EU General Data Protection Regulation (GDPR) Enforcement Set to Begin on May 25

By Suz Redfearn

The European Union (EU) General Data Protection Regulation (GDPR) is set to become enforceable in just over a month, which is causing new work for those in clinical research, and carrying with it a brutal fine for noncompliance.

“The data are the blood of clinical research, so we’ve got to make sure our processes and policies are in place for this,” said Mark Barnes, partner at the law firm Ropes & Gray, as well as co-director of the Multi-Regional Clinical Trials Center of Harvard University and Brigham and Women’s Hospital, and a lecturer at Yale Law School.

The new regulations standardize and strengthen the protection of personal data across the EU and for data from other countries being processed within the EU. The rule, Regulation (EU) 2016/679, replaces the Data Protection Directive 95/46/EC, which mandated that individual European countries handle data privacy themselves. Come May 25, they will all have to follow the new rule, which expands the definition of personal data to include any information that could be used to identify a person.

What will research sector companies need to change? They’re going to have to identify the data that is being processed, where it is transferred to, who is processing it, what it is used for, any risks and processes it may undergo and make sure all employees and vendors are trained.

FDA Releases Guidance on Next-Generation Sequencing with an Eye on Easing Path to Market

By Donna Gorman and James Miessler

The FDA released two final guidance documents related to next-generation sequencing (NGS) and one draft guidance on investigational in vitro diagnostics (IVDs) in oncology trials. All three documents offer test developer recommendations for a more efficient path to market.

The two final guidance documents provide NGS test developers with recommendations for designing, developing and validating tests, as well as using genetic variant databases to support clinical validity.

The first guidance, Use of Public Human Genetic Variant Databases to Support Clinical Validity for Genetic and Genomic-Based In Vitro Diagnostics, encourages developers to use clinical evidence found in FDA-recognized public databases to support clinical claims for their tests. The agency said this will ensure accurate clinical evaluation while providing developers with an efficient means of gaining marketing clearance or approval for new tests.

The guidance describes the FDA’s considerations for recognizing publicly accessible genetic variant databases as sources of valid scientific evidence during premarket review, and also spells out how database administrators can apply to the FDA for inclusion in the program.

FDA Commissioner Scott Gottlieb said the agency “recognizes the tremendous potential of NGS technology to guide and improve
FDA Recommends Early, Pre-Approval Trials in Pediatrics for Systemic Dermatitis Drugs

The FDA published a new draft guidance outlining how early Sponsors should incorporate pediatric patients, and relevant age groups, for systemic therapies for atopic dermatitis (AD). The agency previously recommended that Sponsors submit pre-approval data on the use of topical products, but did not recommend pediatric studies of systemic drugs until after adult approval. The new draft guidance recommends Sponsors initiate pediatric studies early in development, typically after obtaining initial evidence from early-phase adult studies. In addition, Sponsors should discuss the specifics of their pediatric programs with the FDA as early as possible, as pediatric study plans are required to be submitted within 60 days after an end-of-Phase II meeting. The FDA said it is important to study all relevant age groups, including children younger than two years of age. A sequential approach may not be needed, except for safety concerns, technical issues or the need for information from older subpopulations to inform further study designs. Juvenile animal toxicity studies should also be considered before enrolling human participants. If approved, Sponsors should provide as much information as possible when labeling in regard to pediatric use. The agency said it is also planning a separate guidance to address the technical aspects of drug development for pediatric patients with AD. The draft guidance is available here: www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm603702.pdf.

CVS Planning First Clinical Trials to Develop Home Dialysis Machines

CVS Health is planning to develop in-home dialysis machines through the company’s first clinical trials and an eventual FDA submission. Following experience with at-home care through the company’s infusion provider, Coram, as well as its relationships with payers through Caremark, CVS hopes to reshape the dialysis treatment business model and kidney care space, said Alan Lotvin, executive vice president and head of CVS Specialty. CVS plans to approach the project in stages, first focusing on early disease identification and patient education, followed by the development of a comprehensive home program for hemodialysis and peritoneal dialysis. According to the company, the device’s design is intended to make home dialysis simple and safe, in order to facilitate longer, more frequent treatments.

FDA Adopts ICH Update to 17-Year-Old Pediatric Clinical Trial Guideline

The FDA adopted an addendum updating the ICH’s E11 guideline on pediatric clinical trials, outlining ethical considerations, age classifications, pediatric drug formulations, practicalities in clinical trials and approaches to optimizing drug development. The new revision, issued by the ICH in 2016, recommends sponsors build early consensus with international agencies, and identify key pediatric populations and subgroups; methodologies and trial design elements; and any knowledge gaps in developmental physiology, disease pathology or data in adult populations or related compounds. According to the addendum, when obtaining child assent, relevant elements of informed consent should be provided appropriate to the child’s capability to understand. The absence of dissent or objection should not be interpreted as assent. In addition, it may be necessary for assent to be reassessed as the child matures over the course of a study — as well as obtain informed consent once the child reaches legal age. Sponsors should also consider the need for different formulations or doses across subgroups, as well as ethical considerations across international regions, the guidance said. In addition, computer simulations can fill knowledge gaps in efficacy, safety and pharmacokinetics, and help determine appropriate dosing strategies. When extrapolating data, the ICH recommends considering differences in geographic and developmental factors and warns that direct pediatric safety data may still be necessary for approval. The original E11 guideline was first published by the ICH in 2000. The addendum, E11 (R1), has since been adopted by Japan’s Ministry of Health, Labour and Welfare as well as the EMA, where it went into effect in February. The E11(R1) addendum is available here: www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM530012.pdf.

NIH Publishes Detailed PanCancer Atlas to Help Inform Clinical Research

Researchers funded by the NIH published a detailed genomic analysis of molecular and clinical information from over 10,000 tumors representing 33 types of cancer, summing up the work of The Cancer Genome Atlas (TCGA). “This project is the culmination of more than a decade of groundbreaking work,” said NIH Director Francis Collins. “This analysis provides cancer researchers with unprecedented understanding of how, where and why tumors arise in humans, enabling better informed clinical trials and future treatments.” Known as the PanCancer Atlas, the work was made available as a collection of 27 papers see NIH Publishes on page 3.®
across several Cell journals, complementing the more than 30 tumor-specific papers published by TCGA over the past 10 years. The project included cancer genome sequencing as well as gene and protein expression profiles, and associated them with clinical and imaging data, the NIH said. The NIH is planning a three-day symposium this September, focused on TCGA's legacy and the future of large-scale cancer studies.

**Henry Ford Health System to Launch Pancreatic Cancer Clinical Research Center**

Henry Ford Health System plans to launch a pancreatic cancer research center following a $20 million gift from an anonymous donor, which will house investigator-initiated clinical trials. The gift will help establish a multi-institutional pancreatic consortium, led by Henry Ford, as well as endowed funds to support the hiring of an administrative director and clinical and research leaders. The center will focus on global collaborations to develop new methods for early detection, including validating biomarkers and translating them into screening tests, as well as using artificial intelligence to analyze clinical medical records and radiologic studies to identify patterns in medical records that may provide an earlier diagnosis. David Kwon, director of surgical oncology at Henry Ford Cancer Institute and director of the Multidisciplinary Pancreas Clinic at Henry Ford Hospital, will help to oversee the cancer center.

**Billion-Dollar NIH Opioid Initiative to Accelerate Clinical Testing of Safer Pain Treatments**

The NIH launched a new interagency effort to accelerate the clinical development of solutions to the national opioid crisis, such as non-addictive pain therapies and addiction treatments, following a near-doubling of federal funding from Congress to $1.1 billion in fiscal 2018. The HEAL Initiative, for Helping to End Addiction Long-term, plans to launch a longitudinal study to follow patients after surgery or the onset of acute pain to identify biomarkers for those more likely to transition to chronic pain. The NIH also plans to use innovative imaging and neurotechnologies developed through the BRAIN Initiative to identify new targets for treatment of chronic pain and biomarkers to predict treatment response — as well as define best practices for pain management using non-drug and integrated therapies for specific conditions. In addition, public-private partnerships to develop new pain medicines will share research data and match researchers with previously abandoned pharmaceutical compounds.

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Within GDPR, controls around consent have been tightened, stating that any request for consent must be given in a clear, intelligible easily-accessible form, and that the purpose for data processing must be connected to that consent. In addition, a study subject must be able to tell what material constitutes consent versus any other documents they are given. Consent must use simple language, and GDPR dictates that it must be as easy to withdraw consent as it is to give it.

There’s also the complicated issue of “the right to be forgotten,” which is part of GDPR and centers on study subjects who decide they want their data removed from a study. This conflicts with the expectation under good clinical practice (GCP) that data about a subject be kept even after they say they no longer want to participate in a study, as well as guidance from the FDA and from Europe that now dictates that researchers keep the data up until that point, said David Forster, chief compliance officer for WIRB-Copernicus Group.

Under GDPR, said Forster, when these issues come up, the expectation is that there will be a weighing of the value of the information for public interest versus the subject’s right to be forgotten.

“Theoretically, that scientific purpose should have enough weight to rule against the right to disappear,” said Forster, who added that if people can pull their data, those working in research fear that data for that trial can become skewed.

Though the rule — passed in 2016 — now will apply only to citizens of the EU, so many international companies have work there, the GDPR has the potential to become the de facto worldwide regulation that covers data privacy, said Forster.

To be ready for GDPR by May 25, Barnes said those working in clinical research that touches EU residents must:

1. identify all data flows in and out of the EU
2. make sure that all of their documents and legal relationships are conformed to adhere to the GDPR, “which means a lot of documents are going to have to be executed or amended,” and
3. conform to internal standard operating procedures so they can vindicate the individual right and responsibilities that are part of what they have to do, as organizations, to comply with GDPR.

“All of those things have to be accommodated in the way we plan and conduct our studies, and that means this directly affects the clinical trial document, the protocol, the clinical trial agreement with the sites, the informed consent forms and the internal SOPs in our companies and of academic medical centers in the U.S. that are sponsoring research or doing research within the 31 countries that are affected by the GDPR,” said Barnes. “I think a lot of the universe has just now begun to wake up to what needs to be done. The affect is going to be profound.”

GDPR rules don’t just apply to those conducting clinical trials, but also their employees, customers and subcontractors. Thus, clinical trial companies will have obligations to make sure rules are in place and followed throughout the various reaches of the trial they’ve sponsored. To that end, said Forster, many in the field are rewriting contracts with vendors to make sure vendors understand the importance of reporting any and all possible GDPR breaches to the contracting company.

And the fines are potentially colossal — up to four percent of annual global revenue or €20 million, whichever is higher.

“The fines are significant and that’s why everybody is so worried about this,” said Forster. “This is terrifying for larger companies.”

That’s the bad news.

The good news is that enforcers of the new regulation are much more likely to focus on technology giants for the next year than on clinical research.

“I think the first wave of enforcement is going to be Facebook, Google, Microsoft, Apple — the large technology firms that are already the focus of compliance concerns,” said Barnes, predicting that it may take a year or two for EU authorities to turn their attentions to biomedical research and the flow of data into and out of European countries.
FDA Guidance (continued from page 1)

patient outcomes” and said the agency is “developing a policy approach to keep pace with fast-moving NGS technologies that give patients and clinicians confidence in these panels’ analytical and clinical validity, while still allowing these sequencing systems to be efficiently updated as new genes, or gene variants, or improved algorithms come online.”

According to Gottlieb, “We believe that this guidance will encourage expert-based crowd sourcing of NGS evidence generation, curating and data sharing—which can all advance the development of high-quality precision medicine treatments and diagnostics.”

The second guidance, “Considerations for Design, Development, and Analytical Validation of Next Generation Sequencing (NGS)–Based In Vitro Diagnostics (IVDs) Intended to Aid in the Diagnosis of Suspected Germline Diseases,” provides recommendations for designing, developing and validating NGS-based tests used to diagnose individuals with suspected genetic diseases. The guidance describes how the FDA evaluates premarket submissions to determine how accurate a test is at detecting a particular genomic change.

The FDA developed the guidelines because current regulatory approaches are “appropriate for conventional diagnostics” that measure a limited number of chemical substances, while new sequencing technologies can examine millions of DNA variants at a time, and require a more “flexible approach to oversight that is adapted to the novel and evolving nature of these tests.”

In providing regulatory oversight for NGS in vitro diagnostic tests, the agency hopes to encourage the development of the rapidly evolving technology while ensuring that the devices are safe and effective.

Draft Guidance

The draft guidance introduces an optional submission process for determining the risks or non-risks of using an investigational in vitro diagnostic in a clinical trial involving an oncology investigational drug.

According to the guidance, Investigational In-vitro Diagnostics in Oncology Trials: Streamlined Submission Process for Study Risk Determination, the submission process determines whether the use of an investigational IVD in a clinical trial for an oncology therapeutic is a significant risk (SR), nonsignificant risk (NSR) or exempt. The trial may require an investigational device exemption (IDE) approval if it is found to be a SR, the guidance stated, in addition to an investigational new drug application (INDA).

A single sponsor should be prepared to hold communications with the FDA about the IND and should submit information about the oncology development program to either CBER or CDER, who will consult CDRH to determine its risk factor.

That information includes how the sponsor will apply investigational IVD results to the clinical trial, what they know about the prevalence of the biomarker in the patient population, and the specimen type that will be collected for investigational IVD testing, the guidance stated. In addition, if a biopsy is required for the IVD testing, the sponsor should note any potential risks.

FDA Commissioner Scott Gottlieb stated that the guidance will “encourage greater innovation and accelerate the adoption of tools that can increase the productivity of clinical research and improve the delivery of cancer care.”

FDA Releases Final Guidance for Special Protocol Assessments

By Zack Budryk

The FDA finalized guidance on its special protocol assessment (SPA) program that offers sponsors an advanced declaration from the agency that their trial designs, clinical endpoints and statistical analyses are acceptable.

The guidance finalizing the agency’s May 2016 draft details the procedures for submitting an SPA request, the content necessary to make such a request, the FDA’s assessment process, what happens if the FDA and the sponsor do not agree on trial protocols and when changes can be made to SPA agreements.

The guidance outlines the options for sponsors who receive a “No Agreement” letter from the agency. Such sponsors can initiate the trials without an SPA agreement, hold off on the trial to address the non-agreement in writing or request a Type A or biological product development Type 1 meeting to discuss the non-agreement.

The FDA also has the option to rescind an SPA agreement, although this is very rare and has occurred in fewer than one percent of the more than 1,000 SPA agreements the agency has issued since 1997. It can occur when division directors or senior management identify a substantial scientific safety or efficacy safety after the trial has begun. This could include:

- Identification of safety concerns for either the product or its pharmacological class
- The discovery of false or mistaken information or data in the SPA materials submitted by the sponsor

Five main protocols are eligible for SPA approval, including: protocols for animal carcinogenicity; drug substance and drug product stability; trials that aim to form the primary basis of an efficacy claim; and clinical studies necessary to prove interchangeability or biosimilarity; as well as animal efficacy protocols for studies intended to prove primary evidence of effectiveness required for approval or licensure.
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CROs have come to realize that regular engagement with investigative sites is critical to study success. Increasingly, access to high quality investigative sites has become more competitive. This limited access contributes to more costs to CROs related to site identification, selection and training. The increasingly competitive landscape confirms the critical need for CROs to focus on establishing valuable and steady site engagement practices.

Even before a study starts, CROs can encourage engagement among trial sites and staff to develop a sense of ownership, and lead to an increase in momentum toward completing a trial successfully. Inspiring friendly competition between sites will add to the collective impetus to drive a study forward.

Once a study has begun, CROs can distribute a study-wide newsletter on a recurring basis, for example, to give them the ability to publicly recognize the efforts made by sites. Highlighting and recognizing the metrics from a high-enrolling Investigator validates and engages the site, and provides a key performance metric for all other sites to strive toward.

Opportunities for increased site engagement extend past regular and more frequent communication. A CRO can implement an automated payment system and provide an adequate explanation of each payment, for example, to ensure sites receive timely payments and don’t spend extra time hunting down additional support documentation.

But the process of engaging clinical sites on a regular basis is not limited to the duration of the study; CROs are looking to expand these relationships in the interim between projects as a means to maintain strong partnerships. Establishing regular collaboration among site and CRO staff provides a platform to identify common issues faced by Investigators and site personnel, and develop actionable plans to overcome these obstacles.

Principal Investigators increasingly are recognized as key contributors to the overall design of a trial. Soliciting input from Investigators and site staff early in the development phase will lead to optimized study efficiencies throughout a program. Affording the opportunity for an Investigator to weigh in on the study protocol ensures that the operational aspects of the trial will align with common processes at their site, and will provide valuable input related to inclusion/exclusion criteria that will ultimately improve the patient experience and drive study enrollment.

CROs committed to maintaining a site-centric model, focus on providing ample tools and resources to allow Investigators the opportunity to provide value to patients. In turn, Investigators are more inclined to work with CROs that actively look for ways to enable a patient-centric experience by seeking feedback from sites and implementing processes to decrease site burden. Recognizing the pivotal role of Investigators as a fundamental connection to a desired patient population, is a key step toward streamlining the drug development process and optimizing clinical trial efficiency.

The increased focus on patient-centricity in clinical research is another area where the CRO-site relationship can be important. Realizing the importance of patient-focused trials, CROs are working cooperatively with sites to implement measures that focus on improving the patient experience.

Brittany Parker is the Director of Marketing and Communications at Total Clinical Trial Management. She works closely with research sites and study staff to execute current programs and develop ongoing, long-term relationships. Please visit www.totalcro.com for more information.
### Drug & Device Pipeline News

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KEYTRUDA Monotherapy Met Primary Endpoint in Phase III Study

Merck announced that the pivotal Phase III KEYNOTE-042 trial evaluating KEYTRUDA, Merck’s anti-PD-1 therapy, as monotherapy for the first-line treatment of locally advanced or metastatic non-small cell lung cancer met its primary endpoint of overall survival. KEYNOTE-042 is an international, randomized, open-label Phase III study investigating KEYTRUDA monotherapy compared to standard-of-care platinum-based chemotherapy in patients with locally advanced or metastatic PD-L1 positive (TPS ≥1 percent) NSCLC. Patients had no EGFR or ALK genomic tumor aberrations and had not previously received systemic therapy for advanced disease. The primary endpoint is OS with TPS of ≥50 percent, ≥20 percent and ≥1 percent, which were assessed sequentially. The secondary endpoints are PFS and objective response rate (ORR). The study enrolled 1,274 patients randomized 1:1 to receive either KEYTRUDA (200 mg fixed dose every three weeks). The safety profile of KEYTRUDA in this trial was consistent with that observed in previously reported monotherapy studies involving patients with advanced NSCLC.

Upadacitinib Meets all Primary Endpoints in Rheumatoid Arthritis Study

AbbVie announced positive top-line results from the Phase III SELECT-COMPARE clinical trial showing that after 12 weeks, upadacitinib (15 mg, once-daily) met the primary endpoints of ACR20a and clinical remissionb versus placebo. All ranked secondary endpoints were also achieved versus either placebo or adalimumab (40 mg every other week). SELECT-COMPARE is a Phase III, multicenter, randomized, double-blind, study designed to evaluate the safety and efficacy of upadacitinib compared to placebo and adalimumab in adult patients with moderate-to-severe Rheumatoid Arthritis. The study showed that at week 12, 71 percent of patients receiving an oral once-daily dose of upadacitinib 15 mg achieved an ACR20 response, compared with 36 percent of patients receiving placebo. A significantly higher proportion of patients receiving upadacitinib achieved clinical remission compared with placebo at week 12 (29 percent versus 6 percent, respectively). The trial is ongoing and includes a 48 week randomized, double-blind treatment period followed by a long-term extension study of up to five years.

Therapix Biosciences Announces Topline Results of Phase IIA TEL AVIV announced top-line results from its investigator-initiated Phase IIA study, suggesting that THX-110 (which is a combination of dronabinol (Delta-9-tetrahydracannabinol) and palmitoylethanolamide (PEA)) significantly improved symptoms over time in adult subjects with Tourette syndrome. The study was a single-arm, open-label trial, in which each subject both received one daily treatment of the drug via oral administration and was followed-up for a period of 12 weeks. Sixteen subjects participated in the study and received THX-110 at Yale University. The study showed that these 16 subjects with medication-refractory TS had a reduction of tic symptoms (paired t-test: YGTSS-TTS mean difference (mean +/- SD) =7.9 +/- 8.4, t= 3.7, df=15, p=0.002) from baseline (YGTSS-TTS: 38.4 +/- 8.3) to endpoint (YGTSS-TTS: 30.5 +/- 10.9). This resulted in an average tic reduction of 21 percent across the entire sample. Improvement over time with treatment was also observed when generalized linear models were used to analyze repeated measures data on the YGTSS-TTS. THX-110 demonstrated no significant effects on comorbidity.

Pfizer Stops Phase III Trial of Axitinib

Pfizer announced that the Phase III ATLAS trial evaluating INLYTA (axitinib) as adjuvant therapy for patients at high risk of recurrent renal cell carcinoma (RCC) after nephrectomy was recommended to stop the trial at a planned interim analysis due to futility. The recommendation was based on the study failing to demonstrate a clear improvement in the primary endpoint of extending disease-free survival (DFS) for patients treated with INLYTA compared with patients treated with placebo. Although NLYTA has had a significant impact on the treatment of patients with advanced RCC worldwide in its currently approved indications, no new safety signals were observed. ATLAS (A Randomized Double-Blind Phase III Study of Adjuvant Axitinib Versus Placebo in Subjects at High Risk of Recurrent RCC)(NCT01599754) is a global, multicenter, randomized double-blind Phase III trial that investigated the clinical efficacy and safety of adjuvant INLYTA (5 mg twice daily) versus placebo in patients (n=724) at high risk of recurrent RCC following nephrectomy. Patients were closed up to three years (for a minimum of one year) in the study and the primary endpoint was disease-free survival (DFS).
Upcoming Event Highlights

Conferences
MAY 10, 2018
West Coast Symposium on Expanded Access
An all-day event for the drug, device, diagnostics and clinical trial communities. An all-star cast of presenters will probe Expanded Access from every angle — regulatory, scientific, business, patient safety and liability.
San Francisco, CA
[ VIEW ALL CONFERENCES ]

Training Programs
MAY 1-31, 2018
Program Phlebotomy Training — Two Day Training
Various locations
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Webinars
APRIL 23, 2018
Managing Cybersecurity Risks in the Medical Device and Healthcare Sectors
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