CenterWatch Weekly
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In this issue

Government Shutdown Temporarily Ends or Delays Some FDA Work

Congress's failure to pass a government spending bill last weekend means much — but not all — of the FDA's work will stop until the government is funded. Firms should be aware that scheduled meetings with FDA will more than likely need to be postponed and rescheduled, said Steven Grossman, deputy executive director of Alliance for a Stronger FDA.

"Certainly, medical product companies with near-term expectations — review meetings, initiating clinical trials, etc. — are faced with the possibility of slippage in their development timelines," he said.

U.S. Government staff who work on activities that involve "the safety of human life" are

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FDA to Begin Publishing Clinical Study Reports & Possibly Select CRLs

By Conor Hale

A new FDA pilot program will publish information from sponsor-produced clinical study reports (CSR) — starting with documents volunteered by companies following a drug's approval — as part of broader agency efforts to boost transparency in clinical trials and streamline the review process.

Making CSRs publically available will provide more clarity on the FDA's decision-making process, as well as offer detail into the clinical evidence submitted in successful NDAs, according to FDA Commissioner Scott Gottlieb, who described clinical transparency as a tide that can lift all boats.

Specifically, the CSR pilot program will publish the study report body, trial protocol and amendments, as well as statistical analysis plans. Patient privacy, trade secrets and confidential commercial information will continue to be redacted.

"This will be the first time that the FDA is proactively disclosing clinical summary

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NEJM: Right-to-Try Laws Could Still Undercut FDA Authority, Even if Ineffective

By Conor Hale

While the versions of federal right-to-try legislation pending on Capitol Hill are expected to have a limited impact on access to experimental therapies — and, therefore, limited potential to increase harm to terminal patients — they still represent a broader effort to weaken medical product regulation and FDA oversight, according to a new piece in the *New England Journal of Medicine*.

The bills target "alleged barriers to early access that aren't actually rate-limiting — barriers that may even benefit patients — while leaving others in place," wrote Steven Joffe and Holly Fernandez Lynch, medical ethicists from the University of Pennsylvania's Perelman School of Medicine.

By cutting the FDA out of the process, they wrote, patients would be denied the

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Government Shutdown (continued from page 1)

expected to keep working — and many FDA activities can fit this characterization. Adverse event reporting for all products, recall reviews and potential recall decision-making, etc., will continue, said John Avellanet, managing director and principal consultant at Cerulean Associates. "Anything that could directly impact public health will continue," he said.

"Under a shutdown, two out of five FDA employees are furloughed," said Wayne Pines, president of healthcare at APCO Worldwide. A 2018 Department of Health and Human Services shutdown contingency plan states that many of its workers would be immediately furloughed, including all food inspectors, but some activities will continue.

For example, routine establishment inspections are now on hold, said Avellanet. "FDA will make a decision later, pending how long the shutdown is, whether to postpone, conduct abbreviated, or skip any missed routine inspections," he added.

Avellanet noted that for-cause, whistleblower and safety signal inspections will continue as normal.

FDA personnel whose work is funded by outside user fees, such as PDUFA, would be able to keep working. But Grossman noted an important caveat: "Most product review programs are a mix of taxpayer and user fee funding, so will be staffed but not fully staffed."

During the 2013 government shutdown that lasted 16 days, the FDA published a notice that stated it would continue to accept and proceed with reviews for any submissions that the agency received user fees for before the shutdown. The FDA also published notices in 2013 announcing which activities would continue and which would stop until the funding issue was resolved.

But there is still hope that the impasse can be resolved quickly. "We do not think a shutdown will extend beyond the coming week (five missed days), but there is no doubt that a longer shutdown will have a proportionally greater impact on the agency," said Grossman.

All requests for comments to the FDA were referred to the Office of Management and Budget, which did not respond to requests for comment.

Industry Briefs

Informed Consent Common Rule Revisions Delayed for Six Months, But Certain Changes Can Continue

The federal government pushed back its revisions to the Common Rule for an additional six months — making the announcement less than 36 hours before the changes were set to take effect Jan. 19 — and warned the public to expect additional delays down the line.

The Common Rule encompasses the federal regulations and policies that govern the protection of human research subjects, including informed consent procedures and institutional review boards, and spans at least 16 departments and agencies.

The new implementation date is currently set for July 19 — but HHS, the Consumer Product Safety Commission and the Environmental Protection Agency, as well as the departments of Veterans Affairs, Defense, Commerce and others, are all currently developing a new proposed rule to further delay the changes, which were first announced in January 2017.

Until then, sponsors must continue to comply with current regulations, until the so-called "2018 regulations" finally go into effect — causing disruptions with companies participating in Common Rule-agency funded research that planned to comply with the Jan. 19 implementation date.

However, companies can begin implementing certain new elements of informed consent before July 19 — because they are not prohibited by current law, according to the HHS Office of Human Research Protections.

"Institutions may begin implementing provisions of the revised Common Rule that do not conflict with the pre-2018 Common Rule," OHRP said in announcing the delay this week.

However, certain new provisions cannot be implemented early, such as the elimination of the need for continuing review in certain circumstances.

"Because the pre-2018 regulations require continuing review at least annually for all ongoing non-exempt human subjects research, halting continuing review for such research before that date would be considered non-compliance," OHRP said.

Oracle Survey Polls Challenges for Implementing Digital Trial Management Systems

A new survey described the main challenges for clinical trial professionals using current randomization and trial supply management and interactive response technology systems — with over 70 percent of respondents pointing to a lack of flexibility, integration with other platforms and the time burden it takes to deploy new trials as their major frustrations. The online survey, conducted by Oracle Health Sciences and Informa Engage, found that 92 percent reported having to make changes to their RTSM/IRT systems.

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Trial Transparency (continued from page 1)

reports from sponsors to the public," he said.

"It can enable stakeholders to better address common challenges in the product development process, identify areas requiring additional postmarket research and generate the data necessary to meet the FDA's gold standard for assuring safety and efficacy," Gottlieb said Tuesday at a transparency symposium hosted by the Johns Hopkins Bloomberg School of Public Health.

In addition, the FDA hopes to use this initiative to make its clinical review processes more efficient, in the pursuit of team-based drug reviews in CDER.

By allowing the publication of a CSR, and linking that clinical data to the several, disparate memos produced by FDA staff in the course of a review, the agency will be able to consolidate the documents into a single memo, Gottlieb said — one that would outline the consensus or disagreements shared among reviewers.

Additionally, delivering a consolidated review opinion would lend itself to a more team-based approach, he said, describing pushes in CDER to move toward the more collaborative process employed in medical devices. And in the future, this transparency will be essential to establish new, trustworthy review pathways for technologies such as real-world data, wearables and advanced trial designs.

CDER plans to start with nine, hopefully novel NDAs, covering a variety of disease areas, and will begin reaching out to sponsors this month to gauge interest. In addition to a dedicated FDA webpage, the published CSRs will appear in the Drugs@FDA portal, alongside a drug's approval information after it is granted.

The agency is also exploring its legal authority to publish complete response letters (CRLs) it believes have significant public health value.

Unfortunately, processing, redacting and publishing all individual CRLs — a goal long-sought by FDA transparency advocates and investors — would present too much of a challenge to the agency's workload and would be "administratively burdensome," Gottlieb said.

"This will be the first time that the FDA is proactively disclosing clinical summary reports from sponsors to the public."

—Scott Gottlieb, FDA Commissioner

However, the relevant letters could contain important safety findings that could inform clinical practice and research, possibly by warning companies away from potentially futile or duplicative studies, or harmful drug-drug interactions.

Certain types of letters could include those that request additional clinical trials, or for products belonging to a class of already marketed drugs, Gottlieb speculated.

But Gottlieb doesn't want this initiative to turn into a simple clearinghouse for investor information, or for inside looks into a company's performance. "We have policies in place to make referrals to the SEC," should any discrepancies exist, Gottlieb said. "This has to have some bottom-line value to patients."

As to whether the FDA's approach will become mandatory, Gottlieb said that will be worked out through the pilot. By comparison, the European Medicines Agency began its effort to publish clinical study reports and protocols from all new drug submissions, regardless of approval status, in October 2016 (CWWeekly, Oct. 24, 2016).

In addition, the FDA plans to increase the transparency and trackability of studies registered on ClinicalTrials.gov by adding each study's unique, eight-digit NCT number to all agency communications about specific drugs and clinical trials, including product labeling and advisory committee meeting materials.

"Members of the patient, academic and scientific communities can then use this number to follow and track clinical research from a drug's development throughout the regulatory process," Gottlieb said.

Thomas Wicks, chief strategy officer for TrialScope, described including the NCT number as an interesting initiative that will bring clarity to the agency's decisionmaking, but cautioned the number alone may not provide the full picture.

"Applications submitted to the FDA may also include clinical trials that were not required to be posted on ClinicalTrials.gov," Wicks said. "An alternative might be to include the trial sponsors' unique study ID for all studies submitted in an application, and then provide the NCT number where available."

The NCT number may also allow for more accurate third-party assessments of disclosure compliance, he said.

The symposium, in which Gottlieb announced the program, was originally intended to focus on the publication of a new blueprint for transparency at the FDA, published as a special supplement to the Journal of Law, Medicine & Ethics. The supplement covers five key focus areas and offers several recommendations — some of which ended up being pre-empted by the agency's announcement of the CSR and NCT initiatives.

Namely, the FDA should disclose more information about key milestones in the application process, such as clinical holds, Special Protocol Assessments and requests for pediatric studies, as well as offer more insight into its analysis, decisionmaking and generic review processes.

In addition, the blueprint for transparency authors urged the FDA to take a more active role in correcting misleading information in the marketplace, and to disclose data that would help the public better understand certain medical products.

The blueprint and accompanying articles are available here: **http://aslme.org/media/downloadable/files/links/j/l/jlme-45-4-supp-full-download_1.pdf**.

Right-to-Try (continued from page 1)

benefit of safety recommendations and other protocol changes offered by the agency.

Rep. Morgan Griffith (R-Va.), sponsor of one of the federal bills, disagreed that right-to-try would threaten the agency's authority.

"The FDA's regulatory role is meant to protect people from unreasonable risk or harm by medical treatments or products," Griffith said. "I don't think their mission is undercut if a person confronting a terminal illness, who understands the risks, consults a doctor and pays for the treatment, decides an experimental treatment is the best course to pursue."

But many drugs that appear promising in early development are later not proven safe or effective, cautioned the NEJM authors, who also warned about the lack of publicly available information for prescribers. In addition, expanding access to experimental drugs to patients outside clinical trials may delay the generation of data used for approval.

According to FDA Commissioner Scott Gottlieb, the agency makes safety-related changes in approximately 10 percent of expanded access requests — including modifications to dosing amounts, patient monitoring and informed consent — based on access to confidential commercial information unavailable to physicians and the public.

In addition, the FDA grants almost all expanded access applications, Gottlieb told a House health subcommittee during an October 2017 hearing on right-to-try. That same day, the agency also loosened the requirement that physicians receive approval from a full, convened IRB — instead allowing them to proceed with clearance from the chair or a designated board member — as a way to accelerate access.

Meanwhile, a nationwide campaign led by the Goldwater Institute, a libertarian think tank, has resulted in the passage of 38 state right-to-try bills, with six becoming law in 2017.

Largely, the legislation aims to bar the FDA from restricting a terminal patient's access to drugs that have passed Phase I trials, deny the agency from considering any resulting outcomes in their eventual product review and insulate pharmaceutical companies and physicians from legal liability.

"By cutting the FDA out of the process, patients would be denied the benefit of safety recommendations and other protocol changes offered by the agency."

—Steven Joffe and Holly Fernandez Lynch, medical ethicists from the University of Pennsylvania's Perelman School of Medicine

Three different federal bills are pending in the House, one having passed the Senate in August, and the idea has been largely favored by the White House.

Last week, Vice President Mike Pence said he met with Gottlieb to discuss the importance of passing such a bill, writing on Twitter: "It's about restoring hope and giving patients with life threatening diseases a fighting chance. Let's get this DONE." As governor of Indiana, Pence signed his state's right-to-try bill into law in 2015.

In a White House meeting with pharmaceutical industry executives in January of last year, President Donald Trump expressed how he was personally disturbed by the idea of terminal patients not being able to access experimental treatments.

"I am glad the concept of right-to-try has gained traction and hope to see a right-to-try bill, whether mine or someone else's, sent to the President's desk soon," said Griffith.

The House could bring up legislation as early as the last week of this month, according to the sponsor of another version, Rep. Andy Biggs (R-Ariz.). In a recent Washington Examiner editorial, Biggs said he was promised a floor vote on the topic by the end of January; however, the House is not in session the week of Jan. 22, instead returning Jan. 29.

The patchwork of differing state laws can create compliance headaches for pharmaceutical companies wishing to respond to right-to-try requests, and the current federal proposals do not do enough to smooth over the "substantial quirks" that fall along state lines, according to Alison Bateman-House, a bioethicist and assistant professor at NYU Langone Medical Center.

Texas, for example, bars manufacturers from charging for treatment, while other states allow it. Four more states' laws do not apply to patients being treated in hospitals. Arizona does not allow primary care providers to request investigational treatments, while Oregon's policy does not apply to patients under 18. Still more states have varying definitions of "terminally ill."

"Regulatory folks at companies are going to have to know who's getting the drug, and it's going to vary what kind of protections or rules are demanded," said Bateman-House, who co-chairs a NYU working group on expanded access. "And, of course, patients travel from state-to-state to seek specialty care."

"I've definitely gotten calls from pharmaceutical companies wanting to know what this means for them," she added. "It's anyone's guess. ... It's legally sticky."

This past week, Janssen, the pharmaceutical arm of Johnson & Johnson, announced that it would not field right-to-try requests as a matter of policy. Instead, physicians can continue to submit requests through traditional expanded access pathways, Janssen said. Neither right-to-try laws nor expanded access programs can compel a manufacturer to grant a request.

The company said it will not evaluate any requests that do not allow for input from the FDA, which Janssen described as an impartial stakeholder — citing the agency's access to confidential information and oversight as critical to ensuring patient safety.

Three Questions

Zikria Syed, VitalTrax

CWWeekly *presents this feature as a spotlight on issues faced by executives in clinical research. This week, writer Karyn Korieth spoke with Zikria Syed, co-founder and chief executive officer of VitalTrax, which has developed a clinical trial network called PatientWing that makes it easier for patients to find and enroll in clinical trials.*

Q The industry is starting to appreciate the importance of patient centricity, but there is little consensus about what it means. How do you define patient centricity?

A The industry is still trying to figure out what patient centricity means. Many times, when people in the industry talk about patient centricity, they mean engaging patients in a conversation about clinical research. But we need to go beyond that. For that, we can take a cue from other industries, which want to service the customer. The patient is the customer, even in a clinical trial. Service begins with helping patients find clinical trials, engaging them, making it easy to participate, keeping them informed and allowing them to give feedback on their experience.

"I am hopeful that a more open, crowdsourcing-type model will enable better patient engagement."
Zikria Syed, co-founder and chief executive officer, VitalTrax

Today in clinical research, patients are treated as subjects, not partners. When they participate in a trial, they don't know much about the trial beyond their own participation. For example, they are not informed whether the drug was approved or not and have to seek out that information on sites like ClinicalTrials.gov or scour industry publications. They deserve to know. Providing that information directly to patients can significantly improve their experience in the clinical trial. Technology can be used to create a secure channel to enable that communication.

Q While patient-centric drug development has become a buzzword, the industry has been slow to implement processes and programs that achieve this goal. What can be done to drive adoption of patient centricity in clinical research?

A It requires a longer-term strategy of informing and empowering patients then enabling them to participate in clinical trials.

Given the pressures the industry is under to bring new treatments to market, pharma companies and CROs are focused on recruiting for their current trials and not as focused on the longer-term approach to expand the population of patients willing to participate in clinical trials. With the focus on current trials, they want to use databases to seek out the patients, find them, talk to them and bring them into the trial. What they are doing is like direct marketing. This is a very tactical solution as opposed to informing, educating and empowering patients to make their own decisions. A strategic solution gives patients the power and the ability to easily find clinical trials and enroll in them. No one ultimately knows for sure what will work, but I think empowering patients is where the industry needs to go to grow the patient population in clinical trials.

Q Many studies have found that online clinical trial registries are difficult to navigate and don't provide the information patients want before considering clinical trial participation. How can this issue be addressed?

A The industry tends to be extremely risk averse. Pharma companies are very cautious when describing clinical trials, so they do a poor job of explaining how a treatment could benefit patients. Clinical trial listings often include technical jargon and trial procedures, but not why they are doing the research and how it brings something new that improves on existing treatments. It's a deep, systemic problem in the industry. It is left to the sites to inform patients about the research study. But many times, the sites are not the ones sponsoring the trial and are the vehicle for executing the trial, so they can't really talk about it the same way the sponsors could.

I am hopeful that a more open, crowdsourcing-type model will enable better patient engagement where both sides can communicate more openly. Technology has revolutionized many industries. If you think about Airbnb, it's all crowdsourcing. In clinical research, while it is difficult to adopt new technologies, these types of ideas hold some of the biggest promise.

Our vision is to create a database of clinical trial listings and provide a crowdsourcing model that encourages sites and sponsors to update the information and publish the information that is helpful to patients. In addition to basic trial information such as the number of visits, duration and the drug, they could explain what to expect in the trial and why patients should participate. This gives sponsors a great vehicle to publicize their trials. Similarly, sites can opt in and promote themselves, since sites are interested in being known in the local region as somebody who conducts clinical research. Since it's a completely open network, anybody can go in and see the information. Patients can type in a condition and a geography and get a list of trials. If they clicked on a trial, it would give them more information about the trial and allow them to apply online.

It's about empowering people to share their information. We believe it encourages greater sharing of information when everybody can see it. People maintain their profiles on LinkedIn and Facebook because others can see it. It's a more sustainable, meaningful model. I don't think anyone would disagree that the industry needs to be more strategic in recruiting patients. The timing is right for change in the industry.

Drug & Device Pipeline News

Company	Drug/Device	Medical Condition	Status	Sponsor Contact
Tetra Bio-Pharma	PPP005	safety study	Phase I trials planned in Canada	tetrabiopharma.com
Constellation Pharmaceuticals	CPI-1205	oncology	Phase Ib/II trials initiated	constellationpharma.com
CytRx	Aldoxorubicin	metastatic pancreatic cancer	Phase Ib/II trials initiated enrolling 173 subjects	cytrx.com
Transgene	TG4010	MUC1 expressing tumors	Phase II trials initiated enrolling 39 subjects	transgene.fr
Ophthotech	Zimura (avacincaptad pegol)	autosomal recessive Stargardt disease (STGD1)	Phase IIb trials initiated enrolling 120 subjects	ophthotech.com
MiMedx	AmnioFix Injectable	recalcitrant plantar fasciitis pain	Phase III trials initiated enrolling 164 subjects	mimedx.com
LivaNova	Aortic Valve Implant	reporting of reduced leaflet motion	Post-Market trials initiated enrolling 230 subjects in the U.S. and Canada	livanova.com/home.action
Aspyrian Therapeutics	RM-1929	locoregional recurrent head and neck squamous cell carcinoma	Fast Track designation granted by the FDA	aspyriantherapeutics.com
Centrexion	CNTX-4975	pain associated with knee osteoarthritis	Fast Track designation granted by the FDA	centrexion.com
Concert Pharmaceuticals	CTP-543	moderate to severe alopecia areata	Fast Track designation granted by the FDA	concertpharma.com
Cour Pharmaceuticals	TIMP-GLIA	Celiac disease	Fast Track designation granted by the FDA	courpharma.com
Benitec BioPharma	BB-301	oculopharyngeal muscular dystrophy	Orphan Drug designation granted by the FDA	benitec.com
Helsinn, MEI Pharma	pracinostat	acute myeloid leukemia	Orphan Drug designation granted by the EMA	helsinn.com
Novartis	Kymriah (tisagenlecleucel)	relapsed or refractory diffuse large B-cell lymphoma	Priority Review granted by the FDA, Accelerated Assessment granted by the EMA	novartis.com
ACON Laboratories, Innovus Pharma	UriVarx Urinary Tract Infection test strips	overactive bladder, urinary incontinence	FDA administration clearance	innovuspharma.com
AstraZeneca, Merck	Lynparza (olaparib)	deleterious or suspected deleterious g*BRCA*m HER2-negative metastatic breast cancer	FDA approved	astrazeneca-us.com
Avion Pharmaceuticals	Balcoltra (levonorgestrel and ethinyl estradiol tablets and ferrous bisglycinate tablets)	oral contraceptive	FDA approved	avionrx.com
Boehringer Ingelheim	Gilotrif (afatinib)	metastatic non-small cell lung cancer with non-resistant EGFR mutations	FDA approved	boehringer-ingelheim.us
GlaxoSmithKline	Fluarix Quadrivalent (Influenza Vaccine)	flu in patients 3 years of age or older	FDA expanded indication approved	us.gsk.com/en-us
Innovus Pharma	Xyralid (DIN 02471434)	pain and symptom relief for hemorrhoids	Health Canada approved	innovuspharma.com
Myriad Genetics	BRACAnalysis CDx	HER2-negative metastatic breast cancer with germline BRCA mutation	FDA approved	myriad.com

Trial Results

Novan's SB208 Antifungal Program Presents Positive Phase II Results

Novan announced Phase II efficacy and safety data for SB208, a topical, silicone-based gel under development for the treatment of fungal infections of the skin and nails. In a Phase II double-blinded, randomized, vehicle-controlled, dose-ranging clinical trial, the tolerability, safety and antifungal activity of SB208 was evaluated in 222 patients with clinical signs and symptoms of tinea pedis, or Athlete's Foot. Patients were randomized evenly to one of three active or vehicle treatment arms, applying either SB208 Gel (2%, 4% or 16%) or vehicle once-daily for two weeks, followed by a four-week post-treatment observation period. In the primary efficacy analysis of subjects with evaluable culture results, 61.3% (p=0.209) of patients treated with SB208 2%, 80.6% (p=0.002) of patients treated with SB208 4% and 74.2% (p=0.016) of patients treated with SB208 16% achieved negative fungal culture at day 14 versus 45.5% of patients treated with vehicle. The percentage of patients achieving mycological cure at the day 14 visit was 34.4% (p=0.305) of the patients treated with SB204 2%, 50.0% (p=0.009) of the patients treated with SB208 4% and 53.1% (p=0.010) of patients treated with SB208 16% versus 23.5% of patients treated with vehicle. At day 42, the highest mycological cure rates were observed in 58.8% of patients treated with SB208 16% (p=0.020 compared to vehicle). The percentage of patients achieving clinical cure at day 42 was 14.3% of the patients treated with SB208 2%, 29.7% of the patients treated with SB208 4% and 25.0% of patients treated with SB208 16% versus 14.3% of patients treated with vehicle. The overall incidence of adverse events was low (nine subjects or 4%) and similar in all groups. None of the treatment emergent adverse events were determined to be related to the study medication, and no patients discontinued treatment or dropped out of the study due to an adverse event. Based on the positive data generated in this SB208 Phase II dose-ranging trial, Novan intends to evaluate potential partnerships to advance the antifungal candidate into later stages of development.

RedHill Biopharma Announces Final Results From Phase II Study With BEKINDA for IBS-D

RedHill Biopharma reported top-line final results from the Phase II clinical study with BEKINDA 12mg (RHB-102) for the treatment of diarrhea-predominant irritable bowel syndrome (IBS-D). An independent review and analysis of the final results, provided to the company, confirmed that the Phase II study with BEKINDA 12mg successfully met its primary endpoint, improving the primary efficacy outcome of stool consistency (per FDA guidance definition) by an absolute difference of 20.7% vs. placebo (p-value=0.036). The final top-line results improve upon the previously announced top-line results (absolute difference of 19.4%, p-value=0.05). Results from the BEKINDA Phase II study suggest that they compare favorably with previously reported efficacy outcome values from studies of Xifaxan (rifaximin) and Viberzi (eluxadoline) across all three efficacy endpoints. The randomized, double-blind, placebo-controlled Phase II study evaluated the efficacy and safety of BEKINDA 12mg in 126 subjects over 18 years old in the U.S., who received either BEKINDA 12 mg or placebo, once daily, for a period of eight weeks. RedHill plans to meet with the FDA in the first half of 2018 to discuss the design for one or two pivotal Phase III studies with BEKINDA 12mg for IBS-D.

BioLineRx Announces Partial Monotherapy Results From Phase IIa COMBAT Study

BioLineRx announced partial results from the monotherapy portion of BL-8040's Phase IIa COMBAT study showing that BL-8040 increases infiltration of T cells into the tumor in patients with metastatic pancreatic cancer. The Phase IIa study, named the COMBAT study, is an open-label, multicenter, single-arm trial designed to evaluate the safety and efficacy of the combination of BL-8040 and KEYTRUDA (pembrolizumab) in over 30 subjects with metastatic pancreatic adenocarcinoma. The partial results from the BL-8040 monotherapy portion of the COMBAT trial show that BL-8040 was safe and well-tolerated. BL-8040 also induced an increase in the number of total immune cells in the peripheral blood, while the frequency of peripheral blood regulatory T cells (Tregs), known to impede the anti-tumor immune response, was decreased. In addition, analysis of available biopsies (n=7) showed infiltration of various types of effector T cells, known to attack cancer cells, into the tumor periphery and tumor micro-environment (TME). In this regard, the results show up to a 15-fold increase in CD3+ T cells, and up to a two-fold increase in CD8+ T cells, in the TME of 43% (3/7) of the patients, after five days of BL-8040 monotherapy.

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.

For conferences, webinars, training programs and job postings,
Join the LinkedIn JobWatch group!

Featured Jobs

Clinical Research Coordinator
ABCT
Las Vegas , NV

Clinical Scientist
Syros Pharmaceuticals
Cambridge, MA

Senior Clinical Research Coordinator
Elligo Health Research
Cincinnati, OH

Clinical Project Manager
Leidos Biomedical Research, Inc.
Frederick, MD

Clinical Trials Assistant
Apex Life Sciences
Raleigh, NC

Research Study Coordinator
VIOME, Inc.
Mountain View, CA

Clinical Research Coordinator
Dorn Research Institute
Columbia, SC

Project Specialist
Premier Research
Durham, NC

Clinical Research Assistant
St. Josephs Hospital and Medical Center
Phoenix, AZ

Health Outcomes Research Advisor
CVS Health
Woonsocket, RI

Microbiology Clinical Trial Scientist
BioMerieux Inc.
St. Louis, MO

Asstiant Clinical Research Coordinator
UC Davis Health System
Sacramento, CA

Clinical Trials Data Analyst I
Baylor Scott & White Health
Temple, TX

Clinical Compliance Lead
Boehringer Ingelheim
Ridgefield, CT

Nurse Investigator
Oklahoma Board of Nursing
Oklahoma City, OK

Registered Nurse
The James J. Peters VA Medical Center
Bronx, NY

Clinical Trials Manager
Sterling-Hoffman Life Sciences
Newark, CA

Clinical Research Study Coordinator
Alpha Research Associates
Dayton, OH

Clinical Project Manager
Thor Life Sciences
Raleigh, NC

Clinical Regulatory Specialist
Turesol
Phoenixville, PA

[VIEW ALL JOB LISTINGS]

Upcoming Event Highlights

Conferences

FEBRUARY 7-8, 2018

Investigator Initiated Sponsored Research (IISR) 2018
CBI's IISR 2018 is the only annual event dedicated exclusively to helping you and your organization improve your IISR Programs by providing innovative and forward-thinking approaches to support collaborative partnerships, promote proactive contracting, financial planning and integrate best practices in clinical operations for medical affairs excellence in the global expansion of clinical trials.
Boston, MA

FEBRUARY 13-18, 2018

Scope Summit for Clinical OPS Executives 2018
SCOPE will offer three days of in-depth discussions in 18 different conferences, three plenary keynote sessions and interactive breakout discussions focused on advances and innovative solutions in all aspects of clinical trial planning, management and operations.
Orlando, FL

MARCH 6-8, 2018

FDAnews ICH E6 GCP Interactive Workshops
Get all the ICH E6 (R2) training you need with three days of hands-on workshops aimed at helping you understand and comply with new requirements.
Raleigh, NC

APRIL 4-5, 2018

Let's Improve Clinical Trials Today!
The forum will discuss how we can bridge people and processes, technology and regulations.
Oxon Hill, MD

[VIEW ALL CONFERENCES]