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CenterWatch Weekly

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August 10, 2020

Ethics Expert Says Challenge Trials Are Being 'Mulled Over' in the U.S., UK

By James Miessler

The University of Oxford and the National Institutes of Health (NIH) are considering launching human challenge trials if enrollment requirements in standard COVID-19 studies can't be met.

A leading ethics expert who has justified the use of challenge studies says they are being mulled over in the U.S. and UK for COVID-19, using a weaker form of the virus to intentionally infect trial participants.

The University of Oxford is currently preparing a weakened virus agent that researchers may potentially use in a challenge study, said Arthur Caplan, a professor of bioethics at New York University Grossman School of Medicine and the founding director of its medical ethics division, at last week's WCG Clinical COVID-19 webinar.

"I know that at least there, they're getting ready if they don't get enough enrollment on the standard model to move toward the challenge study direction," he said.

Preparations are also being made in the U.S., including at NIH, "so we could see an argument being made to do the challenge study."

He contends that challenge studies can provide stronger, faster data and be designed so that participants are monitored closely and given medical care in the case of adverse events. He has argued in the past that in some instances challenge trials can be justified from an ethical perspective

see **Ethics Expert Says** on page 8 »

Sponsors Place More Administrative Burden on Sites than Regulators, Survey Shows

By Mike Ingram

Sites feeling overwhelmed by increasing administrative responsibilities lay more blame on sponsors' shoulders than on additional compliance rules set by regulators.

Sponsor requirements that vary wildly from study to study, increasing protocol complexity and multiple amendments create a burden far beyond that placed by increased regulation. In fact, sites' perception of increased regulatory requirements has dropped dramatically over the past five years.

Roughly 80 percent of sites responding to a recent Complion survey said the burden associated with administrative tasks for a single study has increased over the past two years, either "significantly" (41 percent) or "somewhat" (39 percent), continuing a five-year upward trend.

When asked to pinpoint areas that contributed to an increased overall burden, 59 percent of the more than 200 respondents singled out "increased diversity in each sponsor's requirements." The same percentage cited "increased site responsibilities," and 53 percent chose "increased protocol complexity."

Increased regulatory requirements also were cited by 53 percent of respondents, but that figure is a 20 percentage point drop from Complion's previous survey, conducted in 2015. Only 28 percent of 2020 respondents chose "increased reporting require-

see **Sponsors Place More** on page 9 »

COVID-19 Update

COVID-19 Drug Research Roundup

COVID-19 Vaccines:

Chinese pharmaceutical company **Sinopharm Group** has announced the launch of a COVID-19 vaccine trial in Brazil, which will be the fourth major COVID-19 vaccine trial performed in that country. Sinopharm plans on seeking regulatory approval for the trial in the next two weeks. Currently, the company's vaccine candidate is being investigated in 15,000 volunteers in the United Arab Emirates.

According to the **Russian Defense Ministry**, a COVID-19 vaccine tested in Russia recently demonstrated immunity in all participants who received the drug. This news follows an earlier announcement from Russia's State Research Centre of Virology and Biotechnology Vektor, which stated that the organization will begin production of a COVID-19 vaccine in November. Once developed and approved, this vaccination will be free of charge in the country.

A study from the **Hong Kong Polytechnic University** and the **Macao University of Science and Technology** has shown that a recombinant vaccine which blocks protein receptor-binding domain binding to ACE2, the key enzyme implicated in COVID-19, induced high levels of antibodies in animal models. The study investigators observed no obvious side effects associated with the vaccine.

Kentucky BioProcessing, a subsidiary of British American Tobacco, has begun working on an experimental COVID-19 vaccine using tobacco plants. The company has cloned a portion of COVID-19's genetic sequence and developed a potential antigen, which was subsequently inserted into tobacco plants for reproduction. Kentucky BioProcessing expects the reproduced purified antigen to enter preclinical testing in the next few weeks.

Novavax's COVID-19 vaccine candidate NVX-CoV2373 generated strong immune responses in healthy volunteers who received two 5mcg or 25mcg injections of the vaccine, according to preliminary findings from the company's phase 1 trial. Each participant who received a dose of the candidate in the trial produced neutralizing antibodies, and those who were treated with an adjuvanted vaccine exhibited a T-cell response against COVID-19. Currently, Novavax is waiting to hear from the FDA before the company can begin the second phase of the trial in the U.S. and Australia. Novavax recently received $1.6 billion from the U.S. government's Operation Warp Speed to make 100 million doses of its vaccine for delivery in 2021.

The **National Institutes of Health (NIH)** has launched clinical trials to test the utility of monoclonal antibodies for treating mild-to-moderate COVID-19. The four trials conducted by the NIH are part of the Accelerating COVID-19 Therapeutic Interventions and Vaccines program, a public-private collaboration which aims to expedite the production of much-needed drugs and vaccines.

BioNTech and **Fosun Pharma** have initiated a phase 1 trial in China that will study the mRNA-based COVID-19 vaccine candidate BNT162b1. A total of 144 healthy volunteers in the trial will be treated with either a placebo or two different doses of the vaccine candidate 21 days apart. The companies have stated that 72 participants have already received treatment doses.

Zydus Cadila, a drug company based in India, has stated its COVID-19 vaccine candidate ZyCoV-D was safe and well-tolerated in a phase 1 trial. Animal studies have already demonstrated that the ZyCoV-D produces high levels of neutralizing antibodies against the virus responsible for COVID-19. Now Zydus Cadila is set to launch the phase 2 portion, which will test the candidate's safety and immunogenicity in more than 1,000 healthy volunteers.

COVID-19 Treatments:

Members of the **COVID R&D Alliance** — namely **AbbVie**, **Amgen** and **Takeda Pharmaceutical Co.** — have enrolled the first set of patients in the I-SPY COVID Trial (Investigation of Serial Studies to Predict Your COVID Therapeutic Response with Biomarker Integration and Adaptive Learning), which is testing the efficacy of cenicriviroc, apremilast and icatibant against COVID-19 in severely ill and hospitalized patients who require high-flow oxygen.

Eli Lilly's monoclonal antibody LY-CoV555 is currently being studied in two COVID-19 clinical trials by the **NIH**. One of the trials is a phase 3 study of 300 hospitalized patients with mild-to-moderate COVID-19 who have been randomized to either receive a placebo or LY-CoV555 in addition to Gilead Sciences' antiviral remdesivir. A separate phase 2 trial from the NIH is studying whether LY-CoV555 can reduce the duration of COVID-19 symptoms through 28 days and increase the number of patients with undetectable virus. Eli Lilly also began a phase 3 trial of LY-CoV555 to see if the monoclonal antibody can prevent COVID-19 in residents and staff at long-term care centers.

The NIH's **National Institutes of Allergy and Infectious Diseases** has launched a

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COVID-19 Update

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phase 3 trial of Gilead Sciences' remdesivir with Merck's anti-inflammatory drug Rebif (interferon-beta-1a) for treating hospitalized COVID-19 patients. The trial, which will assess the combination treatment's impact on recovery time compared to treatment with remdesivir alone, looks to enroll 1,000 patients across 100 sites in the U.S. and overseas. Preliminary results are expected this fall.

In June, **Vopec Pharmaceuticals** began human clinical trials on an herbal Siddha formulation, Amrta Karuna, for the treatment of COVID-19. Findings from the now-completed trial show that treatment with the herbal formulation was associated with a significant reduction in hospital quarantine compared with treatment with a placebo. Additionally, treatment with Amrta Karuna was associated with significantly reduced C-reactive protein inflammatory levels and reduced lactate dehydrogenase tissue damage levels. **Agastiya Biotech** is currently conducting confirmatory *in vitro* studies of the formulation in the U.S.

Aerpio Pharmaceuticals and the U.S. government have reached an agreement to initiate a randomized trial studying the effects of razuprotafib, a selective small molecule inhibitor of vascular endothelial protein tyrosine phosphatase, for the prevention and treatment of moderate-to-severe COVID-19. The Medical Technology Enterprise Consortium will grant up to $5.1 million in funding for the trial, while Aerpio will also back the trial with approximately $2.8 million.

The FDA has greenlighted a phase 3 clinical trial that will test the safety and efficacy of bucillamine for the treatment of mild-to-moderate COVID-19. The approval to proceed with this trial was granted to **Revive Therapeutics**, which plans to start the phase 3 study in September at up to 10 sites in the U.S.

Algernon Pharmaceuticals has enrolled its first patient in a phase 2b/3 COVID-19 study of NP-120, an NMDA receptor inhibitor. Sites in the U.S., Australia, Romania and the Philippines are currently participating in the trial. Algernon plans on enrolling 150 patients in the phase 2b trial. Once positive preliminary data is achieved, the trial will move into phase 3. The company is working on determining the expected enrollment rate and an expected completion date.

Relief Therapeutics and **NeuroRx** have been handed FDA approval to begin a phase 2/3 trial of inhaled RLF-100 (aviptadil), a synthetic form of a natural peptide that has been shown to block replication of the virus in lung and immune cells, for preventing respiratory failure in patients with moderate-to-severe coronavirus infections. The first phase of the trial will sign up severe, hospitalized patients who do not have respiratory failure. Should early results prove promising, the trial will broaden to include patients at home with mild-to-moderate COVID-19.

Industry Briefs

NIH Instructs Drug and Medical Device Manufacturers to Post Missing Trial Data

In response to a federal court ruling made in February, the National Institutes of Health (NIH) has issued new rules for data transparency that mandate clinical trial sponsors submit missing data for studies conducted between 2007 and 2017.

According to a July 30 NIH draft letter describing the ruling, no definite deadline has yet been set for the submission of data for trials of currently approved drugs or devices, but the NIH does indicate these data should be provided "as soon as possible." For trials of investigational drugs or devices that are not currently approved, the NIH states the trial data must be submitted within 30 days following the data of approval, licensing or clearance by the FDA.

Trial sponsors who fail to submit required results information could face monetary penalties, yet specific fines were not mentioned in the NIH letter. In addition to imposing fines, the NIH or FDA may also withhold remaining grant funding from noncompliant clinical trial sponsors.

Top FDA Brass Weigh in on Regulatory Safeguards in COVID-19 Vaccine Trials

Three top FDA officials, including Commissioner Stephen Hahn, last week shared with their medical peers the agency's primary considerations when reviewing COVID-19 vaccine trials, reassuring them that these vaccine candidates would face the same level of scrutiny as all other FDA-approved products.

Hahn, along with Center for Biologics Evaluation and Research Director Peter Marks and Deputy Commissioner for Medical and Scientific Affairs Anand Shah, wrote in an opinion piece published on the *Journal of the American Medical Association* website that the physician leaders of the agency "unequivocally state that candidate COVID-19 vaccines will be reviewed according to the established legal and regulatory standards for medical products."

In the case of COVID-19 vaccine candidates specifically, the FDA will focus on three factors, the officials say. First, it will ensure that any vaccine is manufactured in accordance with all of FDA's quality standards and that its safety and effectiveness are verified.

Second, to be effective in a widespread population, the agency is stressing the need for COVID-19 vaccine sponsors to focus on populations disproportionately affected by the pandemic, including racial and ethnic minorities, older adults and people with medical comorbidities. "Inclusion of diverse populations, including older individuals, in trials is necessary for a comprehensive assessment of product safety and effectiveness and to properly inform clinical decision-making," the officials wrote.

Sponsors also should consider additional trial safeguards for special populations, such as children and pregnant women, to guarantee they can be included safely in trials, they say.

Third, the FDA will discuss with sponsors their plans for postmarket surveillance of vaccines that are approved before a large volume of safety evidence is available.

The authors also note that current vaccine trial enrollments of 15,000 to 20,000 far exceed the FDA benchmark of more than 3,000 patients needed to build a reliable safety database.

To read the article, click here: https://bit.ly/2PLYyBT.

Hahn Vows FDA Won't Cut Corners on Vaccine Reviews, Reaffirms Timeline

As concerns mount over the FDA coming under undue pressure to approve a COVID-19 vaccine, FDA Commissioner Stephen Hahn said again yesterday that the agency won't take any shortcuts.

Hahn said the agency will hold researchers to strict scientific standards even as the research moves at lightning pace, shooting down rumors of any coercion aimed at influencing the agency's actions.

"I have been asked repeatedly whether there has been any inappropriate pressure on the FDA to make decisions that are not based on good data and good science, he said. "I have repeatedly said that all FDA decisions have been, and will continue to be, based solely on good science and data," he said.

With phase 3 trials ongoing for several vaccine candidates, the agency intends to begin evaluating candidates in the fall to determine which ones are "truly viable," Hahn said, reaffirming that COVID-19 vaccines must demonstrate at least 50 percent efficacy to secure the agency's approval.

Making predictions on the timing for an Emergency Use Authorization (EUA) or approval is impossible, he said, adding that "any vaccine authorized for widespread use will meet the appropriate standards for quality, safety and efficacy."

Once agency scientists identify a candidate that meets the safety and efficacy standards required by regulations, the government will immediately set up a pathway to make the vaccine available, Hahn said.

Advocacy group Public Citizen, in a letter sent yesterday to U.S. health officials, including Hahn and Center for Biologics Evaluation and Research Director Peter Marks, expressed concerns about the FDA considering EUAs to allow widespread vaccine distribution, rather than putting vaccine candidates through the normal approval process.

The consumer group criticized Hahn and Marks for saying that the use of EUAs for vaccines is on the table. Using that pathway to get a vaccine to the public would raise concerns about its safety and effectiveness, and could scare off patients from taking it, the group said.

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Industry Briefs

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"No vaccine for mitigating or preventing pandemics or epidemics of infectious disease has ever been distributed without full FDA approval based on a thorough evaluation of data from completed clinical trials," the group noted.

Read the Public Citizen letter here: https://bit.ly/2XEQ5oq.

FDA Grantees to Share Work on New Standard COAs and Endpoints at Public Meeting

Three clinical research groups funded by the FDA will present their work on clinical outcome assessments (COA) and standardized endpoints at a virtual public meeting Aug. 28.

The teams of investigators representing Duke University, Northwestern University and Albert Einstein College of Medicine received grants from the agency's Standard Core Clinical Outcome Assessments and Endpoints pilot program last September. Duke's work focuses on acute pain therapeutics in infants and young children, and Northwestern is developing COAs and endpoints for a range of chronic conditions that assess physical function. The Einstein team, in collaboration with Vector Psychometric Group, is addressing COAs and endpoints for migraine clinical trials.

The grantees will also receive feedback from meeting attendees on which of the developed standard core COA sets and endpoints support regulatory decision-making and which ones hold the most relevancy to patients. The Standard Core COA and Endpoints pilot program was developed as part of the FDA's Patient Focused Drug Development efforts.

The FDA also will announce plans for future grants and meetings at the virtual event. The deadline for applying for grants in 2020 is Oct. 14. The 2020 grants will focus on volume or fluid overload (hypervolemia) and related impacts, age-appropriate domains of pediatric daily function, the mechanics of swallowing and motor production of speech, and systemic sclerosis.

To register for the virtual public meeting, click here: https://bit.ly/31udWbj.

For information on the pilot program and applying for 2020 grants, click here: https://bit.ly/30BiMUP.

Data Point

Top-Trafficked Clinical Trial Listings, February to July 2020

Rank	Condition	Share of Traffic
1	COVID-19	15.1%
2	Oncology	5.0%
3	Plastic Surgery	3.6%
4	Obesity/Weight Loss	3.3%
5	Infertility/Pregnancy	2.5%
6	Fibromyalgia	1.8%
7	Sleep Disorders	1.4%
8	Hair Loss	1.3%
9	Polycystic Ovarian Syndrome	1.3%
10	Depression	1.0%

According to data from WCG CenterWatch iConnect, a proprietary database of clinical trial listings, COVID-19 trials are the most viewed by iConnect users, representing 28 percent of total traffic to the website in June/July. Oncology trials came in second at about 5 percent. Overall traffic on the iConnect website increased 11 percent between April and July, indicating growing interest in trial participation in general.

Source: WCG CenterWatch iConnect

Up and Coming

This feature highlights changes in clinical trial organizations' personnel.

Acadia Pharmaceuticals

Mary-Lacey Reuther has been hired by Acadia Pharmaceuticals to fill the role of vice president of government affairs and policy. Most recently, Reuther was senior director of federal affairs at Astellas Pharma.

Alnylam Pharmaceuticals

Yvonne Greenstreet, chief operating officer at Alnylam Pharmaceuticals, will assume the dual roles of president and chief operating officer at the company starting Oct. 1.

AnaptysBio

Paul Lizzul has been named chief medical officer of AnaptysBio. Prior to this position, Lizzul was global development lead for inflammation at Amgen.

ANI Pharmaceuticals

Nikhil Lalwani has been appointed president and CEO of ANI Pharmaceuticals. Lalwani was previously the CEO of Cipla USA.

Arcutis Biotherapeutics

Bethany Dudek has been named vice president of quality at Arcutis Biotherapeutics. Dudek recently served as executive director of quality Europe at Kite Pharma.

Aslan Pharmaceuticals

Kenneth Kobayashi, former senior medical director of Dermira, has been appointed chief medical officer of Aslan Pharmaceuticals.

Aspen Neuroscience

Jeanne Loring, co-founder and chief scientific officer of Aspen Neuroscience, has assumed the role of special adviser to the company's research and development committee.

CN Bio

James Craven has been named chief commercial officer at CN Bio. Prior to this new appointment, Craven was director of market strategy and commercial delivery at Brooks Life Sciences. Additionally, CN Bio has named **Brian Manning**, former senior director of business development at InSphero, as the company's U.S. head of sales.

CureVac

Franz-Werner Haas, chief corporate officer of CureVac, has assumed his new role of CEO at the company. CureVac has also named **Igor Splawski**, former executive director and site head at Novartis, as its chief scientific officer.

Dicerna Pharmaceuticals

Shreeram Aradhye has been appointed executive vice president and chief medical officer at Dicerna Pharmaceuticals. Previously, Aradhye was executive vice president and chief development officer at Axcella Health.

Disc Medicine

Jonathan Yu has been named senior vice president of corporate strategy at Disc Medicine. Previously, Yu was co-founder and vice president of corporate strategy, finance and operations at Qpex Biopharma. Disc also named **William Savage** as vice president of clinical development. Savage most recently served as senior medical director at Magenta Therapeutics.

Excision BioTherapeutics

Excision BioTherapeutics has appointed **TJ Cradick**, former head of genome editing at CRISPR Therapeutics, to the role of chief scientific officer.

Integrity Laboratories

Integrity Laboratories has appointed **Maria Cekanova** its chief scientific officer. Previously, Cekanova was director of the translational research laboratory and research associate professor of oncology at the University of Tennessee.

Legend Biotech

Board members at Legend Biotech have named **Frank Zhang** CEO of the company. Zhang will step down from his current position of CEO at GenScript.

Melinta Therapeutics

Christine Ann Miller, who most recently served as a leader in the global and U.S. product portfolio for Novartis subsidiary Sandoz, has been named president and CEO of Melinta Therapeutics.

MiMedx Group

MiMedx Group has appointed **Rohit Kashyap** to the positions of executive vice president and chief commercial officer. Kashyap was most recently president of global commercial at Acelity.

Mission Therapeutics

Mission Therapeutics has promoted **Paul Thompson**, the company's vice president of clinical development, to the role of chief scientific officer. Mission also promoted **Nick Edmunds** from his role as vice president and head of DUB Discovery to the role of chief technology officer.

NBE-Therapeutics

Bertrand Damous will step down from his position of CEO at GeneProt to join NBE-Therapeutics as its new CEO.

NeoPhore

NeoPhore has appointed **Martin Drysdale** to the role of vice president of drug discovery. Drysdale was most recently the head of the drug discovery unit at the Cancer Research UK Beatson Institute.

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Up and Coming

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Nura Bio

Nura Bio has tapped **Alpna Seth**, former chief operating officer of Biogen, as its newest CEO.

Oxurion

Grace Chang, former chief medical officer at Notal Vision, has been named chief medical officer at Oxurion.

Parexel

Jorge Camarero has been appointed to a vice president position at Parexel. Camarero was previously a Committee for Medicinal Products for Human Use alternate member at the European Medicines Agency.

PharmOptima

Anthony Rohr will now lead PharmOptima, a member of Genesis Drug Discovery & Development, as its newest CEO. Formerly, Rohr was senior director of lab operations at MPI Research.

Premier Research

Cassandra Matney has been named senior medical director of Premier Research. Matney was previously a senior manager of medical affairs liaison at Astellas Pharma.

Regulus Therapeutics

Denis Drygin has been appointed chief scientific officer at Regulus Therapeutics. Drygin was most recently vice president of research and development at Pimera.

Selecta Biosciences

Selecta Biosciences has appointed **Peter Traber** to the role of chief medical officer. Traber has been serving as interim chief medical officer for the company prior to this full-time appointment.

Swedish Biomimetics

Zsolt Lavotha, former CEO of Orexo, has been appointed acting CEO of Swedish Biomimetics.

Synlogic

Antoine Awad, head of technical operations of Synlogic, has been promoted to the role of chief operating officer.

Valo Therapeutics

Valo Therapeutics has found its newest CEO in **Paul Higham**, an industry veteran who formerly served as CEO at Glycotope and Immatics Biotechnologies.

Viroclinics Biosciences

Davide Molho has been appointed CEO of Viroclinics Biosciences. Molho most recently served as CEO of Evolution Research Group.

Features

Ethics Expert Says

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(*CenterWatch Weekly*, May 18). Additionally, trials can be structured to pose less risk, such as by starting with younger subjects who have a lower chance of dying, he said.

On the other hand, critics of challenge studies argue that they violate the "do no harm" principle by deliberately infecting patients, aren't that much faster, pose too great a risk and are especially immoral without a strong rescue therapy. They also believe that not enough patients will consent to participating.

"Yes, it's dangerous, but I don't think the risk is too high," Caplan said. "And the consequences of not going faster is the world is exposed both to the damage of the virus and the economic consequences."

He noted that many past studies have been done without a rescue therapy, including other challenge studies on vaccines, and added that 1Day Sooner, an advocacy organization for patients interested in participating in COVID-19 challenge trials, has had thousands of people sign up as volunteers. Currently, the website lists 32,665 patients in 140 countries who have expressed interest in participating.

"A couple places are already building the weakened virus right now to get ready should it come to the point where we decide — a sponsor or government — to do a challenge study model," he said. "I think the model is worth considering."

In a July 15 letter to the NIH, more than 125 of the world's top scientists called on the U.S. government to start conducting human challenge trials to accelerate COVID-19 vaccine development.

"Yes, it's dangerous, but I don't think the risk is too high. And the consequences of not going faster is the world is exposed both to the damage of the virus and the economic consequences."

—Arthur Caplan, professor of bioethics at New York University Grossman School of Medicine

Citing the urgency of finding a vaccine for the deadly virus, the scientists — among them 15 Nobel laureates as well as the director of Oxford University's large COVID-19 vaccine program — say the ethical objections to infecting healthy volunteers with a disease that has no known cure are outweighed by the common good.

In a similar letter sent to the FDA in April, 35 U.S. lawmakers also encouraged the use of challenge trials, saying "justifiable risks may be taken" (*CenterWatch Weekly*, April 27). The agency responded by suggesting animal testing could be used instead.

NIH Director Francis Collins' previously stated position on the subject has been that challenge trials are open to discussion, but that the NIH is not yet ready to move forward with a human challenge trial plan.

At the webinar, Caplan also expressed criticism of a lack of peer review of COVID-19 research articles and papers. He says a lack of peer review has become apparent during the pandemic, which has seen research move at lightning pace. According to Caplan, medical journals are not conducting the same amount of peer reviews they did pre-pandemic, and preprint servers "are often throwing the papers out there with very minimal review of what's there."

"Journals are speeding up the time they have to review articles in the plague era, from submission to publication. Thousands of papers are also being uploaded on open access preprint servers without really going through the normal peer review process," he said. "We face a big peer review problem."

NYU's Retraction Watch, which has been keeping track of retraction notices and expressions of concern about COVID-19-related research, has seen a sharp rise in retractions, he said, including some in big name journals like the *New England Journal of Medicine* and the *Annals of Internal Medicine*. These big journals have had to pull papers either because the authors did not submit raw data for confirmation or had sample sizes that were underestimated, Caplan said.

"A lot of these studies get into social media. The press and the media have an unending appetite for solutions to the COVID pandemic," he said. "Bad science moves quickly to the public."

Caplan called for the scientific community to start waiting for confirmation and begin testing promising initial hypotheses in real trials to be sure that "junk" science is not promoted and recommended that more money and resources be put toward peer review overall.

"The system can't take publication pressures in a plague. It just wasn't built for that, and it's getting overwhelmed," he said.

Features

Sponsors Place More

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ments" from regulators (e.g., adverse events, protocol deviations, etc.), also a sharp drop from the 53 percent response in 2015.

Jaclyn Clark, marketing manager for survey sponsor Complion, a clinical research software firm, says those numbers are in line with what the company hears anecdotally in its conversations with sites. "When we talk with sites, one of the things we hear about is the diversity of what sponsors are asking for," Clark says. "Every sponsor is coming to them with different interpretations of regulations, different mandates, and different portals and tools" to be used during a study.

She says sites can ease some of their burden by advocating for more standardization among studies. While sponsors may have preferred tools and technologies for handling study data, they often are open to sites using their own systems as long as they have a proven track record.

"Sites feel like they have to comply with whatever the sponsors require, but there are ways for sites to take more control," she says. "The sites are responsible for what the sponsors are accountable for." In other words, Clark says, sponsors want to ensure that the data produced by a study is sound, but sites are the ones doing the work that will ensure that's the case. So it's in the best interest of sponsors for sites to feel empowered and confident in the tools they're using.

The 2020 survey also shows some sites are taking steps to combat the problem; 43 percent of respondents said the bulk of regulatory tasks were handled by specialists, while only 34 percent assigned that work to a study coordinator or nurse. In 2015, the numbers leaned in the opposite direction, with 46 percent of sites using a study coordinator and only 28 percent using a regulatory specialist.

Principal investigators (PI) also have been relieved of some of the burden, the survey shows. Only 7 percent of sites said PIs handled administrative tasks in 2020, down from 19 percent in 2015.

Those numbers would seem to confirm the data on perceived regulatory burden, Clark notes, if sites are increasingly feeling the need to hire a specialist to handle those tasks.

Among the most time-consuming tasks singled out by survey respondents in 2020, managing study documents took the top slot at an average of 8.8 hours per week, followed by initial regulatory file preparation (8 hours per week), managing and reviewing correspondence (5.9 hours per week), document creation (5.4 hours per week) and reviewing documentation (5 hours per week). The vast majority of sites (90 percent) reported that between one and 10 staff members are involved in administrative tasks.

Of the roughly $15,000 per study that 2020 respondents said they spend on administrative work, the survey found that sites are only reimbursed by sponsors for, on average, $10,200. The discrepancy between cost and reimbursement is highest for training site staff on regulatory compliance ($1,700 cost to $200 reimbursement), training on a sponsor's or CRO's regulatory web portal ($1,400 cost to $400 reimbursement) and maintaining a study archive ($2,400 cost to $1,200 reimbursement).

Half of all respondents said they follow internal, standardized processes and regulatory file structures across all studies, while slightly less than half (43 percent) said they follow the compliance processes and file structures outlined by the sponsor for each study.

The survey also found that only 19 percent of sites currently use third-party document management systems to store study documents electronically. Of the sites not currently employing such systems, 80 percent said they have no plans to purchase one in the next two years. Roughly 63 percent said they send at least some portion of their documentation to a third party for archiving purposes.

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Drug & Device Pipeline News

Company	Drug/Device	Medical Condition	Status	Sponsor Contact
COVID-19 Trials and Actions				
BioAegis Therapeutics	recombinant human plasma gelsolin (rhu-pGSN)	hospitalized patients with severe COVID-19 pneumonia	first patient enrolled in phase 2 trial	bioaegistx.com
Eli Lilly AbCellera	LY-CoV555	prevention of SARS-CoV-2 infection and COVID-19 in residents and staff at long-term care facilities	initiation of phase 3 trial	lilly.com abcellera.com
Revive Therapeutics	Bucillamine	patients with mild-moderate COVID-19	clearance to proceed with a phase 3 trial granted by the FDA	revivethera.com
ANA Therapeutics	ANA001 (niclosamide capsules)	hospitalized patients with COVID-19 who are not on ventilators	IND approved by the FDA	anatherapeutics.com
Calidi Biotherapeutics Personalized Stem Cells	allogeneic mesenchymal stem cells	COVID-19 and pneumonia	IND approved by the FDA	calidibio.com personalizedstemcells.com
NeuroRx	RLF-100 (aviptadil) for inhaled use	patients with moderate and severe COVID-19 in order to prevent progression to respiratory failure	IND approved by the FDA	neurorxpharma.com
Abiomed	left-sided Impella heart pumps	left ventricular unloading and support to COVID-19 patients who are undergoing ECMO treatment and develop pulmonary edema or myocarditis	Emergency Use Authorization (EUA) granted by the FDA	abiomed.com
Co-Diagnostics Clinical Reference Laboratory	CRL Rapid Response self-administered COVID-19 test	SARS-Cov 2 detection	EUA granted by the FDA	codiagnostics.com crlcorp.com
Seegene	Allplex 2019-nCoV Assay, a real-time RT-PCR test	SARS-Cov 2 detection	EUA granted by the FDA	seegene.com
Siemens	ADVIA Centaur COV2G and Attelica COV2G	semi-quantitative tests to estimate the quantity of a patient's antibodies produced against COVID-19 viral infection	EUA granted by the FDA	new.siemens.com
Vela Diagnostics	ViroKey SARS-CoV-2 RT-PCR Test	SARS-Cov 2 detection	EUA granted by the FDA	veladx.com
Other Trials and Actions				
Gan and Lee Pharmaceuticals	GLR2007	advanced solid tumors	initiation of phase 1 trial	ganlee.com
Innovent Biologics	IBI322	advanced malignancies	first patient dosed in phase 1 trial	innoventbio.com
Keros Therapeutics	KER-047	anemia and fibrodysplasia ossificans progressiva	patient dosing complete in planned dosing cohorts	kerostx.com
MODAG	anle138b	multiple system atrophy	completion of phase 1 trial	modag.net
Personalized Stem Cells	autologous stem cells	knee osteoarthritis	patient enrollment complete in phase 1 trial	personalizedstemcells.com

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Drug & Device Pipeline News

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Company	Drug/Device	Medical Condition	Status	Sponsor Contact
SAB Biotherapeutics	SAB-176	seasonal influenza	first patient dosed in phase 1 trial	sabbiotherapeutics.com
TFF Pharmaceuticals	voriconazole inhalation powder	invasive pulmonary aspergillosis	patient dosing complete in phase 1 trial	tffpharma.com
Algernon Pharmaceuticals	NP-120 (Ifenprodil)	idiopathic pulmonary fibrosis and chronic cough	first patient dosed in phase 2 trial	algernonpharmaceuticals.com
Clovis Oncology	Lucitanib in combination with Opdivo (nivolumab)	advanced gynecological solid tumors	first patient enrolled in phase 2 portion of phase 1/2 trial	clovisoncology.com
Hepion Pharmaceuticals	CRV431	non-alcoholic steatohepatitis	first patient dosed in phase 2 trial	hepionpharma.com
KBP Biosciences	KBP-5074	patients with advanced (stage 3b/4) chronic kidney disease and uncontrolled hypertension	patient dosing complete in phase 2b trial	kbpbiosciences.com
Lexicon Pharmaceuticals	LX9211	diabetic peripheral neuropathic pain	initiation of phase 2 trial	lexpharma.com
Oncopeptides	melflufen in combination with dexamethasone	patients with relapsed refractory multiple myeloma	first patient enrolled in phase 2 trial	oncopeptides.com
Palatin Technologies	PL9643	dry eye disease	patient enrollment complete in phase 2 trial	palatin.com
MyoKardia	mavacamten	patients with obstructive hypertrophic cardiomyopathy who have been referred for septal reduction therapy and are refractory to current therapeutic options, including those who have severe symptoms (NYHA Class IV)	first patient dosed in phase 3 trial	myokardia.com
Redhill Biopharma	RHB-204	adults with pulmonary nontuberculous mycobacteria disease caused by mycobacterium avium complex (MAC) infection	IND for phase 3 trial approved by the FDA	redhillbio.com
Synthetic Biologics	SYN-020	multiple indications, including radiation enteropathy secondary to pelvic cancer therapy	IND approved by the FDA	syntheticbiologics.com
BioCryst Pharmaceuticals	BCX9930	paroxysmal nocturnal hemoglobinuria	Fast Track designation granted by the FDA	biocryst.com
Biosight	BST-236 (aspacytarabine)	acute myeloid leukemia in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy	Fast Track designation granted by the FDA	biosight-pharma.com
PolyPid	D-PLEX100	prevention of postabdominal surgery incisional infections	Fast Track designation granted by the FDA	polypid.com
ReViral	sisunatovir	serious RSV infection	Fast Track designation granted by the FDA	reviral.com
Cerecor	CERC-006	lymphatic malformations	Orphan Drug designation granted by the FDA	cerecor.com

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Drug & Device Pipeline News

(continued from page 12)

Company	Drug/Device	Medical Condition	Status	Sponsor Contact
Eloxx Pharma	ELX-02	cystic fibrosis	Orphan Drug designation granted by the FDA	eloxxpharma.com
Tyme	SM-88 (racemetyrosine)	pancreatic cancer	Orphan Drug designation granted by the FDA	tymeinc.com
Sonoran Biosciences	SBG003 (tobramycin and vancomycin hydrogel)	postabdominal surgical site infection	Qualified Infectious Disease Product (QIDP) designation granted by the FDA	sonoranbiosciences.com
Axsome Therapeutics	AXS-12	cataplexy in patients with narcolepsy	Breakthrough Therapy designation granted by the FDA	axsome.com
Ethicon	transbronchial microwave ablation technology	soft tissue lesions	Breakthrough Device designation granted by the FDA	ethicon.com
Eyenuk	EyeArt autonomous AI System	diabetic retinopathy	approved by the FDA	eyenuk.com
Genentech	Tecentriq (atezolizumab) plus Cotellic (cobimetinib) and Zelboraf (vemurafenib)	BRAF V600 mutation-positive advanced melanoma	approved by the FDA	gene.com
GlaxoSmithKline	BLENREP (belantamab mafodotin-blmf)	patients with relapsed or refractory multiple myeloma who have received at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor and an immunomodulatory agent	approved by the FDA	gsk.com
Greenwich Biosciences	Epidiolex (cannabidiol) [CBD] oral solution	seizures associated with tuberous sclerosis complex in patients one year of age and older	approved by the FDA	greenwichbiosciences.com
Janssen Pharmaceuticals	Spravato (esketamine) CIII nasal spray, taken with an oral antidepressant	depressive symptoms in adults with major depressive disorder (MDD) with acute suicidal ideation or behavior	approved by the FDA for expanded indication	janssen.com
Life Spine	PLATEAU-A Ti Anterior Lumbar Spacer System	anterior column reconstruction	approved by the FDA	lifespine.com
Morphosys Incyte	Monjuvi (tafasitamab-cxix) in combination with lenalidomide	relapsed or refractory diffuse large B-cell lymphoma	approved by the FDA	morphosys.com incyte.com
Medtronic	InterStim Micro neurostimulator and InterStim SureScan MRI leads	rechargeable device to deliver sacral neuromodulation (SNM) therapy for treating overactive bladder, fecal incontinence and nonobstructive urinary retention	approved by the FDA	medtronic.com
Stryker	Neuroform Atlas Stent System	patients with aneurysms in the back of the brain	approved by the FDA	stryker.com

Research Center Spotlight

Research Center Spotlight *is a monthly selection of clinical research centers who have Research Center Profile pages posted on CenterWatch.com. Included in their annual subscriptions, company profiles are randomly selected to appear in this section, providing added exposure for their expertise and services in conducting and managing clinical studies.*

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Access Clinical Trials

Nashville, TN
615.320.6076
act@accessclintrials.com

Access Clinical Trials is a research center and multispecialty physician network providing access to a unique patient population of urban and rural patients.

CAMC Institute

Charleston, WV
304.388.9960
kristi.sutphin@camc.org

CAMC Institute is a centralized clinical research center affiliated with West Virginia University. CAMC is experienced in conducting phase 2-4 clinical trials evaluating a myriad of therapeutic areas.

Central Florida Endocrine and Diabetes Consultants

Maitland, FL
407.636.6961
lgoggin@cfendocrine.com

Central Florida Endocrine & Diabetes Consultants is a private practice with a staff of six endocrinologists, a podiatrist, dietitian, diabetic educator and certified clinical research nurse. CFEDC offers quality, comprehensive endocrine care and clinical research.

Family Care Research

Boise, ID
208.621.2501
jilll@injurycareresearch.com

Family Care Research is a dedicated research clinic conducting phase 2-4 studies.

Oklahoma Heart Hospital Research Foundation

Oklahoma City, OK
405.608.1281
Lcordell@okheart.com

OHHRF and its for-profit subsidiary, Oklahoma Cardiovascular Research Group, provide cardiovascular trial management services to pharma, medical device and biotech companies.

Oregon Urology Institute

Springfield, OR
541.284.5508
stephanie@oregonurology.com

Established in 1929, Oregon Urology Institute is the oldest urologic practice between Portland, Ore., and San Francisco and has been conducting phase 2-4 clinical trials for more than 25 years.

Rush University Medical Center - Treatment Research Center

Chicago, IL
312.942.5592
Linda_M_Skaggs@rush.edu

The Treatment Research Center is part of the Rush University Medical Center's Department of Psychiatry and has been conducting industry- and government-sponsored clinical trials in mental health for 15 years.

Upstate Clinical Research Associates

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upstatecra@gmail.com

Upstate Clinical Research Associates is a dedicated, multitherapeutic research center with extensive experience in conducting phase 2-4 trials.

Virginia Research Center

Midlothian, VA
804.893.2273
Christina@VirginiaStudy.com

Virginia Research Center is a private practice-based clinical trial center serving the greater Richmond, Va., area.

Vital Prospects Clinical Research

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Vital Prospects Clinical Research Institute, founded in 2007, is a dedicated multidisciplinary research center serving the state of Oklahoma.