Common Rule Confusion Clouds Industry Preparedness

By Mike Bassett

As the January 19 implementation date of the revised Common Rule approaches, the question remains as to whether or not implementation of the revised rule will be delayed — leaving many feeling uncertain.

There has been a degree of uncertainty about the implementation of the revised Common Rule ever since its release in January 2017, said Amy Dow, an attorney with Epstein, Becker & Green's healthcare and life sciences practice.

Days after the final rule was adopted, it was subject to a regulatory freeze imposed by the new Trump administration. By last summer, research institutions and organizations "were growing weary" about the lack of information regarding the status of the January 19 implementation date, as well as the lack of guidance regarding many of the rule's more complex provisions, Dow said.

Since then two proposed rules have appeared on the Office of Management and Budget (OMB) website. The first, posted in October, was a proposal for a one-year delay in the implementation date of the Common Rule revision while allowing the use of three burden-reducing provisions during the delay year. On January 4 another proposed rule appeared suggesting implementation of the complete rule could be delayed.

This has caused even more uncertainty within the regulated community, said David Borasky, vice president, IRB compliance, WIRB-Copernicus Group's Clinical Service Organization.
Alex Azar Takes Senate Questions in Bid to Become HHS Secretary

Democrats on the Senate Finance Committee grilled President Trump’s nominee for HHS secretary, former Eli Lilly executive Alex Azar, and attempted to tie him to price hikes of several products during his tenure as head of its U.S. business unit. Republicans once again touted his industry experience as a positive. Azar himself agreed that drug costs are too high, and listed one of his major priorities as working to reverse the incentives that drive manufacturers to raise their prices — while still ensuring discovery and innovation through well-funded clinical trials and research. The committee’s ranking member, Sen. Ron Wyden (D-Ore.), described how Lilly more than doubled the list prices for Forteo, Effient and Stratera, as well as its top-selling diabetes blockbuster Humalog, during the five years that Azar was president of Lilly USA. Wyden also cited how, nearly one year ago, Trump described pharmaceutical companies as “getting away with murder” in terms of prescription drug costs. “I don’t know that there is any drug price of a branded product that has ever gone down, from any company, on any drug in the U.S., because every incentive in this system is toward higher prices,” Azar told the committee Jan. 9. Azar also said the government should look at a more direct negotiation of lower prices under Medicare, but cautioned that a single, national formulary could end up restricting patient access.

EMA Plans to Update CNS and Cancer Guidelines in 2018

The European Medicines Agency’s working groups plan to update and publish several guidelines on clinical investigations of central nervous system diseases and cancers, with drafts expected in 2018. In oncology, a new draft guideline is expected on the use of minimal residual disease as an endpoint for multiple myeloma trials, with a draft available by the end of the first quarter 2018, and a final version by the end of the year. In addition, revisions of the EMA’s guideline for evaluating anticancer products will cover new clinical endpoints, biomarkers, interim analyses and data maturation, as well as estimands. The EMA’s oncology panel also plans to adopt an ICH question-and-answer document on nonclinical evaluation of pharmaceuticals related to the S9 guideline. The CNS guidelines, expected by the end of the year, cover treatments for migraines, depression, bipolar disorder, epilepsy, Alzheimer’s disease and dementia. In its work plan for the coming year, the EMA’s CNS working party described the documents as needing to be brought in line with recent scientific advancements. Some guidelines date back to 1998, such as the one for epilepsy, although others were last revised in 2014 and 2015. The EMA plans to hold a public workshop during its development of the epilepsy guideline, as well. However, these goals could be subject to change — especially as the EMA faces a challenging year brought on by Brexit, according to the EMA’s executive director, Guido Rasi. “Preparing for the agency’s move to Amsterdam and the United Kingdom’s withdrawal from the European Union will occupy the time of many staff members that we would rather spend on activities that make a difference to public health,” said Rasi, in an end-of-the-year message. “We will have to refocus on our core tasks and adjourn some initiatives.”

CRI, Canadian Cancer Trials Group Launch Immunotherapy Collaboration

The Cancer Research Institute and the Canadian Cancer Trials Group plan to launch new immunotherapy clinical trials as part of a global, multi-year collaboration. CRI, a U.S.-based nonprofit, plans to use its Anna-Maria Kellen Clinical Accelerator program as well as industry partnerships to organize the clinical study of combination therapies. CRI stated how basket, umbrella and adaptive clinical trial designs will be needed to efficiently evaluate permutations of the over 900 cancer immunotherapies currently in the development pipeline. The Ontario-based academic research cooperative group, CCTG, runs Phase I, II and III trials in over 80 Canadian institutions, as well as internationally, and is supported by the Canadian Cancer Society.

Survey Finds Professionals Already Experimenting with AI Applications

Interest in artificial intelligence, deep learning and natural language processing is growing, with 44 percent of surveyed life science professionals saying they’re already using or experimenting with AI in their research, according to a poll conducted by the Pistoia Alliance. Nearly 95 percent expect to see an increase in the use of machine learning in the next two years, but see access to quality clinical data and necessary technical expertise as barriers to widespread adoption. To overcome them, collaborations over data standards, benchmark sets and access will be essential. The survey, polling 374 senior professionals, found that 46 percent of AI projects currently take place in early discovery or preclinical research phases while 30 percent of natural language processing projects are used in during early-phase clinical trials. Other AI applications included clinical development and imaging analyses, as well as biomarker discovery and patient stratification. By comparison, 11 percent said they are not using AI at all, with 27 percent eschewing natural language processing and 30 percent reported no use of machine learning.
Common Rule (continued from page 1)

Copernicus Group. “Even with these [two proposed rules] being posted to the OMB website, OHRP (Office for Human Research Protections) has been unwilling to bare any details regarding their approach to the rulemaking process.

“And they haven’t definitely said whether the [rule] that came out last week supersedes the one that came out in October,” he noted. “So the regulated community is essentially operating in the dark.”

The result, according to Borasky and Dow, is that there are concerns about how prepared organizations and institutions are for the January 19 implementation date.

“Many of the final rule’s changes require the expenditure of significant resources for revisions of policies, procedures and documents, training and updates to information systems,” said Dow. “Research institutions may have been hesitant to expend already limited resources to make these changes in light of the uncertain status of the final rule’s provisions.”

Borasky suspects that the steps many organizations have taken to prepare for the implementation date have been “uneven” or taken longer than expected because they were hoping they would receive guidance on some of the new areas of regulation contained in the revised rule — several of which will impact clinical trial management.

“It bears repeating that the revised common rule only applies to research funded by a Common Rule agency, so the impact on industry-sponsored clinical research is really minimized,” Borasky pointed out. “That said, the provisions of the revised rule that will have the greatest immediate impact on the management of clinical trials are tied to its informed consent provisions.”

These include provisions such as the inclusion of key information in informed consent documents, described in the revised rule as a “concise and focused presentation of the key information that is most likely to assist a prospective subject of legally authorized representative in understanding the reasons why one might or might not want to participate in the research.”

“This is a completely new area of regulation, so there is no precedent for it,” Borasky said. “And it is especially challenging because the requirement is very vague and it’s not clear what will be considered to be in compliance.”

Borasky pointed out that another provision that has caused some consternation is one requiring that consent forms for certain federally funded clinical trials be posted on a public website.

“It’s going to be established as a registry,” he said. “However, no information has been provided about this registry, so, in theory, there’s an aspect of the rule — if it goes into effect next week — that has no mechanism for complying with it. That’s certainly going to be a challenge.”

There’s also some confusion about another informed consent provision that could impact clinical trials, Borasky said. For studies on stored identifiable data or identifiable biospecimens, researchers will have the option to rely on broad consent obtained for future research as an alternative to seeking IRB approval to waive the consent requirement.

“For those sponsors or investigators that want to exercise this ‘broad consent’ option for certain kinds of research, it’s not entirely clear how it is intended to be operationalized,” he said.

All of this uncertainty is further complicated, Borasky pointed out, by the fact that the FDA won’t be harmonizing its regulations with those of the common rule agencies “for quite some time.”

“The 21St Century Cures Act calls for the harmonization of human subject protection regulations between the FDA and the common rule agencies,” but as Borasky pointed out, the FDA will have to go through its own, time-consuming, rulemaking process.

What would be the impact of an implementation delay?

A delay would definitely allow more time for agency guidance on implementing the changes required by the rule, Dow said. “And it will give affected research institutions the opportunity to make the necessary changes and educate their stakeholders to facilitate compliance.”

On the other hand, Borasky said an implementation delay would represent “wasted effort.”

“Every IRB I’m aware of has invested some effort in planning for these changes, and for many the investment has been significant,” he said. “It’s been a lot of effort preparing for a rule that we could learn won’t go into effect, and while that may bring relief to some, it will leave a number of us scratching our heads and wondering why we spent so much time, effort and money preparing for the implementation of this rule.”

“We have to be all in and assume that it will go into effect,” Borasky said. “For IRBs that means not waiting until the 18th to make sure everything is in place.”

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10 years? With all of the advances in technology, the ability to transform and manipulate data, we are still no better than 10 years ago.”

Another shock? Getz said that research sponsors and CROs reported using their primary electronic data capture systems to collect and manage traditional data from case report forms and central and local labs — but not to collect and manage data from newer sources, including electronic health/medical records, mobile devices and social media communities.

This can create a silo effect that drags down the process.

“Historically, researchers have been reluctant to use primary health data because it has been too difficult to manage, and typically raised concerns with quality, completeness and usability,” said Wayne Kubick, chief technology officer of Health Level Seven International. “This has caused extra work for sites and sponsors, and often contributed to discrepancies between source data and study databases.”

However, things are changing for the better, Kubick said, thanks in large part to provisions in 2016’s 21st Century Cures Act that require providers to make data more accessible through APIs.

The Tufts CSDD study also found that 77 percent of sponsors and CROs have difficulty loading data into their primary EDC system due to compatibility, technical demands and integration challenges. Sponsors and CROs currently use an average of six applications to support clinical trial activities.

“The ultimate surprise was to see how troubling this complexity is to the development times,” said Getz.

“Companies are using everything from wearable devices and social media to mobile applications, collecting biomarker data, and it’s just remarkable that a high proportion of data collected is not captured in EDC but captured in other programs and only integrated much later in the process.”

The research also showed that protocol changes are the most common reason for delays in building study databases, accounting for 45 percent of database build delays reported by sponsors and CROs. Frequency of releasing the final study database after the first patient visit is associated with longer downstream delays and inefficiencies.

“All 257 drug developers surveyed by Tufts CSDD reported using electronic data applications in clinical trials — but 26 percent of sponsors and 52 percent of CROs said they are still using paper case report forms in some investigations.”

“Start to think about the root cause of that,” said Johnston, adding that it could be a lack of CRO involvement in early planning stages.

Companies may not have had enough time to deploy a full database, which would make getting started on paper easier for them. “A necessity due to their situation, rather than something they would prefer or plan,” she said.

In addition, there could have been a subset of studies more conducive to the use of paper forms, which could have been faster to change and implement. Those benefits could outweigh the risks for certain sponsors, Johnston said.

Are the troubles and delays just a natural part of the transition companies must make as technology advances, giving them more nifty tools for handling the influx of disparate data and speeding studies up? For now, he said, the expertise is not there. Pharma companies do not have in-house IT teams positioned to handle this.

“It would be interesting to see this segmented further into traditional pharma and biotech companies,” said Johnston. “Is it a deep seated mind-set, a technology gap, regulatory gap? Are we too set in our ways to see if there is a better way of doing this?”

My other thought would be, maybe this is good enough for a majority of the cases? Disappointing, but good enough?” she said.

Today’s electronic data capture systems were never designed to handle the upcoming avalanches of data in future trials, including from case report forms and wearables, Johnston said.

“It is going to be an excessive amount of data and hidden within will be the proverbial pile of gold,” she said, adding that the traditional clinical operator will likely need to think about data in a different way, using purpose-built tools.

Getz predicts that the industry will begin outsourcing much of this work to niche CROs with expertise in data integration. Getz also expects that the industry may soon begin looking outside itself for experts in other industries — although sweeping, effective solutions may not come for a few years.

“I think companies are finding short-term approaches that are helping them meet the objectives of their protocol requirements, but as our study has shown, that really just adds more time and variability,” Getz said. “When we’ll really start to see acceleration is anybody’s guess.”
## Drug & Device Pipeline News

<table>
<thead>
<tr>
<th>Company</th>
<th>Drug/Device</th>
<th>Medical Condition</th>
<th>Status</th>
<th>Sponsor Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chimerix</td>
<td>brincidofovir</td>
<td>adenovirus infection related to pediatric transplant</td>
<td>Phase I trials initiated in 141 subjects in the U.S. and Europe</td>
<td>chimerix.com</td>
</tr>
<tr>
<td>Oncolix</td>
<td>Prolanta</td>
<td>advanced ovarian cancer</td>
<td>Phase I trials initiated</td>
<td>oncolixbio.com</td>
</tr>
<tr>
<td>Immix Biopharma</td>
<td>IMX-110</td>
<td>advanced Solid Tumors</td>
<td>Phase I/IIa trials planned</td>
<td>immixbio.com</td>
</tr>
<tr>
<td>Aptevo Therapeutics</td>
<td>otlertuzumab</td>
<td>peripheral T-cell lymphoma</td>
<td>Phase II trials initiated enrolling 24 subjects</td>
<td>aptevotherapeutics.com</td>
</tr>
<tr>
<td>Novaliq</td>
<td>NOV03</td>
<td>dry eye disease</td>
<td>Phase II trials initiated</td>
<td>novaliq.com</td>
</tr>
<tr>
<td>Akcea Therapeutics</td>
<td>AKCEA-APOCIII-LRx</td>
<td>hypertriglyceridemia, established cardiovascular disease</td>
<td>Phase IIb trials initiated</td>
<td>akceatx.com</td>
</tr>
<tr>
<td>CymaBay Therapeutics</td>
<td>seladelpar</td>
<td>primary biliary cholangitis</td>
<td>Phase II/III trials initiated</td>
<td>cymabay.com</td>
</tr>
<tr>
<td>Minoryx Therapeutics</td>
<td>MIN-102</td>
<td>adrenomyeloneuropathy</td>
<td>Phase II/III trials initiated globally</td>
<td>minoryx.com</td>
</tr>
<tr>
<td>Semnur Pharmaceuticals</td>
<td>SP-102</td>
<td>lumbar radicular pain/sciatica</td>
<td>Phase III trials initiated enrolling 400 subjects in the U.S.</td>
<td>semnurpharma.com</td>
</tr>
<tr>
<td>Semnur Pharmaceuticals</td>
<td>SP-102</td>
<td>lumbar radicular pain/sciatica</td>
<td>Fast Track designation granted by the FDA</td>
<td>semnurpharma.com</td>
</tr>
<tr>
<td>Avadel Pharma</td>
<td>FT 218</td>
<td>narcolepsy</td>
<td>Orphan Drug designation granted by the FDA</td>
<td>avadel.com</td>
</tr>
<tr>
<td>Spruce Biosciences</td>
<td>SPR001</td>
<td>congenital adrenal hyperplasia</td>
<td>Orphan Drug designation granted by the EMA</td>
<td>sprucebiosciences.com</td>
</tr>
<tr>
<td>AbbVie</td>
<td>upadacitinib (ABT-494)</td>
<td>moderate to severe atopic dermatitis</td>
<td>Breakthrough Therapy designation granted by the FDA</td>
<td>abbvie.com</td>
</tr>
<tr>
<td>Global Blood Therapeutics</td>
<td>voxelotor</td>
<td>sickle cell disease</td>
<td>Breakthrough Therapy designation granted by the FDA</td>
<td>gbt.com</td>
</tr>
<tr>
<td>Amgen</td>
<td>Xgeva (denosumab)</td>
<td>prevention of skeletal-related events in patients with multiple myeloma</td>
<td>FDA expanded approval</td>
<td>amgen.com</td>
</tr>
</tbody>
</table>

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**Acceleron Announces Preliminary Results from ACE-083 Phase II Trial**

Acceleron Pharma announced positive preliminary results for the first two cohorts in Part 1 of the Phase II clinical trial with ACE-083 in patients with facioscapulohumeral dystrophy (FSHD), a rare genetic muscle disorder that results in progressive focal muscle loss and weakness. The company plans to initiate Part 2 of the ACE-083 FSHD Phase II trial during the second quarter of 2018. Part 1 is an open-label, dose-escalation study of ACE-083 designed to evaluate safety as well as changes in total muscle volume in up to 36 patients with FSHD. Preliminary results include data from 23 patients evaluable for magnetic resonance imaging (MRI) among two different cohorts (11 patients with tibialis anterior weakness and 12 patients with biceps brachii weakness). Each patient received ACE-083 (150mg or 200mg) as a unilateral intramuscular injection once every three weeks for 12 weeks. Total muscle volume changes were measured by MRI relative to baseline at three weeks after the last injection of ACE-083. Based on overlap in dosing on a milligram per gram muscle analysis, dose cohorts were pooled for the analyses of each muscle. Strength and function tests are being explored in Part 1 to assist with the design of the randomized, double-blind, placebo-controlled Part 2 of the study.

**BerGenBio Meets First Efficacy Endpoint in Phase II Trial**

BerGenBio reported that the first efficacy endpoint has been met in its Phase II clinical trial evaluating BGB324 (bemcentinib) in combination with erlotinib in patients with advanced non-small cell lung cancer (NSCLC) who have progressed on an approved EGFR inhibitor (ClinicalTrials.gov Identifier: NCT02424617). The trial (known as BGBCC004) is designed to test the hypothesis that selective AXL inhibition with the once-daily oral small molecule bemcentinib may reverse and prevent resistance to erlotinib, a therapy targeting constitutively active epidermal growth factor receptor (EGFR) signaling — a pathway frequently upregulated in cancers, particularly NSCLC. The trial is enrolling patients with activating EGFR mutations across three settings. Arm A is designed to determine the daily dose of bemcentinib that can be safely administered in combination with erlotinib in patients who have received prior erlotinib therapy. Arm B follows a Simon-like two-stage design evaluating the ability of bemcentinib to restore sensitivity to EGFR targeted therapy when given in combination with erlotinib in patients who have progressed on prior therapy with an approved EGFR inhibitor and that are negative for the T790M mutation. An overall disease control rate of 33 percent was reported in patients who completed at least one cycle of treatment (n=9) thus providing preliminary proof of concept that bemcentinib can restore sensitivity to EGFR targeted therapy in some patients. Arm C is designed to evaluate the ability of bemcentinib to prevent acquired resistance to EGFR targeted therapy when given in combination with erlotinib first line. This arm is recruiting patients with interim results expected mid-2018.

**Positive Results From a Analysis of Delcath PHP Therapy**

Delcath Systems issued results of a multicenter retrospective analysis of Delcath’s PHP Therapy. The study was conducted by researchers from Moffitt Cancer Center (Moffitt) in Tampa, FL, and the University Hospital Southampton (UHS) in the United Kingdom. Patients in the study were treated at the two centers between December 2008 and October 2016. Patients received up to four PHP treatments at UHS and up to six PHP treatments at Moffitt. All patients received at least one PHP treatment, the median number of treatments per patient was two and a total of 134 PHP treatments had been administered. Results showed that of the 51 treated patients, 22 (43.1 percent) showed a partial response, three (5.9 percent) showed a complete response and 17 (33.3 percent) had stable disease. The six-month overall and hepatic disease control rates were 64.7 percent and 70.6 percent, respectively. Survival analysis showed median overall survival of 15.3 months at the time of data cut off. One year overall survival was 64.6 percent. Safety analysis showed that 19 patients (37.5 percent) had Grade three or four non-hematologic toxicity. Cardiovascular toxicity was seen in 17.6 percent of patients, a rate comparable to the company’s prior Phase III study. The system has not been approved by the FDA, and is undergoing Phase III clinical testing in the U.S. as an investigational product.

**Alder Announces Eptinezumab Meets Primary and All Key Secondary Endpoints**

Alder BioPharmaceuticals announced that eptinezumab, its lead investigational product candidate for migraine prevention targeting calcitonin gene-related peptide (CGRP), met the primary endpoint in its pivotal Phase III PROMISE 2 clinical trial with very high statistical significance vs. placebo (p<0.0001) for both dose levels tested in the trial following a single quarterly infusion. In addition, eptinezumab met all key secondary endpoints with very high statistical significance vs. placebo including prevention beginning Day One (p<0.0001) and 50 percent (p<0.0001) and 75 percent (p<0.0001) responder rates month one through month three. Furthermore, 15 percent of eptinezumab patients had no migraines (i.e., 100 percent response) for a full three months (p<0.0001 unadjusted). Safety and tolerability were similar to previously reported eptinezumab studies. The observed safety profile in this study, to date, is consistent with previously reported eptinezumab studies. Adverse event rates among eptinezumab-treated subjects were similar to placebo-treated subjects. Commonly reported adverse events for eptinezumab, occurring at an incidence of 2.0 percent or greater, were nasopharyngitis (common cold) (6.3 percent), upper respiratory infection (4.0 percent), nausea (3.4 percent) and urinary tract infection (3.1 percent), arthralgia (joint pain) (2.3 percent), dizziness (2.6 percent), anxiety (2.0 percent) and fatigue (2.0 percent). If approved by the FDA, eptinezumab will be the first-to-market migraine prevention infusion therapy, with 100 percent of the treatment dose available upon administration.
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