wcg™

The CenterWatch Monthly

In This Issue

January 2023 A CenterWatch Publication Volume 30, Issue 01

EU-CTR Faces Rough Transition Amid Industry Concerns

By Jason Scott

The two-year transition to the new EU Clinical Trials Regulation (EU-CTR), set to begin Jan. 31, 2023, may be off to a rocky start, according to several experts that attribute much of the concern to the function of the Clinical Trials Information System (CTIS) at the heart of the new regulatory scheme.

The EU-CTR, which covers all 30 countries in the European Economic Area (EEA), replaces the previous EU Clinical Trial Directive adopted in 2001 and attempts to address harmonization and transparency problems caused by countries implementing the directive differently based on specific national laws.

By contrast, the EU-CTR employs a one-size-fits-all approach that eliminates the need for trial sponsors to submit separate trial applications to regulators and ethics committees in each EU nation in which the trial will take place. Instead, sponsors will send all submissions, reports and other data through the CTIS portal, a single-entry point for submitting, assessing and authorizing clinical trial applications (CTA) (*The CenterWatch Monthly*, March 1, 2022).

And therein lies the problem. The industry as a whole has been quite cautious about implementing the EU-CTR and early CTIS uptake by stakeholders has, thus far, been disappointing, according to Pierre-Frédéric Omnes, executive director of TransPerfect Life Sciences.

Early adopters have usually consisted of "larger organizations that had to pilot trials to validate their EU-CTR implementation strategy," Omnes told *The CenterWatch Monthly*. And while "quite a lot of mono-national trials" have adopted the new system, "many multinational ones have been processed via the CT Directive route, probably to avoid either novelty or the procedural/portal glitches that have been reported."

Worldwide Clinical Trials' Sarah Bly, associate director of regulatory intelligence, and Aman Khera, vice president and global head of regulatory strategy, point to pipeline rather than organization size as a determiner of CTIS portal adoption.

"Those with a single drug in the development pipeline — and therefore a lot of risk should the submission get delayed — may have been more likely to wait and observe the CTIS roll-out to mitigate potential snags or hold-ups," Bly and Khera wrote in an email. Whereas larger organizations "with more products in the pipeline (and therefore less risk from delays to a single product's submission) may have wanted to gain intelligence on the new process sooner," they explained.

see **EU-CTR** on page 4

Six Steps to Optimizing SOP Development and Use

By James Miessler

Standard operating procedures (SOP) are not just necessary for keeping a trial on track, they are mandatory for the FDA and the first documents requested during an inspection. They must be clear, comprehensive and — most important — followed to the letter if a site is to survive close scrutiny.

To achieve those goals, sites should use a six step plan for developing new SOPs that will ensure they are effective and compliant with regulatory expectations. Those six steps, according to Trevor Cole, senior manager of client delivery for WCG Avoca, are define; measure; analyze; develop; review and revise; and approve, control, train and maintain.

1. Define

The first step consists of defining the organization that will use the SOP and the functional area/topic of the procedure. In this step, think about what activities will be conducted under the SOP and what resources will be needed to carry them out, as well as your own

see **Six Steps** on page 4

Regulatory Update

EU Paper Tasks Sponsors, Investigators with Oversight of Decentralized Trial Data

In trials using decentralized elements, sponsors and investigators have ultimate responsibility for ensuring the integrity of the data generated, says a draft EU guideline, placing additional oversight duties on their plates.

The release of the paper by the European Medicines Agency (EMA), European Commission and Heads of Medicines Agencies comes at a time when researchers have expressed concern about regulatory barriers to decentralized trials (DCT) (*CenterWatch*, Dec. 12).

"Introducing decentralized elements should be considered as an extension of the … site with the inclusion of the trial participants' home, resulting in an additional obligation of oversight for investigators and sponsors," the draft says.

"The protocol should reflect that the sponsor and the investigator are in full control of their respective areas of responsibilities at all times, e.g., with respect to the data processing, the communication flow and, ultimately, the rights, safety, dignity and well-being of the trial participants and reliability of the trial data," the paper reads.

For example, sponsors and investigators should ensure the assignment of activities to different parties is well defined whenever a DCT methodology is introduced. Clearly document which tasks are done when, by whom and in which setting, such as at the trial site or the patients' homes, as well as how the required oversight by the sponsor or investigator will be achieved. An overview of the workflow for these tasks should be laid out generally in the protocol and in greater detail in a protocol-related document, the guidance says.

In addition, trial-specific activities shopped out to a service provider should be specified in a written agreement between the responsible party (as directed in ICH E6) and the provider.

When a sponsor chooses a provider and the investigator is not involved in the agreement, the contract between the sponsor and investigator should clearly document that agreement between the sponsor and service provider when it relates to tasks under the investigator's responsibility, the guidance says. By doing this, the investigator can agree or disagree to the use of service providers for medical care-related trial tasks.

The guidance also offers the EMA's perspective on informed consent in DCTs, the delivery and administration of investigational products at home, the conduct of trial-related procedures at home, data collection and management, and trial monitoring.

Read the full draft guidance here: https://bit.ly/3hDQLau.

FDA Issues Updated Guidance on Developing Pulmonary Tuberculosis Drugs

The FDA says a single, well-controlled trial may be used to support a drug candidate for treatment of pulmonary tuberculosis (TB) if additional confirmatory evidence is available, in a revised draft guidance.

The 23-page document, which replaces a November 2013 draft, includes detailed recommendations for nonclinical models, early phase studies and trial design considerations, including how to demonstrate efficacy using superiority or noninferiority trial designs.

For demonstrating efficacy, the agency suggests that a "single adequate and well-controlled trial in subjects with pulmonary TB," supported by other confirmatory evidence, such as evidence of antimycobacterial activity from nonclinical data or phase 2 trials, "may provide evidence of effectiveness when the single trial demonstrates a clinically meaningful and statistically robust treatment effect."

The revised draft also includes additional information on the inclusion of children in studies, safety considerations and labeling. The draft does not deal with drug development for latent TB infection or for extrapulmonary TB.

The FDA noted that treatment of TB includes more than one drug in a treatment regimen and that sponsors may be developing more than one investigational drug as part of a new combination regimen, adding that they should consult with the FDA early during development of their plans to develop TB drugs as part of a combination regimen.

Sponsors should also assess potential drug-drug interactions that may occur during coadministration with other antimycobacterial drugs, such as antiretrovirals, because many TB patients have comorbidities and receive medications for those conditions.

The deadline for comment on the draft is Feb. 13, 2023.

Read the FDA draft guidance here: https://bit.ly/3huXSSD.

FDA Proposes More Detailed Annual Reporting for INDs

The FDA has issued two proposed rules on investigational new drug applications (IND) that would require more detailed IND reports and exemptions for clinical trials for drug uses of a food, dietary supplement or cosmetic product.

Under the proposed rule on annual reporting requirements, sponsors would be required to provide the agency with a yearly FDA development safety update report (DSUR) that follows the International Council for Harmonization's (ICH) E2F DSUR guidelines.

see **Regulatory Update** on page 3

Regulatory Update

continued from page 2

The provision would make the yearly update required of sponsors more detailed and comprehensive than the IND annual report currently mandated by FDA regulations. Among a number of elements, the DSUR includes an overall safety analysis and a summary of cumulative safety information.

The rule is being put forward to address the growing complexity of trials. In the agency's view, requiring a DSUR that assesses risk at a deeper level than the current annual report will help the agency and sponsors identify and manage potential risks, cut down the amount of unnecessary risks trial participants are exposed to and improve the FDA's assessment of trials conducted outside the U.S.

"Because FDA intends that the DSUR be consistent with the format and content of submission of the DSUR supported by ICH, the annual reporting process for sponsors would be more efficient by supporting one format for submission to FDA and multiple regulatory authorities in the European Union (EU) and other countries and regions," the proposed rule reads.

The second proposed rule would exempt certain trials of legally marketed foods for human consumption (including conventional food and dietary supplements) and cosmetics from requiring an IND when the product is being studied for use as a drug. This would apply to trials that aren't meant to support a drug development plan or labeling change and trials that do not present significant risks to participants, among other factors.

The proposed provisions "are intended to reduce the regulatory burden of conducting such studies while retaining protections for human subjects," the agency said.

Should the proposed rule be finalized, sponsors should be aware that the exempted trials must comply with other regulations meant to protect the rights and safety of participants, including informed consent and IRB review requirements, the agency said.

The comment deadline on the proposed rules is March 9, 2023.

Read the proposed rule on DSURs here: https://bit.ly/3Fcth4h.

Read the proposed rule on IND exemptions here: https://bit.ly/3W1p6iq.

FDA Adopts ICH E19 Guidelines on Selective Safety Data Gathering

In an effort to improve the efficiency of late-stage and post-approval trials, the FDA has endorsed the International Council for Harmonization's (ICH) E19 guidelines, which offer considerations for selectively collecting safety data, in recent final guidance.

In the view of the FDA, selective safety data collection — the reduced collection of certain safety data after careful, thoughtful consideration — can lead to greater productivity in trials and enable larger-scale research efforts. The ICH E19 guidelines, titled "A Selective Approach to Safety Data Collection in Specific Late-Stage Pre-Approval or Post-Approval Clinical Trials," mainly pertains to safety data in interventional post-approval trials but may be applicable in phase 3 trials in certain instances.

In situations where there is strong understanding and documentation of a drug's safety profile, gathering comprehensive safety data may only add limited clinical knowledge, the FDA's final guidance explains. In these circumstances, a more thought out and selective safety data gathering approach may be useful.

"By tailoring the method and streamlining the approach to safety data collection, it may be possible to carry out clinical trials with greater efficiency. This may facilitate the conduct of large-scale efficacy and safety clinical trials with large numbers of participants and long-term follow-up," the FDA said.

The guidance goes into general principles, such as on justifying selective safety data collection, ensuring the safety of participants, data that should generally be collected and benefit-risk factors to consider when selectively gathering data, as well as sections on implementing a more selective approach, practical considerations and how ICH E19 should be considered alongside other guidances and regulations.

The EMA was the first ICH regulatory agency member to endorse the ICH E19 guidelines, doing so at the end of November (*CenterWatch*, Nov. 30).

Read the final guidance here: https://bit.ly/3VTADjW.

EMA Plans New Guidance in Response to Increased Use of Platform Trials

The European Medicines Agency (EMA) is planning to draft new guidance on the planning, operational and reporting challenges inherent to platform trials.

The EMA believes that a "consolidated position" is necessary as industry uses the platform design more and more. Specifically, the agency has begun discussing a guidance on multiplicity and adaptive design that will serve to complement its existing platform trial guidances, not replace or revise them.

Through this guidance, the EMA says it will:

- Clarify terminology and introduce key concepts;
- Describe key methodological topics unique to platform trials and important design features to help guide trial planning and protocol development; and
- Outline the Committee for Medicinal Products for Human Use's position on the increased complexity and uncertainty in decision-making related to platform trials.

The agency said it intends to release a draft guidance in March 2024 and publish the final guidance in December 2024.

Read the EMA's concept paper here: https://bit.ly/3i5EAmP.

EU-CTR

continued from page 1

"The general complexity of study designs, coupled with the many layers of study management and costs, are a recurrent problem for trial sites," said Peter Embley, chief regulatory officer of auditing and regulatory services firm Arriello, highlighting potential hiccups in implementation.

"The current CTIS issue is that clinical trial sites and vendors need to be registered in an organization management service (OMS) to enable them to operate CTIS," Embley said, adding that sometimes "there are issues regarding how OMS and CTIS are connected, disallowing certain vendors to be added to the CTIS vendor database."

The European Medicines Agency (EMA) addressed the problem in a Dec. 12 communication to sponsors that provides step-by-step instructions on how to go about the OMS registration process.

The need for training on the new CTIS is another factor delaying sponsors' adoption of the EU-CTR, said Calin Lungu, CEO of pharmacovigilance consulting firm DDCS, although there are a lot of training resources available. The other factor, Lungu says, "is that sponsors fear some authorities are not ready to use CTIS."

And regulators themselves have raised concerns about CTIS's readiness for broad implementation. In November, an open letter from the German Working Group of Medical Ethics Committees and trade associations representing the pharmaceutical industry and research universities asserted that the CTIS portal suffers from "serious deficiencies and is largely unmanageable for all parties involved" and that these deficiencies "have not been eliminated in recent months but have increased."

According to the letter, published on the website of the German industry trade group BPI, there is a "tangible danger that the dysfunction of the CTIS portal will lead to a possible permanent migration of drug trials to other regions of the world." The group recommended delaying the Jan. 31, 2023, implementation date until issues are resolved.

And in December, the Clinical Trials Coordination Group (CTCG) working group of the EU's Heads of Medicines Agencies (HMA) requested that the deadline be moved to 2024 as broad use of CTIS "poses a risk for further delays in the project and might even create additional technical bugs."

Echoing the German group's argument, CTCG said, if "the system fails under mandatory use, the reputational damage to the EU in terms of it no longer being seen as a focal point for conducting high-quality research will be difficult to recover from."

But the EMA remains unmoved. "Some users have experienced problems with the system," the agency admits in a statement on its website, pledging that it "is working closely with member states, the European Commission and stakeholders to improve the CTIS user experience for core CTIS processes by the time the use of the system becomes mandatory for all new applications."

"The one thing that should not happen at this stage," said Omnes, "is a delay in the go live [date] of the CTR compulsory submission for new trials, as this would require a change in the regulation itself and time is now too short for this to happen."

Six Steps

continued from page 1

organization's strategic pledge to quality, Cole says.

"A lot of times, individuals that we work with don't have a clear vision on their organization, which can actually affect the SOPs," Cole said during a presentation at the MAGI West conference in Las Vegas. "Do you have a quality manual or something that talks to your strategy and your leadership commitment to quality as an organization? That's really going to play into any SOP that you develop."

Make a rough draft diagram of how the procedure will work and what will be involved in carrying out the procedure from beginning to end, he advised. The diagram should give a high-level view of the supplier, input, process, output and customer considerations.

Consider, for example, what impact the process may have on trial participants, what stakeholders (suppliers) will be involved in the SOP, what work will go into the process (input), and what will result from that work (output).

2. Measure

In the second step, "measure what's going on with [the] process itself," Cole says. "Break it down into tiny parts and make sure each component is incorporated appropriately."

Create a process map that illustrates the flow of activities in a way that makes the SOP easy to comprehend from start to finish, he advised. Whenever possible, physically go to the place where the task is being carried out and make observations of what is occurring.

It's also wise to connect process map items to regulatory activities that may be required.

3. Analyze

Third, you will want to analyze the quality and efficiency of the process in its

see Six Steps on page 5

Six Steps

continued from page 4

current state. See this as a prime chance to catch inefficiencies, gauge compliance and improve the SOP by observing and interacting with the personnel carrying it out, Cole suggests.

By watching the activity being conducted and following along with your process map, you'll be able to identify bottlenecks, for instance, and operational improvements, such as reducing the number of staff assigned to an activity and using available technology in their place.

This analysis phase is also a great way to engage teams and gather the thoughts of staff members that aren't typically exposed to the process at hand. This step has the potential to serve as a shining example of quality culture in action at your organization.

"Bring in new perspectives of people that are naïve to the process itself. That's where innovation can sometimes be sparked," Cole says. "You want people to ask those questions. Quality culture, being sure people feel free to speak up, this is where you can practice what you preach."

4. Develop

When it comes time to write the SOP, work with your process map and whatever SOP template your organization uses, says Victor Capetillo, site manager for Injury Care and Family Care Research, a Boise, Idaho-based site. Templates should have as much boilerplate language or instruction as possible so that SOP development is consistent.

Every SOP should include sections on purpose, scope, roles/responsibilities, references, the procedure itself and any corresponding SOPs. A revision history and controlled document list is also important. Having a revision history section in SOPs is something that smaller sites — and even sites of larger size — often fail to include.

Capetillo recommends keeping SOP drafts simple and chronological and developed with the end user in mind, with responsibilities assigned based on roles, not individual staff members. It's also important to remember that SOPs aren't confined to words — images can be highly informative and are perfectly acceptable.

5. Review and Revise

The next step in the process is to review the draft using a team-based approach. Capetillo has seen extremely positive results after establishing a multidisciplinary SOP committee to handle the review process and lay out a review schedule.

As you review, determine whether any changes that arise should be made at that moment or placed in a log of future modifications.

Just as in the analysis stage, Capetillo says it's good to include new hires and process-naïve personnel in this phase to prompt innovative changes and educate site staff.

6. Approve, Control, Train and Maintain

The final step in the process involves green-lighting, managing and maintaining the SOP and training site staff on it.

It's important here to document the formal approval of each SOP, control documents by identifying different versions, keep effective dates for each version and have revision synopses for every iteration, Capetillo says.

"So many times, we'll walk into a place and version control is all over the place. Making sure as an organization that you set that standard is important so everyone has a shared understanding — is this a final version? Is it a draft of a revision? They need to know that," Cole adds.

It's also important to keep track of this in the procedure itself. Have a table of revisions and versions and summaries for both in your SOPs to make things easier on your team and FDA inspectors who are scrutinizing them.

Staff training should be planned and documented promptly. Keep in mind that retraining may be necessary as SOPs are revised and enhanced, Capetillo says, and be sure to consider putting staff through "knowledge checks" to confirm their continued understanding and proper use of SOPs.

Study Lead Opportunities

CenterWatch analyzes data in its drug intelligence database to provide advance notice of clinical trials expected to enter the next phase of clinical development soon. Contact information is provided for follow-up. **Sponsors/CROs:** to list an upcoming trial here, contact Leslie Ramsey, 703.538.7661, lramsey@wcgclinical.com.

Company name	Drug name	Indication
phase 1		
Autobahn Therapeutics	ABX-002	Major depressive disorder
Gate Neurosciences	Apimostinel	Acute depressive disorders
Imago BioSciences	Bomedemstat plus venetoclax	Relapsed/refractory acute myeloid leukemia
Cytokinetics	CK-3828136	Heart failure with reduced ejection fraction and other types of heart failure, including right ventricular failure, due to impaired cardiac contractility
Dianthus Therapeutics	DNTH103	Severe autoimmune diseases
Spirita Oncology	E6201 plus dabrafenib	Patients with central nervous system metastases from BRAF V600-mutated metastatic melanoma
Federation Bio	FB-001	Enteric hyperoxaluria
Horizon Therapeutics	HZN-457	Gout
Indaptus Therapeutics	INDP-D101	Advanced/metastatic solid tumors
Sionna Therapeutics	SION-638	Cystic fibrosis
Virogin Biotech	VG201	Advanced solid tumors
phase 1a		
Clarametyx Biosciences	CMTX-101	Moderate community-acquired bacterial pneumonia
VYNE Therapeutics	VYN201	Vitiligo
phase 1b		
Arcutis Biotherapeutics	ARQ-255	Alopecia areata
Bio-Path Holdings	BP1001-A	Solid tumors
Compass Therapeutics	CTX-471 plus Keytruda	Cancers of the lung, head and neck and melanoma
Frequency Therapeutics	FX-345	Sensorineural hearing loss
ImmunoMet Therapeutics	IM156	Pancreatic cancer
iOnctura	IOA-289	Metastatic pancreatic cancer
Rigel Pharmaceuticals	R289	Lower-risk myelodysplastic syndromes

see **Study Lead Opportunities** on page 7

Study Lead Opportunities continued from page 6

Company name	Drug name	Indication
phase 1/2		
BioSight	Aspacytarabine (BST-236) in combination with venetoclax	Acute myeloid leukemia
Beam Therapeutics	BEAM-101	Severe sickle cell disease in adults
Dragonfly Therapeutics	DF9001	Locally advanced or metastatic solid tumors
Dermaliq Therapeutics	DLQ01	Androgenic alopecia
Immuneering	IMM-1-104	Advanced solid tumors with RAS mutations
Qurient	Q901	Advanced solid tumors
SwanBio Therapeutics	SBT101	Adrenomyeloneuropathy
SpliSense	SPL84	Cystic fibrosis patients carrying the 3849+10 Kb C->T mutation
Tyra Biosciences	TYRA-300	Metastatic urothelial carcinoma of the bladder and urinary tract
TRACON Pharmaceuticals	YH001 plus envafolimab and doxorubicin	Sarcoma
phase 2a		
Genentech	RG6501 (OpRegen)	Geographic atrophy secondary to age-related macular degeneration
phase 2		
EmbarkNeuro	ANC-501	Major depressive disorder
AstraZeneca	AZD2936	Stage III unresectable or stage IV non-small cell lung cancer
Baudax Bio	BX1000	Neuromuscular blockade in patients undergoing elective surgery
Cardiol Therapeutics	Cardiol Therapeutics	Recurrent pericarditis
Dragonfly Therapeutics	DF1001	Advanced solid tumors
Escient Pharmaceuticals	EP547	Cholestatic pruritus
Equillium	EQ101	Alopecia areata
India Globalization Capital	IGC-AD1	Agitation in dementia from Alzheimer's disease
Inversago Pharma	INV-202	Diabetic kidney disease
Lynk Pharmaceuticals	LNK01003	Active ulcerative colitis
Kinevant Sciences	Namilumab	Pulmonary sarcoidosis

see **Study Lead Opportunities** on page 8

Study Lead Opportunities continued from page 7

Company name	Drug name	Indication
phase 2 continued		
MoonLake Immunotherapeutics	Sonelokimab	Active psoriatic arthritis
NETRIS Pharma	NP137	Advanced/metastatic solid tumors
Rezolute	RZ402	Diabetic macular edema
Telix Pharmaceuticals	TLX101	Recurrent high-grade gliomas
Ventyx Biosciences	VTX958	Moderate-to-severe plaque psoriasis
Actinogen Medical	Xanamem	Major depressive disorder and cognitive impairment
phase 2b		
Morphic Therapeutic	MORF-057	Moderate-to-severe ulcerative colitis
TC BioPharm	OmnImmune	Acute myeloid leukemia
phase 2/3		
Otsuka Pharmaceuticals Sunovion Pharmaceuticals	Ulotaront	Major depressive disorder
phase 3		
Ayala Pharmaceuticals	AL102	Desmoid tumors
Biofrontera Bioscience	Ameluz and BF-RhodoLED XL	Actinic keratosis on the extremities, neck and trunk
Atea Pharmaceuticals	Bemnifosbuvir (AT-527)	Treatment of COVID-19 in non-hospitalized patients at high risk for disease progression
Celcuity	Gedatolisib	HR+/HER2- advanced breast cancer
Chimerix	ONC201	H3 K27M-mutant diffuse glioma

FDA Actions

The following is a sampling of FDA regulatory actions taken during the previous month, compiled from CenterWatch and third-party sources, including the FDA and company press releases. For more information on FDA approvals, visit centerwatch.com/fda-approved-drugs.

Company name	Drug name	Indication	FDA action
AB Science	Masitinib	Mild-to-moderate Alzheimer's disease	IND approved
AltruBio	ALTB-268	Ulcerative colitis	IND approved
Ananda Scientific	Nantheia A1002N5S	Social anxiety disorder	IND approved
AnHeart Therapeutics	Safusidenib	IDH1 mutant lower grade glioma	IND approved
Ascletis Pharma	ASC11	COVID-19 treatment	IND approved
Ascletis Pharma	ASC10	Monkeypox	IND approved
Asieris Pharmaceuticals	APL-1401	Moderately-to-severely active ulcerative colitis	IND approved
Beam Therapeutics	BEAM-201	Relapsed/refractory T-cell acute lymphoblastic leukemia/lymphoma	IND approved
BioCardia	NK1R+ allogeneic human mesenchymal stem cells	Ischemic heart failure	IND approved
Erasca	ERAS-3490	KRAS G12C-mutated advanced or metastatic solid tumors	IND approved
Gmax Biopharm	GMA131	Diabetic kidney disease	IND approved
Immorna	JCXH-221	mRNA-based COVID vaccine	IND approved
IN8bio	INB-400	Newly diagnosed glioblastoma	IND approved
J INTS BIO	JIN-A02	Advanced non-small cell lung cancer	IND approved
Mabwell	9MW3011	Polycythemia vera	IND approved
Marker Therapeutics	MT-601	Locally advanced unresectable or metastatic pancreatic cancer	IND approved
NeuroSense Therapeutics	PrimeC	Amyotrophic lateral sclerosis	IND approved
NMD Pharma	NMD670	Spinal muscular atrophy type 3	IND approved
Opus Genetics	OPGx-001	Leber congenital amaurosis resulting from biallelic mutations in the LCA5 gene	IND approved
Praxis Precision Medicines	PRAX-562	Pediatric patients with developmental and epileptic encephalopathies	IND approved
Pyxis Oncology	PYX-201	Solid tumors including breast, head, neck and lung and thyroid cancer	IND approved
Pyxis Oncology	PYX-106	Solid tumors including bladder, cholangiocarcinoma, colorectal and kidney cancer	IND approved
SOFIE Biosciences	[18F]FAPI-74	Gastric cancer, cholangiocarcinoma, hepatocellular carcinoma, pancreatic cancer and colorectal cancer	IND approved
Triastek	T21	Ulcerative colitis	IND approved
Vertex Pharmaceuticals	VX-522	Cystic fibrosis patients with a CFTR genotype not responsive to CFTR modulator therapy	IND approved

see **FDA Actions** on page 10

FDA Actions continued from page 9

Company name	Drug name	Indication	FDA action
YS Biopharma	PIKA COVID-19 vaccine	COVID-19	IND approved
Vistagen	PH10	Major depressive disorder	Study May Proceed Letter
Pfizer BioNTech	Omicron BA.4/BA.5-adapted bivalent	COVID-19 vaccine	Emergency Use Authorization granted
Sobi North America	Kineret (anakinra)	COVID-19-related pneumonia in hospitalized adults requiring supplemental oxygen	Emergency Use Authorization granted
AstraZeneca	Imfinzi (durvalumab) plus Imjudo (tremelimumab) plus platinum-based chemotherapy	Non-small cell lung cancer	Approved
CSL Behring	Hemgenix (etranacogene dezaparvovec-drlb)	Hemophilia B	Approved
Ferring Pharmaceuticals	Rebyota (fecal microbiota, live-jslm)	Prevention of recurrence of Clostridioides difficile infection (CDI) in adults following antibiotic treatment for recurrent CDI	Approved
Mirati Therapeutics	Krazati (adagrasib)	KRASG12C-mutated locally advanced or metastatic non-small cell lung cancer	Approved
Provention Bio	Tzield (teplizumab-mzwv)	To delay the onset of stage 3 type 1 diabetes in patients 8 years and older with stage 2 type 1 diabetes	Approved
Rigel Pharmaceuticals	Rezlidhia (olutasidenib)	Relapsed/refractory acute myeloid leukemia in adults with susceptible IDH1 mutation	Approved
ImmunoGen	Elahere (mirvetuximab soravtansine-gynx)	Treatment of previously treated adults with folate receptor alpha-positive, platinum-resistant epithelial ovarian, fallopian tube or primary peritoneal cancer	Accelerated approval granted
Medicines360	Liletta (levonorgestrel-releasing intrauterine system)	Pregnancy prevention for up to 8 years	Approved for extended treatment duration
Seagen	Adcetris (brentuximab vedotin)	Previously untreated high risk classical Hodgkin lymphoma in children 2 years and older	Approved for expanded age indication
SCYNEXIS	Brexafemme (ibrexafungerp tablets)	Reduction in the incidence of recurrent vulvovaginal candidiasis	Approved for additional indication
Jazz Pharmaceuticals	Rylaze (asparaginase erwinia chrysanthemi (recombinant)-rywn)	Acute lymphoblastic leukemia or lymphoblastic lymphoma	Approved for new dosing formulation
Endomag	Magtrace lymphatic tracer	Breast cancer surgery	Approved

wcg CenterWatch
www.centerwatch.com
300 N. Washington St., Suite 200, Falls Church, VA 22046-3431
Phone: 866.219.3440 or 617.948.5100
Customer Service: customerservice@centerwatch.com

Editorial Director: Leslie Ramsey, 703.538.7661, lramsey@wcgclinical.com
Reporter: James Miessler, 703.538.7650, jmiessler@wcgclinical.com
Sales: Russ Titsch, 617.948.5114, russ.titsch@centerwatch.com