the assessment and an inspection scheduled as conditions at the establishment allow."

"Based on my own experience in the agency," Chesney said, "I would imagine that if something came up during one of these remote regulatory assessments that was quite serious and [the FDA] felt it was necessary to pursue it more strongly, they could certainly go and conduct an on-site inspection and gather evidence in that realm in order to have that evidence be usable in some litigation, theoretically."

Chesney says the remote records reviews are meant to be an oversight tool but not to replace the inspection and enforcement responsibilities the FDA has. "They're like all the rest of us, trying to cope with current circumstances and get their job done as efficiently as they can."

It's too early to tell if the FDA would continue to utilize remote regulatory assessments post-COVID. For its part, the agency says, "The FDA continues to assess a full return to our routine inspection capabilities and is evaluating the use of remote assessments when on-site inspections cannot be conducted."

Chesney believes the continued use of remote records reviews "could, for example, extend the FDA's reach and it could end up saving the agency a good deal of money. If they wanted to include a mix of in-person and some remote assessments for a given study, they could probably get more clinical trial sites in less time and for less resource expenditure and [have them run] much more efficiently."

Features

Adoption of EDM Systems

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was hosting about 50 on-site monitoring visits per month, Hinkson said.

With the onset of the pandemic, Pinnacle's trial activity didn't slow but sponsor on-site monitoring came to a halt, creating a data backlog for both sites and sponsors. And because sponsor payments for trial activities are triggered by submission of data from site to sponsor, Pinnacle's revenue began to slow as well.

But because 80 percent of the site's data was housed in electronic systems, Hinkson said, and Pinnacle immediately moved to transfer their paper records as well, sponsors were able to begin remote monitoring, cut down the backlog and restart cash flow.

"It wasn't until we were able to have CROs and sponsors … perform remote data monitoring that we really started to see a reduction to the data backlogs and their related downstream effects," she said.

Pinnacle's experience was so positive that its parent network, Summit Clinical Research, is now considering transitioning all its sites to e-source, said Hinkson, who also serves as vice president of Summit.

There is a cost to making such a transition, acknowledged RealTime CEO Rick Greenfield at the SCRS conference, but it's "extremely minimal" when you consider the benefits and paying for the transition to electronic systems will save them money in the long run.

If a sponsor can save the cost of at least one or two monitoring trips by adopting systems that allow for remote oversight, Levens pointed out, "that probably pays for the system."

Raymond Nomizu, cofounder and CEO of electronic solutions company CRIO, offered an example of potential savings. Assuming a sponsor with 10 sites conducts four on-site monitoring visits to each site and travel expenses average $1,600 per visit, the sponsor saves $64,000 by eliminating monitoring visits. And eliminating the cost of archiving paper records can save an additional $1,000 per site. Taken individually, the savings are small, but they can add up to hundreds of thousands of dollars for a multisite trial.

But beyond costs and savings, there are challenges to electronic system adoption, all three experts agreed. One question sponsors must consider, Nomizu said, is whether the CRA should become a data manager or if the two roles should be separate and the CRA be allowed to focus on protocol compliance, good clinical practice and training. And sponsors moving to 100 percent remote monitoring should establish criteria for when risk factors trigger the need for an on-site visit.

"You also need to think about when you want to escalate to on-site monitoring," Nomizu said. There are times when in-person meetings are necessary to address operational challenges, such as the re-education of site staff and investigating further any issues that might have been flagged by the remote monitoring process.

Workflows will be different, too. Sites need to understand that new systems mean new start-up processes, Levens said. "Not more difficult, just different." And switching to electronic from paper doesn't necessarily mean monitoring visits will be faster.

"The big one here is enforcing site training and adoption," Nomizu said. He encourages sponsors to scrutinize heavily the vendors' track records in training sites and getting them to use the electronic system effectively.

Greenfield and Levens encouraged sites to be ready for change. "It's difficult to get buy-in sometimes," Greenfield said, "and this is something that we really have to champion with our sites that are moving into these systems."

Sites and sponsors should designate a leader or a team of leaders for the transition, Levens recommended. "Your staff will run into challenges and obstacles and you need your people, those champions, that can navigate through those obstacles."

Now that a lot of sites are adopting electronic source systems, sponsors have the opportunity to "work with the site technologies in a way that provides benefit for both" the sponsor and the site, Nomizu said. Data access will be easier and immediate for both sides and remote monitoring will be more seamless, a benefit that will last far beyond the pandemic.

Nomizu discussed three levels of site involvement a sponsor can undertake. At the lowest level, the sponsor merely encourages sites to implement electronic systems and offers to reimburse them for the expense of the technology they choose. "By taking cost off the table, you'll encourage sites to adopt the technology," he said. The drawback at this level is that different sites will be at different stages of adoption and some traditional monitoring may still be necessary.

At the second level, a sponsor could provide its own technology, along with standard templates and processes. "This can be done upfront as part of the contract process where, as a condition of participation, the sites agreed to use the source technology," Nomizu said. The challenge here is that some sites will be unfamiliar with the technology and will need additional training. Also, this approach puts the burden of validating the technology solely on the sponsor, he said.

Sponsors that want to go all in can integrate their entire electronic system with sites' systems – such as eCRF, electronic data capture (EDC) and clinical trial management systems – for seamless transfer of data between sites and sponsors. With this approach, there is no data lag, eCRF files are automatically kept up to date and source data verification is not necessary. It can be difficult to map sites' EDC fields to the sponsor's system, and validation would be needed, Nomizu said.

Drug & Device Pipeline News

Company	Drug/Device	Medical Condition	Status	Sponsor Contact
COVID-19 Trials and Actions				
ARCA Biopharma	AB201 (rNAPc2)	patients hospitalized with COVID-19	IND approved by the FDA	arcabio.com
ImmunityBio	hAd5-COVID-19	COVID-19 vaccine	IND approved by the FDA	immunitybio.com
CytoAgents	GP1681	COVID-19 cytokine storm (hypercytokinemia)	initiation of phase 1 trial	cytoagents.com
Taiwan Liposome Company	TLC19 (liposomal suspension of hydroxychloroquine for inhalation)	prophylaxis of COVID-19	first patient enrolled in phase 1 trial	tlcbio.com
VaxArt	VXA-CoV2-1	oral tablet COVID-19 vaccine	first patient dosed in phase 1 trial	vaxart.com
Enlivex	Allocetra	severe and critical COVID-19 patients	initiation of phase 2 trial	enlivex.com
Rigel Pharmaceuticals	fostamatinib	hospitalized COVID-19 patients	first patients enrolled in phase 2 trial	rigel.com
National Institutes of Health	remdesivir (Vitrakvy) and hyperimmune intravenous immunoglobulin (hIVIG)	adults hospitalized for COVID-19 with symptoms for 12 days or fewer without life-threatening organ dysfunction or organ failure	initiation of phase 3 trial	nih.gov
The CoVIg-19 Plasma Alliance/ National Institute of Allergy and Infectious Diseases	anticoronavirus hyperimmune intravenous immunoglobulin (H-Ig) medicine	hospitalized adults at risk for serious complications of COVID-19 disease	first patients enrolled in phase 3 trial	covig-19plasmaalliance.org
Abbott	AdviseDx SARS-CoV-2 IgM (Immunoglobulin M) lab-based serology test	diagnosis of COVID-19	Emergency Use Authorization granted by the FDA	abbott.com
Other Trials and Actions				
Armata Therapeutics	AP-PA02	pseudomonas aeruginosa infections	IND approved by the FDA	armatapharma.com
Ascletis Pharma	ASC42	nonalcoholic steatohepatitis	IND approved by the FDA	ascletis.com
Nanobiotix	NBTXR3 activated by radiation therapy	lung cancer and esophageal cancer	IND approved by the FDA	nanobiotix.com
Nuvation Bio	NUV-422	patients with high-grade gliomas	IND approved by the FDA	nuvationbio.com
Seattle Gummy Company	allergy gummy medication	allergies	IND approved by the FDA	seattlegummy.com
SoniVie	Therapeutic Intra-Vascular Ultrasound (TIVUS) System	pulmonary arterial hypertension	IDE approved by the FDA	sonivie.com
Amolyt Pharma	AZP-3601	hypoparathyroidism	first patient dosed in phase 1 trial	amolytpharma.com
NANOBIOTIX	NBTXR3 activated by radiation therapy	pancreatic cancer	first patient dosed in phase 1 trial	nanobiotix.com

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Drug & Device Pipeline News (continued from page 10)

Company	Drug/Device	Medical Condition	Status	Sponsor Contact
Sumitomo Dainippon Pharma Oncology	TP-1454 administered alone and in combination with ipilimumab and nivolumab	advanced metastatic or progressive solid tumors	first patient dosed in phase 1 trial	sdponcology.com
Bold Therapeutics	BOLD-100 in combination with FOLFOX	advanced gastric, pancreatic, colorectal and bile duct cancers	phase 1b trial initiated	bold-therapeutics.com
Celldex Therapeutics	CDX-0159	chronic spontaneous urticaria	first patient dosed in phase 1b trial	celldex.com
Evelo Biosciences	EDP1815	mild to moderate atopic dermatitis	patient enrollment complete in phase 1b trial	evelobio.com
Regulus Therapeutics	RGLS4326	autosomal dominant polycystic kidney disease	first patients dosed in phase 1b trial	regulusrx.com
Castle Creek Biosciences	FCX-013	moderate to severe localized scleroderma	first patient dosed in phase 1/2 trial	castlecreekbio.com
Linnaeus Therapeutics	LNS8801 in combination with Keytruda (pembrolizumab)	advanced cancer	first patient dosed in phase 1/2 trial	linnaeustx.com
Alessa Therapeutics	Biolen device	localized sustained delivery of bicalutamide into the prostate of men scheduled for prostate surgery for treatment of nonmetastatic prostate cancer	first patient enrolled in phase 2 trial	alessatherapeutics.com
Evelo Biosciences	EDP1815	mild to moderate psoriasis	first patient dosed in phase 2 trial	evelobio.com
CartiHeal	Agili-C implant	cartilage lesions in arthritic and nonarthritic joints	Breakthrough Device designation granted by the FDA	cartiheal.com
Inventiva	lanifibranor	nonalcoholic steatohepatitis	Breakthrough Therapy designation granted by the FDA	inventivapharma.com
miR Scientific	miR Sentinel PCC4 Assay (miR Sentinelä Prostate Test)	prostate cancer liquid biopsy test	Breakthrough Device designation granted by the FDA	mirscientific.com
Axovant Gene Therapies	AXO-AAV-GM2	GM2 gangliosidosis	Rare Pediatric Disease designation granted by the FDA	axovant.com
Curtana Pharma	CT-179	medulloblastoma	Rare Pediatric Disease designation granted by the FDA	curtanapharma.com
Italfarmaco Group	givinostat	Duchenne Muscular Dystrophy	Rare Pediatric Disease designation granted by the FDA	italfarmaco.com

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Drug & Device Pipeline News (continued from page 11)

Company	Drug/Device	Medical Condition	Status	Sponsor Contact
Oxular	OXU-003	retinoblastoma	Rare Pediatric Disease and Orphan Drug designation granted by the FDA	oxular.com
Y-mAbs Therapeutics	nivatrotamab	neuroblastoma	Rare Pediatric Disease and Orphan Drug designation granted by the FDA	ymabs.com
Orca Bio	Orca-T	patients with blood cancers who are eligible for a hematopoietic stem-cell transplant	Regenerative Medicine Advanced Therapy designation granted by the FDA	orcabio.com
Apexigen	APX005M	esophageal- and gastroesophageal-junction cancer and pancreatic cancer	Orphan Drug designation granted by the FDA	apexigen.com
Ascentage Pharma	APG-115	acute myeloid leukemia	Orphan Drug designation granted by the FDA	ascentagepharma.com
Ascentage Pharma	APG-1252	small-cell lung cancer	Orphan Drug designation granted by the FDA	ascentagepharma.com
Immunomedics	Trodelvy (sacituzumab govitecan-hziy)	adult and pediatric patients with glioblastoma	Orphan Drug designation granted by the FDA	immunomedics.com
Orca Bio	Orca-T	enhancing cell engraftment in patients who qualify for a hematopoietic stem-cell transplant	Orphan Drug designation granted by the FDA	orcabio.com
Redhill Biopharma	RHB-204	nontuberculous mycobacteria disease	Orphan Drug designation granted by the FDA	redhillbio.com
Alexion Pharma	Ultomiris (ravulizumab-cwvz)	adults with paroxysmal nocturnal hemoglobinuria and for atypical hemolytic uremic syndrome	approved by the FDA for new formulation	alexion.com
BioMarin	Palynziq (pegvaliase-pqpz) Injection	adults with phenylketonuria	approved by the FDA for expanded dosing	biomarin.com
CrossBay	CrossGlide ETS Plus, Endometrial Tissue Sampler	endometrial biopsy procedure	approved by the FDA	crossbaymedicalinc.com
FH Ortho	Telegraph Evolution, humeral nailing system	proximal and/or mid-shaft humeral fractures	approved by the FDA	fhortho.com
Harmony Biosciences	Wakix (pitolisant)	cataplexy in adult patients with narcolepsy	approved by the FDA for expanded indication	harmonybiosciences.com
Merck	Keytruda (pembrolizumab)	monotherapy for adults with relapsed or refractory classical Hodgkin lymphoma	approved by the FDA for expanded indication	merck.com
Regeneron Pharmaceuticals	Inmazeb (atoltivimab, maftivimab, and odesivimab-ebgn)	Zaire ebolavirus	approved by the FDA	regeneron.com

JobWatch

The Source for Clinical Research Jobs and Career Resources

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

Jobs via Kelly Services

Clinical Science Lead/Manager
Boston, MA

Clinical Scientist
Hampton, NJ

Clinical Data Manager - NIH
Rockville, MD

Clinical Scientist
New Haven, CT

Wet Chemistry Technician
Holland, MI

Scientific Document Specialist
Beloit, WI

Marketing Mix Analytics Consultant
Whippany, NJ

Clinical Trials Assistant
Whippany, NJ

Clinical Research Associate
San Diego, CA

Vaccine Scientist - NIH
Gaithersburg, MD

Clinical Laboratory Scientist
West Sacramento, CA

Clinical Laboratory Scientist
Valencia, CA

Clinical Research Associate
Mettawa, IL

Direct Hire Associate Scientist I
Seattle,WA

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More Jobs

Clinical Director
Catalina Research Institute
Montclair, CA

Senior Project Manager, Clinical Research Solutions - Veradigm
Allscripts
Work Remotely

Senior Director, Project Management North America
WCG MedAvante-ProPhase
Hamilton, NJ

Clinical Data Manager
WCG Analgesic Solutions
Boston, MA

Data Processor
WCG IRB
Puyallup, WA

Business Development Director
WCG ThreeWire
Work Remotely

Statistical Team Leader
WCG Statistics Collaborative
Washington, DC

Clinical Study Document Processors
WCG IRB
Puyallup, WA

Clinical Research - Operations Specialist
WCG IRB
Cary, NC

Associate Project Manager - Clinical Research Software
WCG IRB
Work Remotely

[VIEW ALL JOB LISTINGS]

Upcoming Event Highlights

Webinars

OCTOBER 21, 2020
How to Generate Reliable Clinical Trial Results: *An Increasing Challenge in the COVID-19 Era*
2:00 p.m. – 3:00 p.m. EDT

OCTOBER 27, 2020
Bringing ClinOps Technology to the Clinical Site: *Stories from the Frontlines*
11:00 a.m. – 12:00 p.m. EDT

OCTOBER 27, 2020
Improving Diversity and Inclusion in Clinical Trials
1:30 p.m. – 3:00 p.m. EDT

Virtual Conferences/Summit

OCTOBER 28, 2020
Data Integrity in the COVID-19 Era and Beyond — Part III: *The Real-World Costs of Data Integrity vConference*
Data integrity expert Sue Schniepp will lead conversations and panels around data in the time of COVID-19.

NOVEMBER 2 – NOVEMBER 12, 2020
MAGI's Clinical Research vConference
This virtual conference offers practical, real-world solutions for those in the clinical research space, as well as the critical networking opportunities you crave.

NOVEMBER 17 – NOVEMBER 18, 2020
15th Annual FDA Inspections vSummit
So much has changed since last year's summit that it sometimes feels difficult to keep up. You'll receive vital information from current and former FDA officials and industry experts aimed at your inspection readiness.

[VIEW ALL EVENTS]