wcg™

CenterWatch Weekly

Join the CenterWatch Community!

October 5, 2020

Trend of Longer Trial Timelines is Likely to Continue

By Charlie Passut

Clinical trial timelines have been lengthening since 2014 and with COVID-19 conditions forcing adaptation and adoption of new technologies and processes, the trend is likely to continue, if not accelerate.

While the primary response to the pandemic represented important, and sometimes transformational, changes in trials, those changes "will likely contribute to even greater complexity and increased levels of customization and operating fragmentation," says Kenneth Getz, director of the Tufts Center for the Study of Drug Development (CSDD).

"Long term, we believe that development speed, efficiency and optimized performance will really come from our ability to best manage complexity, customization and fragmentation," Getz said last week at the Outsourcing in Clinical Trials USA virtual conference. "These macro trends are inevitable."

But other complications "are actually challenging and conspiring against our bold development ambitions. They all suggest that our programs are actually getting longer. If you look at individual tasks and phase-specific cycle times, you'll see that they're all increasing in length and we're seeing high levels if not higher levels of variation, that is one of the macro trends that we're seeing. Protocol complexity and customization and fragmented operating activity — are the primary factors that are impacting our

see **Trend of Longer Trials** on page 8 »

T Cells Could Play Crucial Role in COVID-19 Vaccine and Treatment Trials, Experts Say

By Leslie Ramsey

The first wave of COVID-19 vaccine development has not monitored the response of T cells to the virus, a missed opportunity that should be addressed in the next wave of COVID-19 research, two experts said last week.

"Ongoing vaccine trials do not appear to monitor the T cell response in detail, if at all," said James Rothman, chair of the Department of Cell Biology at Yale University School of Medicine and winner of the 2013 Nobel Prize for medicine.

The robust response of these cells was discovered after most COVID-19 vaccine trials began, he said, adding that "T cell responses need to be assessed after the first wave of approvals [of vaccines] to improve and compare products and their utility, especially in older populations with reduced immune capacity."

Rothman was joined in a WCG Clinical webinar by former FDA commissioner Scott Gottlieb, who acknowledged the potential of T cells to contribute to efforts to vanquish the virus but questioned whether vaccines were the proper application. He said they could possibly be used in COVID-19 treatments.

It's pretty well established, Gottlieb said, that a large percentage of people have in their immune systems T cells that could react with and kill the SARS-CoV2 virus.

"What we don't know is whether that confers any protection," he said. "If it's going to confer protection, it wouldn't be against

see **T Cells Could Play Crucial Role** on page 9 »

COVID-19 Update

COVID-19 Drug Research Roundup

COVID-19 Therapies:

The NIH's **National Institute for Allergy and Infectious Diseases** has halted enrollment of severely ill COVID-19 patients in a phase 3 trial of Merck's Rebif (interferon beta-1a) with Gilead Sciences' remdesivir due to serious adverse events. An interim review of safety data found more adverse events among patients on high-flow oxygen/noninvasive mechanical ventilation who received Rebif compared to those who did not receive the drug. No concerns existed among patients who had less severe COVID-19, and the trial will continue to enroll patients on low-flow oxygen and those not requiring supplemental oxygen.

The FDA has approved a phase 2 study of **FSD Pharma's** investigational COVID-19 signature drug, FSD201. The primary objective of the randomized, multicenter trial will be to determine whether the therapy improves time to symptom relief faster than standard of care alone in 352 hospitalized patients with COVID-19. Dosing of the trial's first patients is expected some time in October 2020.

The FDA has also greenlighted **Stemedica Cell Technologies'** phase 2 trial, which will study the company's intravenous ischemic-tolerant mesenchymal stem-cell treatment in patients with moderate- to-severe COVID-19. Patients in the trial will be randomized to receive either the stem-cell therapy plus placebo or placebo with standard treatment. In emergency use and expanded use programs, Stemedica's treatment was shown to reduce oxygen requirements within just one to two days of treatment initiation in 14 critically ill patients with COVID-19.

A phase 2 trial in the U.S., launched by **GlaxoSmithKline**, is studying investigational rheumatoid arthritis drug otilimab in hospitalized patients with COVID-19 who are receiving oxygen or ventilator support. The monoclonal antibody will be administered via a single one-hour infusion and will be compared with placebo plus standard of care in terms of its ability to reduce the effects of the infection on the lungs. The primary endpoint will be the proportion of patients who are alive and free of lung failure at 28 days.

Regeneron Pharmaceuticals has released early data from its 275-patient phase 1/2/3 COVID-19 trial, which show that antibody therapy REGN-COV2 reduced the proportion of patients with COVID-19 who required additional medical visits compared with placebo. Approximately 7.7 percent and 4.9 percent of patients given the high and low dose of the drug, respectively, required additional visits, while 15.2 percent of patients assigned to placebo required additional medical attention. A phase 2/3 portion of this trial is set to enroll up to 1,300 patients who will be followed for 29 days to examine the association between treatment and viral shedding in the upper respiratory tract. Three other late-stage trials are also investigating REGN-COV2 for COVID-19. Currently, a U.S.-based phase 3 trial is testing the therapy in hospitalized patients with COVID-19, and another study is testing the therapy for infection prevention in people who live with individuals who have been infected.

The **University of Oxford** is getting ready to launch a phase 2 trial of **AbbVie's** anti-inflammatory drug adalimumab in patients with COVID-19 who reside in community care homes. The trial will investigate the drug's anti-inflammatory and prophylaxis effects against the disease. Recruitment of 750 patients across the UK will begin in late October. The Wellcome initiative's COVID-19 Therapeutics Accelerator, in addition to the Bill & Melinda Gates Foundation and Mastercard, is sponsoring the trial.

COVID-19 Vaccines:

Two leading COVID-19 vaccine developers, **AstraZeneca** and **Moderna**, have hit new speed bumps that could delay their promising COVID-19 vaccine candidates, reducing the possibility of a vaccine being ready ahead of the U.S. presidential election on Nov. 3. The FDA has broadened its already-significant investigation into the halted phase 3 trial of AstraZeneca's AZD1222 after a participant in the UK experienced a serious adverse event. The agency is reportedly asking for data from previous studies of similar vaccines that the same researchers worked on. Meanwhile, Moderna CEO Stéphane Bancel said this week that he doesn't expect the company to ask the FDA for an Emergency Use Authorization (EUA) for its vaccine before Nov. 25 at the earliest. He had previously indicated that the vaccine could be ready by early November. Bancel says the company just does not have enough supporting data to file for an EUA yet.

Moderna's COVID-19 vaccine candidate, mRNA-1273, generated an immune

continues on next page »

CenterWatch Weekly
(ISSN 1528-5731)

Beth Belton Editorial Director
Stephanie Akers Production
Russell Titsch Business Development Director

wcg CenterWatch

CenterWatch Main and Editorial Offices
300 N. Washington St., Suite 200, Falls Church, VA 22046
Tel: 866.219.3440 • 617.948.5100
editorial@centerwatch.com / sales@centerwatch.com

Permission requests can be emailed to editorial@centerwatch.com.

Advertising packages and reprints are available:
Email russ.titsch@centerwatch.com or call 703.538.7651.

COVID-19 Update

(continued from page 2)

response in older adults between the ages of 56 and 71, according to new phase 1 trial data. The study administered two 25 mcg or 100 mcg doses of mRNA-1273 one month apart in 40 healthy adult volunteers. The vaccine was well-tolerated and produced significant binding and neutralizing antibodies against COVID-19. Immune responses in this older cohort were comparable to those observed in younger-aged groups, the study found. Currently, Moderna's COVID-19 vaccine candidate is being investigated in 30,000 participants in phase 3 testing in the U.S.

The FDA has placed a partial clinical hold on **Inovio Pharmaceutical's** planned phase 2/3 trial of its COVID-19 vaccine candidate INO-4800, requesting more information before the trial can begin. The hold was not because of any adverse events related to Inovio's ongoing phase 1 trial of the candidate, the company said. Rather, the agency had questions about the late-stage study and about the device that will be used in the trial to deliver the vaccine.

Single doses of **Johnson & Johnson's** (J&J) COVID-19 vaccine candidate AD26.COV2.S generated a strong antibody response in patients, according to early trial data. The company released interim results of a phase 1/2a trial that compared one and two doses of the vaccine vs. a placebo in 1,045 participants. One group was made up of volunteers age 18 to 55 and another group was comprised of adults age 65 to 75. Nearly all participants who were given a single dose generated antibodies to the coronavirus after 29 days, J&J said.

CureVac has initiated its phase 2 trial of CVnCoV, its messenger RNA COVID-19 vaccine candidate, in Panama and Peru. Enrollment will focus on 690 patients between the ages of 18 and 60 as well as those who are 61 years and over. Patients will receive two vaccine doses 28 days apart. According to CureVac, initial results are expected in the fourth quarter of 2020. Around the time the initial findings are released, the study plans on also launching a 30,000-participant global phase 2b/3 trial to examine the efficacy of the vaccine against COVID-19. Phase 1 testing was launched in June in Germany, and CureVac is in the final stages of cutting a supply deal with the EU for 225 million vaccine doses.

Kangtai Biologics, which has collaborated with **AstraZeneca** to develop COVID-19 vaccine candidate AZD1222, is working with the UK-based company to produce up to 200 million doses of the vaccine by the end of next year.

COVAXX has safely dosed its first healthy adult volunteers in its phase 1, open-label, dose-escalation trial of COVID-19 vaccine candidate UB-612. The study, conducted in Taiwan, is evaluating the safety, tolerability and immunogenicity of the vaccine in up to 60 healthy adults between the ages of 20 and 55. Ascending doses of the vaccine will be delivered in two intramuscular injections 28 days apart.

A new trial in India has been launched to investigate **AstraZeneca's** and **Oxford University's** COVID-19 vaccine candidate, Covishield, in 300 volunteers. The Indian Council of Medical Research and the National Institute for Research in Tuberculosis will run the trial.

Russia has announced completion of phase 3 clinical trials of **Vector Institute's** coronavirus vaccine, EpiVacCorona. The country's prime minister has said preparations are being made to approve the vaccine for Russia by Oct. 15.

Researchers from two Chilean universities are gearing up to begin clinical trials of **Sinovac's** and **Johnson & Johnson's** COVID-19 vaccines following recent approvals made by Chile's Institute of Public Health. Chile may also play host to a trial from **AstraZeneca**, which has also applied to start trials in the country.

Dr. Reddy's Laboratories has not yet filed a formal application to begin phase 3 trials of Russia's COVID-19 vaccine, Sputnik V, according to India's Central Drugs and Standards Control Organization. No plans have been made for any Emergency Use Authorization of the vaccine without relevant local data. Still, the first deputy CEO of the Russian Direct Investment Fund (RDIF) has said clinical trials will start in India soon. Additionally, the CEO has said that the RDIF is speaking with Indian companies for contract manufacturing of the vaccine. Russia is also looking to partners in Brazil, China and Korea for a manufacturing deal.

Industry Briefs

FDA Enforcement of Clinical Trial Violations Declining Under Trump

The FDA has been slacking off on enforcement of clinical trial regulations, according to a recent investigation of the agency's inspection statistics that shows a substantial drop in serious citations in the first three years of the Trump administration.

Since 2009, the FDA has conducted about 6,700 inspections of clinical investigators and IRBs, issuing the strongest citation, "Official Action Indicated" (OAI) in only 291 cases (4 percent) for serious, illegal and potentially dangerous clinical trial infractions.

But in the first three years of the Trump administration, that number dropped to 1 percent. In comparison, the eight years of the Obama presidency saw the agency issue OAI citations in about 6 percent of cases, an article in the October issue of *Science* magazine points out.

The article's authors examined 1,600 FDA inspection and enforcement documents issued since 2009, including warning letters and investigator debarment notices, concluding the agency's regulatory enforcement has become "lax, slow-moving and secretive."

The number of warning letters issued to investigators and IRBs also dropped dramatically during the first three years of the Trump presidency. The FDA issued only 12 warning letters from 2017 to 2019, while President Obama's FDA issued 99 from 2009 to 2011, the first three years of his first term, and 36 from 2014 to 2016, the last three years of his second term.

Warning letters in Obama's first term resulted in seven trial and IRB shutdowns and restrictions, but the Trump administration has not followed through with enforcement action on any of its 12 cases.

Noncompliant investigators also got off light under Trump; only two were barred from participating in future FDA-regulated trials. The FDA barred an average of three investigators per year — mostly for data falsification — under President Obama.

The FDA did not dispute the figures in the *Science* article and said that Trump administration policies were not a factor. "The number of warning letters can ebb and flow," the agency wrote in an email.

The reporting of the story was funded by *Science's* Fund for Investigative Journalism.

FDA Encourages Use of New Endpoints in Trials of Opioid Abuse Treatments

Sponsors of opioid use disorder (OUD) treatments should expand their trials beyond collecting evidence for an NDA submission and gather data on additional clinically meaningful outcomes the FDA considers "highly valuable," according to a final guidance the agency released last week.

A change in drug-use pattern, particularly abstinence, is typically used as a primary endpoint for OUD treatment trials, according to the guidance, but the FDA is interested in expanding primary and secondary endpoints to include outcome measures "important to patients and their families, clinicians and the public."

Additional endpoints could include reduction in such adverse outcomes as mortality, need for emergency medical intervention, and hepatitis C infection or reinfection. The guidance also recommends endpoints focusing on change in disease status as measured by standard diagnostic criteria, patient-reported effects on feeling or function (e.g., reduction in intensity of the urge to use opioids) or reduction of opioid use below a clinically significant level.

Sponsors can propose other endpoints, the guidance says, and can study several endpoints or composite endpoints in one trial.

The guidance is virtually unchanged from the August 2018 draft save for a new section on benefit-risk considerations that suggests trials of products associated with a risk of serious adverse events present "compelling demonstrations of clinical benefit" that outweigh the risk. If the investigational drug itself has abuse potential, the guidance says the FDA will consider its positive and negative public health effects, including its effect on nonpatients, such as members of the patient's household.

Drugs intended to provide relief of withdrawal symptoms are not covered by the guidance, the FDA says, because they usually are not sufficient to reduce the risk of returning to opioid abuse.

To read the guidance, click here: https://bit.ly/3lcHLWf.

Bladder, Renal Cancer Trials Should Use Blinded Independent Central Review, FDA Says

Trials of adjuvant treatments for bladder and renal cancer that use disease-free survival (DFS) as the primary endpoint should rely on a blinded independent central review (BICR) to exclude potential participants with metastatic disease, according to two draft guidances the FDA released last week.

The two guidances provide virtually identical recommendations for trial eligibility, imaging assessments, data analysis and interpretation of results. Both recommend that trials use BICR to define DFS and disease recurrence.

Interim DFS analyses are not encouraged, the guidance says, "because immature data may lead to over- or underestimation of magnitude of improvement." However, trial protocols and statistical analysis plans should include a formal interim analysis of overall survival at the time of final DFS analysis.

Comments on the draft guidances are due by Nov. 30.

To read the bladder cancer guidance, click here: https://bit.ly/3d4Am8F.

To read the renal cancer guidance, click here: https://bit.ly/2GdaUln.

continues on next page »

Industry Briefs

(continued from page 4)

Novo Nordisk, Covance Recognized with ACRP-Avoca Quality Awards

Pharma company Novo Nordisk and CRO Covance topped the list of winners of the Association of Clinical Research Professionals (ACRP) and the Avoca Group joint Quality Awards last week.

Finalists for the sponsor and CRO awards were selected based on responses to a survey of sites Avoca conducted in early 2020. Sites were asked to rate CROs and sponsors on a series of attributes related to quality outcomes, including partnership and communication skills, as well as quality of clinical trial design, execution and oversight.

Following Novo Nordisk in the sponsor category were GlaxoSmithKline in second place and AstraZeneca in third place. ICON and PRA Health Sciences were awarded second place and third place, respectively, in the CRO category.

Leukemia Society to Launch Global Pediatric Trial Collaboration

The Leukemia and Lymphoma Society is partnering with PRA Health Sciences to launch the first global master clinical trial on pediatric relapsed acute leukemia.

The Pediatric Acute Leukemia (pedAL) trial will occur at 200 sites in the U.S., Australia, Canada and New Zealand that are part of the Children's Oncology Group network of children's hospitals and will test a variety of novel treatments simultaneously. PRA will provide trial management and oversight.

PedAL's goal is to establish a genetic sequencing process to identify patterns and drivers of the disease, consolidate pediatric cancer data from multiple institutions into a single data set that will be available to researchers worldwide and form a global collaborative to standardize pediatric leukemia drug development efforts.

COVID-19 Prevention Network Deploys Mobile COVID-19 Vaccine Trials

The National Institute of Allergy and Infectious Diseases (NIAID) has partnered with Matrix Medical Network to help more than 20 academic medical centers involved in NIAID's COVID-19 Prevention Network establish mobile health clinics at universities, hospitals and other locations across the U.S.

Mobile clinics will serve communities in Arkansas, Colorado, Florida, Illinois, Kansas, Maryland, Missouri, New Jersey, New York, North Carolina, Texas and Washington

The collaboration, which is part of the Operation Warp Speed initiative and is supported through an agreement with the Fred Hutchinson Cancer Research Center, will reach trial participants who traditionally have difficulty traveling to trial sites, including those who reside in rural locations.

Up and Coming

This feature highlights changes in clinical trial organizations' personnel.

Achieve Life Sciences

John Bencich has been named CEO of Achieve Life Sciences. Prior to this appointment, Bencich served as the company's chief financial and operating officer. **Cindy Jacobs**, former chief medical officer of Achieve, will now serve as president of the company.

Adamas Pharmaceuticals

Adamas Pharmaceuticals has tapped **Adrian Quartel** to serve as its chief medical officer. Quartel most recently was global head of medical affairs at BioMarin.

Arcus Biosciences

Jennifer Jarrett has returned to her position as chief operating officer at Arcus Biosciences after a stint as Uber Technologies' vice president of corporate development and capital markets.

BioAgilytix Labs

Kennon Broadhurst has been appointed vice president of global marketing at BioAgilytix Labs. Most recently, Broadhurst served as global marketing lead for oncology and hematology biosimilars at Amgen.

Boehringer Ingelheim Fremont

Lars Dreesman will take the helm at Boehringer Ingelheim's (BI) U.S. biopharma development and manufacturing business in California. Dreesman leaves his position as head of BI's global quality systems and product compliance.

Day One Biopharmaceuticals

Day One Biopharmaceuticals has tapped **Jeremy Bender** as its new CEO. Bender joins Day One from Gilead Sciences, where he served as vice president of corporate development.

Deep Genomics

Ferdinand Massari has been appointed chief medical officer of Deep Genomics. Massari was most recently the co-founder and leader of Kintai Therapeutics.

Enesi Pharma

Keith Howard has been named Enesi Pharma's chief scientific officer. Formerly, Howard was chief development officer at Vaccitech.

Freeline Therapeutics

Freeline Therapeutics has promoted its vice president of research, **Romuald Corbau**, to take on the role of chief scientific officer.

H-CYTE

Robert Greif has been named CEO of H-CYTE, a regenerative cellular therapeutics developer. Greif most recently served as chief commercial officer and business development leader at Atox Bio.

Inotrem

Biotech company Inotrem has named **Delphine Joyeux** director of regulatory affairs and quality assurance. Most recently, Joyeux was head of regulatory affairs at AB Science. Inotrem also appointed **Simon Lambden**, a current clinical lecturer at Cambridge University, to the role of head of medical science.

Ipsen

Philippe Lopes-Fernandes has been appointed executive vice president and chief business officer of Ipsen. Previously, Lopes-Fernandes was the senior vice president and global head of business development and alliance management at Merck.

Kaleido Biosciences

Kaleido Biosciences's new president and CEO is **Daniel Menichella**. Menichella comes to Kaleido from his former position as CEO of CureVac.

Matrivax Research and Development

Enda Moran has been appointed vice president of process development and chemistry, manufacturing and controls (CMC) at Matrivax Research and Development. Most recently, Moran was the vice president of CMC development and clinical manufacturing at Northern Biologics.

Medable

Medable has appointed **Mary Costello** head of its site and investigator network. Costello was most recently vice president of clinic development and patient advocacy. **Rasmus Hogreffe**, former head of virtual trials at LEO Innovation Lab, has been appointed by Medable to vice president of decentralized trial innovation. Additional hires include **Steve Lesser** to vice president of partner strategy and **Heidi Pfefferkorn** to decentralized solutions leader. Lesser was most recently the lead solutions architect of real-world evidence at SHYFT Analytics, and Pfefferkorn was previously the director of external development operations at Novartis. The former chief marketing officer of GeoPhy, **David Swanger**, was also named by Medable as its new senior vice president of marketing. In addition, **Ching Tian**, who previously served as general manager of data and digital at Novartis, was appointed senior vice president of strategy and solutions.

Montis Biosciences

Karen Zinkewich-Péotti has taken the helm of Montis Biosciences as its CEO. Zinkewich-Péotti was most recently a senior vice president at Ipsen.

PsychoGenics

Daniela Brunner has been appointed chief innovation officer of PsychoGenics. Brunner joined PsychoGenics in 1999 and previously served as its director and senior vice president of behavioral R&D. PsychoGenics has

continues on next page »

Up and Coming

(continued from page 6)

also appointed **Geoffrey Varty** executive vice president of research operations and **Leslie Street** vice president of medicinal chemistry. Varty and Street previously served as head of in vivo pharmacology at Merck and senior director and head of medicinal chemistry at Cortex Pharmaceuticals, respectively.

RespireRx Pharmaceuticals

RespireRx Pharmaceuticals has appointed **David Dickason** senior vice president of preclinical product development. Prior to this appointment, Dickason held senior technical roles at iCeutica and Alkermes.

Silverback Therapeutics

Valerie Odegard, chief scientific officer of Silverback Therapeutics, has added president to her list of duties at the company. Silverback has also promoted **Naomi Hunder** from her previous position of senior vice president of clinical research and development to the role of chief medical officer.

Sonoma Biotherapeutics

Sonoma Biotherapeutics has appointed **Leonard Dragone**, former vice president for early clinical development at Janssen Biopharma, to chief medical officer. **Sejal Hall** has also joined Sonoma as its vice president of portfolio, program and alliance management. Most recently, Hall was executive director, research operations and program management at Audentes Therapeutics. **Susan Lacy** has also been hired by Sonoma to serve as vice president of discovery. Lacy previously served in various director roles during a 20-year tenure at AbbVie.

STADA Group

Yann Brun, former managing director of Exeltis, has assumed the role of executive vice president and head of global development, portfolio, regulatory and business development/licensing at the STADA Group.

TriSalus Life Sciences

TriSalus Life Sciences has named **Steven Katz** as the company's chief medical officer. Katz had served as the chief medical adviser of TriSalus since 2018.

Vertice Pharma

Scott Meyer, chief operating officer of Vertice Pharma, has been promoted to CEO of the company. Prior to joining Vertice in 2016, Meyer was vice president and general manager of Fougera.

Vibalogics

Tom Hochuli, former cell and gene therapy operations head at Lonza, has been named global CEO of Vibalogics.

Features

Trend of Longer Trials

(continued from page 1)

executional performance that drive higher levels of inefficiency and challenge quality in our research."

CSDD found that for an entire new set of 377 drugs and biologics approved by the FDA between 2008 and 2018, the clinical phase took an average of 83.1 months from 2008-2013, but that timeframe grew to 89.8 months for 2014-2018.

Conversely, the regulatory phase shrank from 13.6 months to 11.7 months over the respective timeframes (*CenterWatch Weekly*, July 20). "Some of that is due to the fact that a higher proportion of approvals now are for treatments that are targeting rare diseases," Getz said. Those remedies, plus oncology drugs, represent "one of the dominant areas in our pipelines [that] typically see expedited or accelerated review timeframes." But he also cited longer timeframes through all three clinical trial phases for the 377 new drugs and biologics studied. "We see that the cycle times are getting longer, and the variation has not improved. We continue to see inconsistent practices and performance."

Despite an industry perception that smaller companies tend to enjoy quicker development timelines, Getz said observations by CSDD show the opposite is true. Of the 377 drugs studied, the clinical phase for the top 50 pharmaceuticals with active drugs in the R&D pipeline took an average 80.9 months in the clinical phase and 11.8 months for the regulatory phase. But among non-top 50 companies, the clinical phase was nine months longer (89.9 months) and regulatory approval grew to 13 months. Meanwhile, CSDD estimates that 31 percent of active drugs in the current R&D pipeline are for rare diseases, with 58 percent expected to gain regulatory approval this year.

Durations were also increasing in select executional areas. CSDD found that in 2014-2018, it took an average of 145 days for the study start-up period, up 13.7 percent from the prior 2008-2013 period. The pivotal trial execution segment also grew to an average 854 days and the last-patient-last-visit (LPLV) timeframe extended to 36 days, up 6.3 and 9 percent, respectively, from 2008-2013. In the area of data-management and data-cycle times, "often what we hear is that the largest challenge is the coordination of multiple data sources, some that include the electronic data capture as well as the use of wearable devices, specialty labs and a variety of other data sources, and that presents some challenges."

CSDD also found an alarming disparity between the expected level of diversity in clinical trials and the actual rate of minority participation. For new drugs and biologics approved between 2007 and 2017, the organization found only 5.4 percent participation from the Black and African American community, but the group was expected to make up 15.6 percent, based upon disease prevalence rates and population census figures. The disparity percentage for the demographic was -65.4 percent while the disparity percentage in vaccine trials was -48.2 percent. Latinx was expected to make up 8.2 percent of clinical trials but only accounted for 7.2 percent, with a disparity percentage of -12.4 percent and a disparity percentage in vaccine trials of -31.5 percent. Meanwhile, whites made up 75.9 percent of clinical trials, up from the 67.1 percent expected, with a disparity percentage of 13.6 percent and a disparity in vaccine trials of 112.8 percent.

"Public trust and awareness about clinical research have been negatively impacted by the pandemic," Getz said. "This is going to contribute to ongoing patient recruitment challenges, particularly challenges in recruiting underrepresented communities in our development programs."

Getz said CSDD, through its assessments of performance and interviews with companies, found six strategic operating practices that could be applied across all operating models to shorten drug development timelines — early and open collaboration; patient-engaged design and execution planning; more time upfront dedicated to precollaboration qualification and coordination; a commitment to flexible but consistent execution; anticipated and preplanned design and executional adaptation; and frequent, proactive and clear input from regulators. "That really helps organizations determine whether they feel comfortable assuming a risk and accelerating activity further," Getz said of the final recommendation.

Features

T Cells Could Play Crucial Role

(continued from page 1)

getting the infection; it would be against developing symptomatic disease from the infection. But we don't know a lot about what, if anything, this means."

The question of whether T cells translate to clinical protection against the virus requires a detailed investigation and that currently isn't being done, Rothman said. Of 38 vaccines currently in trials, 34 percent are studying protein subunits and 16 percent are nonreplicating viral vectors, 16 percent are RNA based and 16 percent are inactivated virus. The rest are DNA based and replicating viral vectors.

Gottlieb also strongly defended the FDA's approach to getting a vaccine out to the public in the shortest amount of time, criticizing the Trump administration's apparent attempt to derail a planned guidance the president believes could reduce the chance of having a proven vaccine before the November election.

The Emergency Use Authorization (EUA) guidance that was originally set to be released before the end of September would set the criteria sponsors need to meet to administer their vaccines to the highest-risk populations before formal FDA approval. In an unusual move, President Trump on Sept. 23 said the White House would review the proposed guidance, an action that led many to conclude Trump would bury the document in an effort to keep the FDA from raising standards for emergency authorization.

In fact, the guidance would do the opposite, Gottlieb told attendees at the webinar last week on the potential of using T cells to fight the virus.

The guidance is "technically a lower standard" than that needed for formal FDA approval, Gottlieb said. However, the EUA pathway was basically conceived for moments like this, he said, when there is an urgent need for life-saving solutions.

"What it is, really, is a more flexible standard" that allows the agency to respond quickly to a public health crisis.

There is nothing surprising in the proposed EUA guidance, Gottlieb said, adding that it basically lays out the authorization principles the agency has been discussing with vaccine developers all along, including the need for a vaccine trial to include in the placebo arm at least five severe cases and some cases in older patients. The guidance also would require sponsors of phase 3 trials to track patients for at least two months. "Not allowing the agency to put forward that guidance would be problematic at the end of the day," he said.

"I think the agency needs to be left to its own devices to outline what the approval criteria is," Gottlieb said. "The political sort of intrigue around this process is not helpful."

With **Five Decades** of Clinical Research Experience – **We Are the "Gold Standard" in Ethical Review**

For more than 50 years we have **overseen more research** than all other IRBs combined.

Every day, WCG supports:

- More than **10,000** protocols
- Nearly **24,000** investigators
- More than **112,000** sites

Consider - WCG participates in over **90%** of all FDA New Drug Approvals.

Learn more about working with the gold standard in IRB review:
www.wcgclinical.com/services/irb/

wcg™

wcgclinical.com

Association for the Accreditation of Human Research Protection Programs, Inc. — *Full* Accreditation

Drug & Device Pipeline News

Company	Drug/Device	Medical Condition	Status	Sponsor Contact
COVID-19 Trials and Actions				
Covistat/Ensysce Biosciences	oral nafamostat	acute respiratory failure due to COVID-19	initiation of phase 1 trial	ensysce.com
Covaxx	UB-612	COVID-19 vaccine	first patient dosed in phase 1 trial	covaxx.com
Stemedica Cell Technologies	intravenous allogeneic mesenchymal stem cells	patients with moderate to severe lung injury due to COVID-19	IND approved by the FDA for phase 2 trial	stemedica.com
Windtree Therapeutics	lyo lucinactant	COVID-19 associated lung injury and acute respiratory distress syndrome	IND approved by the FDA for phase 2 trial	windtreetx.com
FSD Pharma	FSD201 (ultramicronized palmitoylethanolamide)	hospitalized patients with COVID-19	initiation of phase 2 trial	fsdpharma.com
Novavax	NVX-CoV2373 (COVID-19 vaccine)	COVID-19	initiation of phase 3 trial	novavax.com
Organicell Regenerative Medicine	Zofin acellular therapy	patients with SARS-CoV-2 who have mild to moderate COVID-19, or who are judged by a healthcare provider to be at high risk of progression to moderate disease	expanded access protocol granted by the FDA	organicell.com
ADial Pharmaceuticals	Assure/FaStep COVID-19 IgG/IgM Rapid Test Device	antibody point-of-care test for COVID-19	Emergency Use Authorization (EUA) granted by the FDA	adialpharma.com
Cepheid	Xpert Xpress SARS-CoV-2/Flu/RSV molecular diagnostic test	qualitative detection of the viruses causing COVID-19, Flu A, Flu B, and RSV infections from a single patient sample	EUA granted by the FDA	cepheid.com
Hologic	Panther Fusion SARS-CoV-2 assay	testing of individuals without symptoms or other reasons to suspect COVID-19 infection	EUA granted by the FDA	hologic.com
Quotient	MosaiQ COVID-19 antibody test	detection of COVID-19 antibodies	EUA granted by the FDA	quotientbd.com
Other Trials and Actions				
Aerie Pharmaceuticals	AR-15512 (TRPM8 agonist) eye drop	dry eye disease	IND approved by the FDA	aeriepharma.com
IRLAB	mesdopetam (IRL790)	levodopa-induced dyskinesias in Parkinson's disease	IND approved by the FDA	irlab.se
Inversago Pharma	INV-101	Prader-Willi syndrome and non-alcoholic steatohepatitis	initiation of phase 1 trial	inversago.com
Kuur Therapeutics	KUR-502	relapsed/refractory CD19-positive malignancies	first patients dosed in phase 1 trial	kuurtx.com
Prelude Therapeutics	PRT1419	relapsed/refractory hematologic malignancies	first patients dosed in phase 1 trial	preludetx.com
Zucara Therapeutics	ZT-01	type 1 diabetes	first patient dosed in phase 1 trial	zucara.ca
BioMarin	BMN 307	phenylketonuria	first patient dosed in phase 1/2 trial	biomarin.com
Codiak Biosciences	exoSTING	advanced metastatic or recurrent, injectable solid tumors	first patients dosed in phase 1/2 trial	codiakbio.com

continues on next page »

Drug & Device Pipeline News

(continued from page 11)

Company	Drug/Device	Medical Condition	Status	Sponsor Contact
Aptinyx	NYX-2925	fibromyalgia	patient recruitment recommenced in phase 2 trial	aptinyx.com
Calithera Biosciences	telaglenastat (CB-839)	nonsmall-cell lung cancer	first patient dosed in phase 2 trial	calithera.com
Concert Pharmaceuticals	CTP-692	schizophrenia	patient enrollment complete in phase 2 trial	concertpharma.com
Ocular Therapeutics	OTX-CSI (cyclosporine intracanalicular insert)	dry eye disease	first patients dosed in phase 2 trial	ocutx.com
Aurinia	voclosporin ophthalmic solution	dry eye syndrome	last patient study visit in phase 2/3 trial	auriniapharma.com
CiVi Biopharma/ Eicos Sciences	CIVI030 (intravenous iloprost)	systemic sclerosis	patient recruitment resumed in phase 3 trial	civibio.com
Eisai	lorcaserin	Dravet syndrome	initiation of phase 3 trial	eisai.com
Harbour BioMed	batoclimab (HBM 9161)	myasthenia gravis (MG) and adult immune thrombocytopenia	first patient dosed in phase 3 trials	harbourbiomed.com
Infinity	eganelisib (IPI-549) in combination with a checkpoint inhibitor and chemotherapy	patients with inoperable locally advanced or metastatic triple-negative breast cancer, in the first-line setting	Fast-Track designation granted by the FDA	infi.com
AbbVie	elezanumab (ABT-555)	spinal cord injury	Orphan Drug and Fast-Track designations granted by the FDA	abbvie.com
Neurophth Therapeutics	NR082 (rAAV2-ND4, NFS-0)	Leber's Hereditary Optic Neuropathy associated with ND4 mutation	Orphan Drug designation granted by the FDA	neurophth.com
CSL Behring	Haegarda (C1 Esterase Inhibitor Subcutaneous [human]	routine prophylaxis to prevent hereditary angioedema attacks in patients 6 years of age and older	approved by the FDA for expanded indication	cslbehring.com
Eton Pharmaceuticals	Alkindi Sprinkle (hydrocortisone) oral granules	replacement therapy for adrenocortical insufficiency in children under 17 years of age	approved by the FDA	etonpharma.com
GlaxoSmithKline	Nucala (mepolizumab)	hypereosinophilic syndrome (HES) without an identifiable non-blood-related cause of the disease in adults and children 12 years of age and older	approved by the FDA for expanded indication	gsk.com
Janssen	Simponi Aria (golimumab)	active polyarticular juvenile idiopathic arthritis and active psoriatic arthritis in patients 2 years of age and older	approved by the FDA	janssen.com
Masimo	Rad-G Pulse Oximeter	pulse oximetry and respiration rate monitoring	approved by the FDA	masimo.com
Pfizer	Xeljanz (tofacitinib)	children and adolescents 2 years and older with active polyarticular-course juvenile idiopathic arthritis	approved by the FDA for expanded indication	pfizer.com
Shionogi	Fetroja (cefiderocol)	hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia	approved by the FDA for expanded indication	shionogi.com
Vertex Pharmaceuticals	Kalydeco (ivacaftor)	children with cystic fibrosis ages four months to less than six months old who have at least one mutation in their CFTR gene	approved by the FDA for expanded indication	vrtx.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

Operations Planner II
Lansdale, PA

Analytical Chemist
Mt Vernon, IN

R&D Scientist - Bioanalytical
Indianapolis, IN

CER Technical Writer
Remote, MA

Lab Support/Sample Control Technician I
Marlton, NJ

Quality System Specialist
Ann Arbor, MI

QA Analyst
Irvine, CA

QC Chemist
San Antonio, TX

Quality Technician
Fife, WA

Research Associate
San Diego, CA

Regulatory Affairs Assistant
Morrisville, NC

Biologist - Virologist
Manassas, VA

[VIEW ALL KELLY SERVICES JOBS]

More Jobs

Clinical Investigator (Internal Medicine)
DM Clinical Research
Houston, TX

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

Associate Data Scientist
WCG Clinical
Plymouth Meeting, PA

Senior Data Scientist
WCG Clinical
Plymouth Meeting, PA

Clinical Research Document Processor
WCG WIRB
Puyallup, WA

Clinical Research - Operations Specialist
WCG Copernicus Group
Cary, NC

Clinical Research Project Coordinator II
WCG MedAvante-ProPhase
München, Bayern DE

Business Analyst
WCG MedAvante-ProPhase
Hamilton, NJ

[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

Webinars

OCTOBER 7, 2020
COVID-19 and "Pandemic Exceptionalism": *The Tension Between Taking Quick Action and Collecting Data in Urgent Medical Settings*
2:00 p.m. – 3:00 p.m. EDT

OCTOBER 13, 2020
Make Virtual Monitoring Work for You: *How eSource Helps Sponsors Monitor Virtually During COVID-19*
11:00 a.m. – 12:00 p.m. EDT

OCTOBER 14, 2020
Make Real-Time, Real-World Data Work for You: *How to Accelerate Clinical Trials and Enhance Market Access*
11:00 a.m. – 12:00 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

Virtual Conferences

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]