COVID-19 Operational Challenges Require New Risk Assessments

By James Miessler

Sponsors and sites must reassess the risks of all their ongoing trials in the face of the COVID-19 pandemic, looking for factors that may increase the severity of already-identified risks and new, unanticipated risks presented by the virus.

“At a minimum … this is a time you need to do a reassessment,” according to Linda Sullivan, executive director of WCG Metrics Champion Consortium (MCC). “You need to go back and reassess the risk in the study in addition to adding questions.”

“There may be some things that weren’t considered high risk, [but] your whole risk profile might have changed,” Sullivan told participants in an online roundtable last week in which MCC members discussed operational challenges, including using local laboratories, remote information gathering and inevitable changes to protocols.

The assessment should consider risks at the study, site and patient levels, Sullivan said, and take into account the potential impact of missing data on the ability to draw conclusions from the trial.

Roundtable participants noted that some organizations are carrying out risk assessments at the enterprise and departmental levels, too.

The discussion among more than 100 clinical operations professionals focused on interpreting new guidance from various regulators and organizations when planning trial adjustments.

see COVID-19 Operational Challenges on page 7 »

Patients Can Be Partners in Continuing Clinical Trials During the Pandemic

By Brandon May

Patient centricity is truly coming to the forefront as sponsors and investigators search for ways to battle the effects of COVID-19 and keep their trials afloat while protecting their participants’ health and safety.

The clinical trials industry is experiencing a shift toward more patient support, particularly for patients whose trials have been postponed or have moved to a strictly remote setting, according to patient advocacy experts. “Given that many trial participants have risk factors that can make exposure to COVID-19 more frightening,” says Lori Abrams, senior director of patient advocacy at WCG Clinical, “those of us in the clinical trials industry need to rethink what care looks like.”

Abrams says patient advocacy groups are increasingly being approached by pharmaceutical companies and CROs to provide timely clinical trial messaging to trial participants, including information on things like trial pauses, on-time and delayed study visits, when and where a study drug will come from as well as temporary study modifications.

“Advocacy groups have their ‘finger on the pulse’ of the patient population and have a clear understanding of the concerns often raised by patients participating in trials,” Abrams told participants in a WCG webinar on best practices for weathering the crisis. These advocacy groups can help research institutions, sites, sponsors and CROs develop COVID-19-specific communications about

see Patients Can Be Partners on page 2 »
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 CenterWatch Weekly will be featuring. To see last week's column, click here.

COVID-19 vaccines:

- Dynavax and Clover Biopharmaceuticals have shaken hands on a research collaboration to develop a COVID-19 vaccine. Clover, a Chinese-based firm, is currently conducting preclinical trials for its protein-based vaccine hopeful S-Trimer, while California-based Dynavax is tapping into its proprietary toll-like receptor 9 (TLR9) agonist adjuvant, CpG 1018, the adjuvant used in its Heplisav-B, an adult hepatitis B vaccine.

- Ology Bioservices and Vanderbilt University Medical Center are working together, with the help of a $14 million Department of Defense (DOD) contract, to develop a monoclonal antibody aimed at both treating and preventing COVID-19 infection.

- Ology is also collaborating with Inovio Pharmaceuticals to manufacture Inovio’s DNA vaccine INO-4800 for prevention of COVID-19 infection. Inovio said its current mission is to scale up manufacturing of the vaccine, which it will ship to DOD for future trials and for emergency use if needed. DOD is currently aiding the two companies through an $11.9 million contract.

- iBio said that its COVID-19 vaccine program’s preclinical immunization studies are currently being conducted at Texas A&M’s University System laboratories through a joint development agreement. The two are working to rapidly produce virus-like particles — non-infectious molecules that imitate viruses — in the hopes of developing a vaccine candidate for trials.

COVID-19 treatments:

- Researchers at four University of California medical centers have begun recruiting for a phase 2 clinical trial to investigate the safety and efficacy of Gilead’s novel antiviral remdesivir for treating adults with COVID-19. The trial will ultimately include approximately 440 participants and is expected to run until April 1, 2023.

- EUSA Pharma has started a clinical trial of siltuximab, an IL-6 targeted monoclonal antibody, to treat patients suffering from serious COVID-19 respiratory complications. Its primary endpoints are reduced need of invasive ventilation, time spent in ICU or 30-day mortality. It will include hospitalized patients prior to admission to an ICU and patients already in need of intensive care. Initial data is expected this month.

- Bold Therapeutics is inviting expressions of interest from other companies to help it develop its novel antiviral agent, BOLD-100, as a treatment for COVID-19. Bold 100 was originally developed for use in treating gastrointestinal cancers.

- CEL-SCI and the University of Georgia’s Center for Vaccines and Immunology are developing a COVID-19 immunotherapy using ligand antigen epitope presentation system (LEAPS) peptide technology. An immunotherapy candidate is being worked on to treat patients at highest risk of death from the virus.

- Algernon Pharmaceuticals has expanded the COVID-19 clinical trial program for its drug NP-120 (ifenprodel), an NDMA receptor antagonist, to include acute lung injury. The study looks to see if the drug can work as a treatment for COVID-19, chronic cough and idiopathic pulmonary fibrosis. The drug has been approved in South Korea and Japan to treat certain neurological conditions and has a supply set aside for compassionate use for the most serious coronavirus patients.

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trials that are patient-friendly and meaningful to patients’ families.

She suggested developing study-related guidance or frequently asked question documents that can be handed directly to advocacy groups to support patient communications. “Instead of waiting to be asked [by an] advocacy group for help,” Abrams said, “ask them for help upfront.” Some patient advocacy groups are partnering with sites to have daily morning Skype calls that allow for face-to-face interaction to share information and develop guidelines for trials, she noted.

Some patients are not receiving any communication and no assurances about the status of their trials, said Mary Elizabeth Williams, a journalist, patient advocate and clinical trial veteran. This lack of communication makes patient advocacy communities an important aspect of clinical trials during the

see Patients Can Be Partners on page 8 »
Trial Disruptions Continue to Increase in Wake of Pandemic

Sponsors, sites and regulators continue to feel the disruptive effects of the COVID-19 crisis and are scrambling to find solutions, leading to trial delays and enrollment suspensions. Here is a sampling of how some organizations are responding to the challenge:

UK Clinical Research Network Pauses Trials to Redeploy Medical Staff to Clinical Care

The UK’s National Institute for Health Research Clinical Research Network, which in 2019 supported more than 6,100 studies, is pulling back from new trial site starts to allow the nation’s research workforce to focus on providing clinical care for COVID-19 patients.

Eli Lilly Delays Trial Starts and Pauses Enrollment

The pharma giant has announced plans to cut back on its trial activities, forgoing most new starts and putting enrollment on hold in most ongoing studies. The company has advised participants already receiving treatment in a Lilly-sponsored trial to continue to follow their protocols as much as possible.

The greatest impact of Lilly’s response may be on its phase 3 trials focusing on Crohn’s disease and ulcerative colitis, which have completion dates as soon as September 2020.

Bristol Myers Squibb Sets Three-Week Delay

The drugmaker will hold new trial starts for at least three weeks, it announced last week, pushing trial initiations back to April 13 at the earliest. The company also recommended pausing early-phase trials involving healthy participants.

Pfizer Hits Pause on Enrollment

Similar to BMS, Pfizer has decided to delay enrollment in new and ongoing global trials for three weeks, with the exception of trials focused on treatments for life-threatening conditions whose participants are running out of options.

Cross-Country Delay Hits Small Biotech

Virginia-based biotech Diffusion Pharmaceuticals expects delays in completion of its phase 2 trial of ambulance-based oxygen delivery in acute stroke. The Los Angeles County Fire Department, which is participating in the trial, has suspended training of its first responders who had been scheduled to participate in the trial.

UK Venture Capital Firm Predicts Serious Delays in Its Pipeline

Syncona Investment Management, which funds trials on cancer and gene therapy treatments, expects those trials to experience at least three-month delays.

Galapagos-Gilead Partnership Holds Enrollment

Belgian drugmaker Galapagos has halted enrollment in seven mid- and late-stage studies of filgotinib, a drug being developed with Gilead Sciences to treat immune system conditions.

New WCG Webinars Provide Expert Insight on COVID-19’s Impact on Clinical Trials

WCG Clinical has launched a weekly webinar series in which panels of experts discuss issues facing clinical trials during the COVID-19 pandemic.

Occurring every Wednesday from March 18 to April 30, the webinars will allow participants to ask panelists their most pressing questions. Recordings of the webinars also will be available.

The next webinar in the series will be held April 1. Participants can submit their questions to the expert panel in advance.

Global Regulatory Workshop Offers Regulatory Considerations, Data Requirements for Phase 1 COVID-19 Vaccine Trials

A meeting report from a regulatory workshop held virtually under the umbrella of the International Coalition of Medicines Regulatory Authorities (ICMRA) provides an overview of new regulatory considerations for the development of COVID-19 vaccines and data requirements for phase 1 COVID-19 vaccine trials.

In the report, delegates from 17 countries and more than 20 global medicine regulatory authorities provide several generally agreed-upon positions regarding the clinical data required to support proceeding with a COVID-19 vaccine to first-in-human clinical trials. The report also provides consensus positions on how to address the theoretical risk of COVID-19 vaccine-induced disease enhancement before proceeding to first-in-human clinical trials.

The report also lays the groundwork on how global regulatory authorities should address the balance between rapid vaccine development and the need to produce sufficient robust data. Read the full report here: https://bit.ly/2WUX4cW.

EMA Guidance Calls for Systematic Planning of Trial Alterations

Sponsors of clinical trials in the EU should create a systematic plan for their COVID-19 response that documents reasons for protocol deviations and other trial adjustments, according to a new draft guidance from the EMA.

Pre-planning for and identifying potential trial disruptions will help separate pandemic-related trial data from those that have not been affected by changes, the agency says. Data collection should continue as long as possible unless participant health or safety is at risk.

The guideline also recommends using an independent Data Monitoring Committee (DMC) — usually used to confirm the likelihood of trial success — to assess the likelihood of the affected trial delivering interpretable results. DMCs also can provide support for restarting normal trial operations after the crisis has passed.

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Comments on the draft must be submitted to EMA by April 25.
Read the draft guidance here: https://bit.ly/2JhBY0w.

UK Regulators to Only Conduct Essential Inspections During COVID-19 Outbreak
Regulators in the UK will only conduct essential on-site inspections of clinical trials, distribution, laboratories, manufacturing and pharmacovigilance during the COVID-19 outbreak, according to new guidances issued last week.

The Medicines and Healthcare products Regulatory Agency (MHRA) says all other inspections will be deferred until further notice.

The guidelines also recommend remote monitoring of participants and replacing in-person visits with phone calls and that on-site inspections associated with the UK government’s response to COVID-19 or other public health risks be prioritized over other trials.


Many Investigators Ceasing New Patient Enrollment, Survey Finds
A survey conducted by Clinical Research IO has found that 24 percent of investigators across 73 different research sites have stopped new patient enrollment due to concerns about COVID-19. Another 37 percent of investigators who responded to the survey say they are considering ceasing new patient enrollment due to COVID-19 safety concerns.

The survey also found that sites are seeing a 9 percent decrease in patient retention, suggesting that one in 10 patients are withdrawing from a trial possibly for fear of exposure to the virus. Approximately 63 percent of sites also reported that they have stopped on-site monitoring by sponsors.

Clinical Research IO says it believes these slowdowns in patient enrollment and retention will result in a significant drop in the number of breakthrough medications that are approved over the next five years.

FDA Concludes the Clinical Data Summary Pilot Program
The FDA has called a halt to its Clinical Data Summary (CDS) pilot program after two years and limited results, saying it will shift its focus to a new application review process that would allow more transparency and access to data from trials of approved drugs.

The agency launched the voluntary CDS pilot in January 2018 to evaluate whether sharing data from FDA-approved drugs’ clinical study reports would be beneficial to sponsors, researchers and the public. After selecting nine sponsors to participate in the pilot, the agency was able to release data from only one approved drug — Janssen’s Erleada (apalutamide) — in March 2018.

Then in June 2019, the FDA announced it was closing enrollment in the pilot and beginning work on the interdisciplinary review program, which the agency says has more potential for data-sharing by involving more parties in the evaluation of drug applications rather than releasing sponsor’s trial summaries. Center for Drug Evaluation and Research Director Janet Woodcock said last week, however, that the FDA may consider sharing specific portions of clinical data summaries as part of the new review process.

Despite its limited success, the FDA says the CDS pilot has helped the agency identify possible approaches to global sharing of clinical trial data, including an independently run international library of data that would allow sponsors to contribute results voluntarily in an anonymous and standardized format.

Ipsen Ends Trial of Pediatric Drug After FDA Partial Clinical Hold
Ipsen has terminated its trial of palovarotene for pediatric treatment of rare bone and tissue diseases after the FDA placed a partial clinical hold due to concerns about patient safety.

The FDA hold prohibited administration of the drug to children age 14 and younger due to fears that the drug may stunt the growth of children with multiple osteochondroma and fibrodysplasia ossificans progressiva (FOP).

Ipsen said the time that has elapsed since the clinical hold was put in place has created gaps in dosing, which may have compromised the integrity of the trial data. Additionally, no efficacy data were yet available when the partial hold was enforced, which may prevent the company from filing for FDA approval for the drug.
This feature highlights changes in clinical trial organizations’ personnel.

**Akcea Therapeutics**
Damien McDevitt has been named CEO of rare disease pharma company Akcea Therapeutics, an affiliate of Ionis Pharmaceuticals. Previously, McDevitt was chief business officer for Ionis.

**Athersys**
Athersys has announced the appointment of Maia Hansen to the role of senior vice president of operations and supply chain. Hansen most recently served as senior partner of global management consulting firm McKinsey & Co.

**Beam Therapeutics**
Beam Therapeutics appointed Christine Swenson to the position of senior vice president of regulatory affairs. Swenson was most recently senior vice president of global regulatory affairs at Moderna.

**Bristol Myers Squibb**
Bristol Myers Squibb has named Elizabeth Mily executive vice president of strategy and business development. Prior to this appointment, Mily was the managing director and chair of life sciences at Barclays.

**Chembio Diagnostic Systems**
Chembio Diagnostic Systems has appointed Richard Eberly as CEO. Previously, Eberly was a managing director at Solid Rock Principled Capital, a healthcare private equity firm.

**CytoDyn**
Jacob Lalezari has been named interim chief medical officer of CytoDyn. Lalezari will continue to serve as CEO and director of Quest Clinical Research.

**Eli Lilly**
Kathryn Beiser will assume the role of vice president of global communications at Eli Lilly. Most recently, Beiser served as senior vice president and chief communications officer at Kaiser Permanente.

**Emmes**
Kathleen Wolf has joined data collection and clinical research monitoring company Emmes as the company’s new vice president of clinical operations. Previously, Wolf was senior director and head of clinical operations at AstraZeneca’s MedImmune.

**Epizyme**
Jeffery Kutok has joined Epizyme as its chief scientific officer. Most recently, Kutok served as chief scientific officer of Infinity Pharmaceuticals.

**ESCAPE Bio**
Paul Wren has been named chief scientific officer of ESCAPE Bio, a biopharmaceutical company focused on neurodegenerative diseases. Prior to joining ESCAPE, Wren was senior director of neuroscience discovery at GlaxoSmithKline.

**EVERSANA**
EVERSANA has named Ed Cox the company’s new executive vice president or strategic alliances and global head of digital medicine practice. Cox was most recently CEO of Dthera Sciences.

**Evoke Kyne**
Julie O’Donnell has been appointed to the role of vice president and global head of digital at Evoke Kyne. Prior to this appointment, O’Donnell was senior director and headed the digital team at pharmaceutical company Lundbeck.

**Freeline**
Biotech company Freeline has brought on Julie Krop as the firm’s newest chief medical officer. Krop comes to Freeline after serving as chief medical officer of AMAG Pharmaceuticals.

**Fusion Pharmaceuticals**
Fusion Pharmaceuticals has found its new chief medical officer in James O’Leary. Prior to joining Fusion Pharmaceuticals, O’Leary was an independent oncology consultant and vice president/chief medical officer of ImmunoGen.

**Genprex**
Gene therapy company Genprex appointed Catherine Vaczy to the role of executive vice president and chief strategy officer. Previously, Vaczy was principal at the Finial Group, where she provided strategic advisory services to early stage biotech firms. Michael Redman has also accepted the role of executive vice president and chief operating officer at Genprex. Prior to this position, Redman was president and CEO of Oncolix.

**Idogen**
Christina Brattström has been recruited as Idogen’s newest chief medical officer. Most recently, Brattström was medical director at Bayer HealthCare.

**Leap Therapeutics**
Douglas Onsi has replaced Chris Mirabelli as president and CEO of Leap Therapeutics. Onsi will continue to maintain his role as Leap’s chief financial officer. Cynthia Sirard, Leap’s vice president of clinical R&D, has been promoted to the role of chief medical officer. Additionally, Mark O’Mahony, vice president of manufacturing at Leap, has been promoted to chief manufacturing officer.

**Morphic Therapeutics**
Morphic Therapeutics has appointed Peter Linde to the role of chief medical officer. Prior to this appointment, Linde was vice president of medical research at Acceleron.

**Nordic Nanovector**
Dominic Smethurst will serve as the interim chief medical officer for Nordic
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Nanovector, replacing Lisa Rojkjaer. Smethurst previously held the role of group medical director of Tusk Therapeutics.

**Oxford BioDynamics**
*Jon Burrows* has been named CEO of Oxford BioDynamics, joining the UK-based company after serving as executive vice president of Oncology Partners, a consulting and clinical advisory firm.

**Qiagen**
*Thierry Bernard* has been named the permanent CEO of Qiagen following the departure of Peer Schatz. Bernard has been with Qiagen since 2015 in the role of senior executive vice president of molecular diagnostics business.

**Ra Medical Systems**
*Will McGuire* has been appointed CEO of Ra Medical Systems. Most recently, McGuire was president and CEO of Second Sight Medical Products.

**Recursion**
*Shafique Virani* has been named chief corporate development officer of AI biotech Recursion. Most recently, Virani was CEO of Navire Pharma and CoA Therapeutics.

**Relmada Therapeutics**
Relmada Therapeutics has announced that *Judy Caron* will join the company as its newest vice president of drug development. Caron was most recently chief operating officer and head of clinical development for Neurana Pharmaceuticals, a company she cofounded in 2012.

**Revive Therapeutics**
*David Boulware*, infectious disease physician-scientist and professor of medicine in the division of infectious diseases and international medicine at the University of Minnesota, has been appointed to the role of scientific advisor for infectious diseases at Revive Therapeutics. Currently, Boulware is the principal investigator for a COVID-19 trial studying the use of prophylaxis hydroxychloroquine after COVID-19 exposure.

**RubrYc Therapeutics**
RubrYc Therapeutics has appointed *Ramesh Baliga* to the role of chief scientific officer. Baliga joins the company from IGM Biosciences, where he served as the vice president of discovery biology.

**Sensei Biotherapeutics**
*Robert Pierce* has been hired by Sensei Biotherapeutics to assume the role of chief scientific officer. Most recently, Pierce was scientific director of the immunopathology lab at the Fred Hutchinson Cancer Research Center.

**Thrive Earlier Detection**
*Matt Franklin* has been named chief commercial officer of Thrive Earlier Detection. Franklin was tapped from molecular diagnostics company ArcherDx, where he served as chief business officer.

**UroGen Pharma**
*Jeff Bova*, previous senior vice president of commercial of UroGen Pharma, has been promoted to the role of chief commercial officer. UroGen has promoted *Marina Konorty* from the role of senior vice president of research and development and head of Israeli operations to executive vice president of research and development and technical operations. *James Ottinger*, UroGen’s senior vice president of regulatory affairs, has also been promoted to the position of executive vice president of regulatory affairs and quality. UroGen also announced the promotion of *Elyse Seltzer*, the company’s senior vice president of clinical development, to the role of chief development officer.

**Urovant Sciences**
*Jim Robinson* has been tapped from his position as chief operating officer of Paragon Biosciences to take on the role of CEO at Urovant Sciences.

**Viracta Therapeutics**
Viracta Therapeutics has appointed *Lisa Rojkjaer* to the role of chief medical officer. Rojkjaer was most recently chief medical officer of Nordic Nanovector, prior to joining Viracta.
COVID-19 Operational Challenges

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EMA guidance issued last week directs researchers to establish measures that prioritize data validity and patient safety, in addition to conducting reassessments as the pandemic develops, weighing trial risks created by COVID-19 against the predicted benefits of the investigational drug to patients and society.

The UK’s Medicines and Healthcare products Regulatory Agency (MHRA) calls for reducing the number of patient visits and considering home delivery of trial drugs when possible.

MCC members wondered if moving to remote patient visits would be seen by regulators as a protocol deviation or even a protocol amendment. Both the EMA and the FDA have reassured sponsors and sites that an increase in protocol deviations is to be expected in the current situation and that they will not consider deviations directly related to COVID-19 as noncompliance with the protocol.

The FDA’s recent guidance on the impact of the pandemic on trials, issued March 18, urges sponsors to use more centralized monitoring practices when appropriate, and recently, the Association of Clinical Research Organizations called for increased centralized monitoring in response to the coronavirus (CenterWatch Weekly, March 23, 2020).

Sullivan also referred members to MCC’s own resources, including guidance on centralized monitoring, which already has been adopted in trials as an adaptation to proximity issues posed by COVID-19.

The group also discussed issues presented by using local laboratories in place of trial sites for critical testing, as both the FDA and EMA suggest.

The FDA recommends that when trial participants cannot make it to an investigational site for protocol-specified visits, other options should be considered, including local labs or imaging centers. In-person visits should be ruled necessary depending on patient safety. The EMA says it is acceptable to do lab, imaging or other diagnostic tests at local labs if they are certified to perform the tests routinely and testing can be done according to local restrictions on social distancing.

MCC members expressed concerns about the lack of standardization of tests across labs, concluding that safety assessments may be better suited for local labs than efficacy or exploratory ones. One participant posed that a lab’s viability will likely depend on the individual study, patient population and therapeutic area, as well as its accreditation and possible use in conducting coronavirus testing. Local labs themselves may present an increased risk to patients if they routinely conduct COVID-19 testing, pointed out another participant.

The UK’s MHRA recommends sponsors consider discontinuing subjects who are at risk if they cannot complete integral evaluations or take critical mitigation steps. This could extend to an entire trial, although sponsors have the option of temporarily halting trials or pausing recruitment, the agency says.

The impact of trial changes on the informed consent procedure was another area of concern for roundtable participants, especially the need for reconsenting current trial patients without face-to-face contact. The EMA advises that any validated, secure electronic system for obtaining informed consent already in use in the trial would be an acceptable method as long as it is in compliance with member nations’ policies.

The FDA and EMA both allow emergency procedures without prior consent. The FDA advises sponsors and clinical investigators to tell their IRBs or ethics committees as soon as possible when they anticipate urgent changes to protocol or informed consent due to the public health emergency.

“Such changes to the protocol or investigational plan to minimize or eliminate immediate hazards or to protect the life and well-being of research participants,” the FDA says “may be implemented without IRB approval or before filing an amendment to the IND or IDE, but are required to be reported afterward.” For protocol changes that will lead to amending data management and/or statistical analysis plans, sponsors should consult the applicable FDA review division, the agency says.

Roundtable participants shared suggestions on information that should be gathered about COVID-19. Recommendations included earliest date of exposure, the date of test result and mitigation strategies taking place locally, such as sheltering-in-place vs. social distancing. One participant recommended that MCC’s eCRF page in development include a hospitalization page to capture information about the virus, such as length of time in hospital.

The group also stressed the importance of documenting protocol deviations as they increase in prevalence alongside COVID-19 developments, and one participant suggested using “COVID-19” prefixes in their names for easy identification.

Other topics of discussion included how changes in data collection may impact the trial’s statistical analysis plan. For instance, does a mortality study need to consider the competing risk of death due to COVID-19?

Roundtable participants noted that COVID-19 infection could be a confounding factor in a clinical trial and debated whether all trials should test participants for the virus.

Ultimately, the group, concluded, trials should focus on the “quality-by-design” principles outlined in ICH E8(R1) to focus on collecting only data that is essential to the trial.

Read the FDA guidance here: https://bit.ly/2J4z92E.

Read the EMA guidance at: https://bit.ly/2xRY1qN.
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COVID-19 pandemic and beyond, Williams said. “When we think about pausing a study, this is not abstract to people who have a rare debilitating disease or for people who are in a late-stage trial for their lung cancer.”

Williams hopes that this global experience will help improve the empathy of investigators for patients who are entering a clinical trial. “This is an unprecedented moment,” she said, “as every single person on the planet knows what it’s like to have your world completely turned upside down in a very short amount of time, which is what patients deal with when they get a diagnosis and enter a trial.”

“I hope this experience will change the treatment of participants as not just data points,” she said, “but as real human beings who are scared and vulnerable.”

According to Jonathan Zung, executive vice president of WCG, sponsors and sites are developing internal guidelines to separate the essential trials from the nonessential ones, with the treatment of patients with COVID-19 being the primary focus. “Research staff are beginning to shift from research studies to supporting patient needs,” Zung said.

In terms of best practices for trials during COVID-19, he said it is important to maintain regular communication among sponsors and CROs to ensure effective bi-directional communication. “It’s important to share what changes have been made at the site level, what changes have been made to study protocol, the availability of the study drug and feedback from study participations,” Zung said. Internal guidelines and documentation can help facilitate these communications across study teams.

The industry is taking the long view, according to Zung. While there appears to be no definitive end date for this pandemic, many institutions, from small independent sites to large academic research centers, are continuing to plan for trials that will commence after the COVID-19 crisis has passed. “It’s important to develop plans for the resumption of clinical studies after COVID-19,” he stressed. Sites need to clearly understand their resource needs for these trials once they ramp back up, and many organizations may need to discuss which tasks need to be handled externally vs. internally for these post-COVID-19 studies.

Webinar speakers fielded hundreds of questions from attendees. Below is an edited excerpt of the question-and-answer session.

Can you define “essential” studies? Also, some sites are saying that sponsors may delay payments. How can sites protect themselves from delayed payments from sponsors?

Studies that provide high potential direct benefit, such as a cancer study or rare disease study where there is no available treatment, are deemed “essential” studies. In terms of delayed payments, we have not heard the speculation or rumors that sponsors may delay payments to the sites. There doesn’t appear to be any evidence of this. – Jonathan Zung, executive vice president of WCG

How can sponsors or sites find appropriate patient advocacy groups?

If you’re a site within a community, the national groups often have local advocacy groups/chapters. For sponsors/CRO affiliates, check in with your sites first to see if they have any relationships with advocacy groups. If not, reach out directly to advocacy organizations that are supporting your disease state. You will be able to offer guidelines and need-to-know information for their patient constituents. – Lori Abrams, WCG senior director of patient advocacy.

What advice would you have for researchers/coordinators/site staff who have to tell participants that the nonessential study will be paused?

For the love of God, don’t use the word “nonessential.” That’s first and foremost. Very often, the language that is used in the clinical world feels devastating to the patient population. To be referred to as “participants” vs. “human subjects,” for example, means a lot. The words you use matter. When you’re saying “nonessential” and you’re pausing the study, it’s like you’re saying to the patient that they’re at the end of the line. It’s important to prioritize language now, while understanding that hard choices still need to be made. Put first and foremost the dignity and humanity of every single patient. Think about ways to have conversations that will support the patient and give them options. – Mary Elizabeth Williams, journalist and patient advocate

If there’s a study that involves infusion or injection, and home healthcare services are put in place to keep people out of the hospital site, who typically sets that up?

I don’t know if there’s anything typical right now with COVID-19, but I would say that at this stage the sites are working with sponsors or CROs to get home healthcare services coordinated and out in the community. It’s being done differently depending on the research site. Some are using satellite clinics for that purpose. It’s really been done on an ad hoc approach from site to site. – Jonathan Zung, executive vice president of WCG

Sites should have close communication with the sponsor to determine the best approach. – Lindsay McNair, WCG chief medical officer

Shouldn’t we assume that sites are going to shut down and won’t be able to perform research?

There are a number of sites and academic research centers that are focused on treating COVID-19 patients and related illnesses, but they’re also still planning on performing new studies once this pandemic ends. Sites are certainly planning studies in a post-COVID-19 world. Many are working on budgets and aspects of study start-up. – Jonathan Zung, executive vice president of WCG

Will local IRB clinicians who are being pulled into treating COVID-19 patients affect IRBs?

Yes, that can happen. That’s why we’re actively seeing research institutions reaching out to us to get active support from one of the WCG IRBs. We’ve been working very closely with these institutions to review protocols so needed therapies can get to patients. – Jonathan Zung, executive vice president of WCG
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## Drug & Device Pipeline News

### COVID-19 Trials and Actions

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<td>emergency expanded access approved by the FDA</td>
<td>bellerophon.com</td>
</tr>
<tr>
<td>PerkinElmer</td>
<td>Coronavirus RT-PCR test</td>
<td>SARS-CoV-2</td>
<td>Emergency Use Authorization approved by the FDA</td>
<td>perkinelmer.com</td>
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<tr>
<td>Quidel Corporation</td>
<td>Lyra SARS-CoV-2 Assay</td>
<td>SARS-CoV-2</td>
<td>Emergency Use Authorization approved by the FDA</td>
<td>quidel.com</td>
</tr>
</tbody>
</table>

### Other Trials

<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>Pliant Therapeutics</td>
<td>PLN-1474</td>
<td>nonalcoholic steatohepatitis (NASH) with liver fibrosis</td>
<td>dosing of first cohort in phase 1 trial</td>
<td>pliantrx.com</td>
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<tr>
<td>EOC Pharma</td>
<td>eftilagimod alpha (IMP321)</td>
<td>metastatic breast cancer</td>
<td>completed patient enrollment in phase 1 trial</td>
<td>equalocean.com</td>
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<tr>
<td>Allakos</td>
<td>subcutaneous antolimab (AK002)</td>
<td>healthy subjects</td>
<td>initiation of phase 1 trial</td>
<td>allakos.com</td>
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<tr>
<td>Inflazome</td>
<td>Inzomelid</td>
<td>Cryopyrin-Associated Periodic Syndrome</td>
<td>completion of phase 1 study</td>
<td>inflazome.com</td>
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<tr>
<td>Ascentage Pharma</td>
<td>APG-2575 in combination with rituximab or acalabrutinib</td>
<td>relapsed/refractory chronic lymphocytic leukemia or small lymphocytic lymphoma</td>
<td>dosing of first subject in phase 1b/2 trial</td>
<td>preipopharma.com/companies/ascentage-pharma</td>
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<tr>
<td>Allakos</td>
<td>antolimab (AK002)</td>
<td>active, biopsy-confirmed eosinophilic esophagitis</td>
<td>initiation of phase 2/3 trial</td>
<td>allakos.com</td>
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<tr>
<td>Allakos</td>
<td>antolimab (AK002)</td>
<td>active, biopsy confirmed eosinophilic gastritis and/or eosinophilic duodenitis</td>
<td>initiation of phase 3 trial</td>
<td>allakos.com</td>
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<tr>
<td>Avadel Pharmaceuticals</td>
<td>FT218 (once-nightly sodium oxybate)</td>
<td>excessive daytime sleepiness and cataplexy in patients with narcolepsy</td>
<td>completion of phase 3 trial</td>
<td>avadel.com</td>
</tr>
<tr>
<td>AgNovos Healthcare</td>
<td>AGN1 Local Osteo-enhancement Procedure (LOEP) Small Volume (SV) Kit</td>
<td>stable vertebral compression fractures</td>
<td>Breakthrough Device designation granted by the FDA</td>
<td>agnovos.com</td>
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<tr>
<td>Prevail Therapeutics</td>
<td>PR006</td>
<td>to slow the progression of frontotemporal dementia with a GRN mutation (FTD-GRN)</td>
<td>Fast-Track designation granted by the FDA</td>
<td>prevailtherapeutics.com</td>
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<tr>
<td>AEGEA Medical</td>
<td>Mara Water Vapor Ablation System</td>
<td>heavy menstrual bleeding</td>
<td>approved by the FDA</td>
<td>aegeamerical.com</td>
</tr>
<tr>
<td>Pfizer</td>
<td>Eucrisa (crisaborole) ointment, 2%</td>
<td>children 3 months of age and older with mild-to-moderate atopic dermatitis</td>
<td>sNDA approved by the FDA</td>
<td>pfizer.com</td>
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</tbody>
</table>