Adverse Event Reporting: When TMI is Risky

By Bill Myers

As sponsors and sites have expanded their global reach, they’ve run into myriad local and regional regulations requiring them to report adverse events in their clinical trials. Hoping to simplify, many sponsors or sites have tried to create a one-size-fits-all form that sends out nearly automated alerts for nearly every single glitch.

“A lot of pharma companies take the approach that they’ve got to be compliant with everyone, so they say, ‘We’ll just send out everything,’” says Steven Beales, WCG’s senior vice president for safety. That might sound OK. [But] you’re wasting site hours and you’re not improving safety because you’re diluting the message.”

A decade ago, for instance, Roche discovered that it was distributing more adverse event warnings from trials than any other drug developer, with nearly a million notices going out to patients, regulators and others at a cost of more than $75 million in one year. As the company expanded through mergers and acquisitions, it was looking at having to dispatch in excess of 25 million alerts every year, Beales says.

The root of the problem was the scattershot regulatory regimes across the globe — Beales and his colleagues analyzed worldwide clinical trial regulation and found at least 40 different variances. “Patient safety is obviously the most important thing we do and sometimes that responsibility is put out nearly automated alerts for nearly every year, Beales says.

FDA Guidance Clarifies Agency Regulations v. Revised Common Rule

By James Miessler

The FDA released new guidance last week on how researchers can comply with both agency regulations and pending Common Rule revisions that protect human subjects in clinical trials.

The guidance focuses on requirements for informed consent, expedited review procedures and IRB continuing review. It says new requirements for informed consent documents in the revised Common Rule — the baseline body of regulations across federal departments and agencies for human subjects in clinical research — don’t conflict with any FDA regulations.

But the agency says IRBs still have to comply with its regulations for expedited and continuing reviews. IRBs must conduct continuing reviews of research at least once a year at “intervals appropriate to the degree of risk,” the guidance says. For expedited review procedures, IRBs must adhere to the 1998 list for FDA-regulated clinical investigations, including those subject to both HHS and FDA regulations.

David Borasky, vice president of quality management for the Copernicus Group Independent Review Board, says this is essentially business as usual, noting the guidance doesn’t reveal anything new about the FDA’s plans for harmonization between agency regulations and the Common Rule revisions.

see FDA Guidance on page 4 »
FDA: Generic Skin Patch Trials

Generic drug developers that use patches, inhalers, eye drops or similar means to deliver meds should hold clinical trials to test for potential side effects of skin irritation and, in the case of patches, adhesion quality, the FDA says.

The agency says it’s worried that skin patches may lose potency if jarred and loosened by everyday movements or conditions (such as moisture).

So in new draft guidance, released last week, it recommends generic drug developers hold separate clinical trials to make sure patches continue to stick and provide promised doses for the duration of treatment.

The guidance urges them to hold single-dose, randomized, two-treatment, two-period crossover trials with participants most likely to use patches to show they can withstand ordinary pressures. The draft, set to replace 2016 adhesion guidance, says single-period two-treatment-per-subject designs may also work if developers can justify why they’re a better option.

Developers should test adhesion several times, and at regular intervals, and use a four-point scale, ranging from 0 (90 percent adhesion or better) to 4 (the patch completely peels off), the agency says.

In another new draft guidance, the FDA further advises developers to measure generics’ potential side effects — most notably skin and/or eye irritation depending on the delivery system employed — against those of their brand name competitors.

It recommends testing them in clinical trials involving a “relatively small population” (i.e., hundreds of patients) and conducted under “relatively provocative conditions” during which researchers repeatedly take off and put back skin patches to see if they retain their holding power.

The best bet, says the FDA: a two-phase trial — the first, a 21-day induction phase during which patches are worn, removed and replaced for the recommended course of treatment.

That phase should be followed by a 14- to 17-day rest period and, then, a “challenge phase” during which patches are put on a new part of the body for 48 hours and the skin is tested for reactions after 30 minutes, 24 hours, 48 hours and, again, 72 hours after the patch’s removal.

Developers are urged to use a seven-point rating scale for skin irritation — from 0 (clear skin) to 7 (“Strong reaction spreading beyond the application site”).

Read the adhesion draft guidance here: www.fdanews.com/10-09-18-ANDAs.pdf.

Read the irritation draft here: www.fdanews.com/10-09-18-ANDAs2.pdf.

China OKs Rabies Vaccine Trials

A Chinese drug company says national regulators have approved pivotal clinical trials for a new rabies vaccine.

YiSheng BioPharma believes its vaccine, called PIKA, can become a “best in class” immunization against this contagious and fatal virus that causes tens of thousands of deaths annually, according to the World Health Organization.

The company plans to begin recruiting participants for its Phase III trials, set to start early next year. The vaccine won orphan status from the FDA in 2016 and has already successfully finished Phase I and Phase II studies in Singapore.

Celgene Claims Win in MS Trial

Celgene Corp’s experimental multiple sclerosis drug helped stave off symptoms better than its rival in clinical trials.

The New Jersey-based pharma announced last week that ozanimod topped Biogen’s Avonex (interferon beta-1a or IFN) in a pair of Phase III trials. In the first trial, called SUNBEAM, researchers randomly gave two different oral doses of ozanimod or IFN to 1,346 relapsing MS patients over a year and then tested their cognitive function, which typically declines as the disease progresses. The ozanimod patients, on average, scored significantly higher than the IFN patients.

The second trial, dubbed RADIANCE, compared the annualized relapse rates for 1,392 patients in the early stages of MS and another 1,267 patients with more advanced cases of the neurological disease who took either ozanimod or IFN. Both sets of patients who took ozanimod suffered fewer relapses or exacerbations than those who took IFN, Celgene says.

MS affects an estimated one million adults in the U.S. and 2.3 million globally; women are up to three times more likely to develop the disease.

There are several types of the condition; left untreated, those who suffer from relapsing MS will develop the more serious secondary progressive form.

Celgene says it plans to apply for FDA approval to market ozanimod.

Sickle Cell Trial, Positive Results

An experimental treatment helped prevent a painful, potentially fatal complication in a clinical trial of patients with sickle cell disease.

Novartis tested crizanlizumab in 132 patients in a Phase II clinical trial over three years to see if it could prevent vaso-occlusive crisis. More than half of the patients received crizanlizumab and the rest were given a placebo.

Researchers continued to monitor them for a year after the trial ended: nearly 36 percent of those in the crizanlizumab group did not suffer a single vaso-occlusive crisis, compared to about 17 percent in the placebo group.

Novartis is currently recruiting patients for a Phase III trial on the drug.
Features

Adverse Event Reporting
continued from page 1

onto the regulatory agency, sometimes onto
the site, sometimes on the ethics commit-
tees, sometimes on the CROs, sponsors,” he
says.

An “adverse event” can be nearly every-
thing from a slight itch to death. Most
rules require reporting it whether or not
there’s conclusive proof that the treatment is
the culprit. According to the FDA, there were
more than 1.8 million drug-related adverse
events last year — about half of them
considered serious. That number includes
drugs that are already on the market but
it suggests an enormous problem for drug
sponsors and sites.

Overwhelmed by the regulatory burdens,
many sponsors or sites simply err on the
side of caution and send out alerts for every
incident. But there’s no guarantee that the
alerts are making a difference for either the
company or the patients. Mass emails, for
instance, might say all the right things about
an adverse event, but companies have no
way of ensuring that patients have actually
read them.

“They’re really sending them out blind.
That opens up you up to inspection or
compliance. Because the inspectors will say,

“A lot of pharma companies
take the approach that
they’ve got to be compliant
with everyone, so they say,
‘We’ll just send out everything.’

—Steven Beales, senior vice
president for safety, WCG

OK, you say you’ve notified so-and-so. How
do you know the email arrived? How do you
know they’ve read it?” Beales says.

Given the sheer volume of alerts, it’s
tough to know if patients are reading them
all if any. Beales says, noting they may be so
common that patients simply disregard or
dismiss them as insignificant.

Despite efforts to bring international
regulations into alignment, it’s unlikely that
reporting requirements will get substantially
easier. In January, for instance, The Oncolo-
gist carried an op-ed urging the FDA to in-
clude data about the duration of an adverse
event in its reporting requirements.

Whether or not that idea catches hold
with regulators, Beales estimates that site
staffs are already spending an average of 10
hours a week just reporting adverse events.

The good news, Beales says, is that
technology has now made it possible for
companies to hone their focus. Advanced
algorithms, once in place, can help determine
whether an event needs to be reported, and
if so, by and to whom: Should an alert go to
patients? Regulators? Sites?

Beefing up a company’s alert system isn’t
easy and it’s not always cheap. It requires a
soup-to-nuts approach, beginning with an
audit. That can sometimes be a logistical
nightmare, especially at the outset. The first
year that he worked with Roche, Beales says,
he and his colleagues discovered the com-
pany was actually under-reporting events by
2 million cases.

A warning sign might be that a company
doesn’t actually know what it costs to send
out alerts, Beales says.

“If they go through their contracts,
they’re going to go, ‘We can’t work out what
we’re spending on this. We don’t have a clear
idea of whether we’re compliant,’” Beales
says.

So, is it worth it to discard the one-
size-fits all approach and go through the
arduous route to a tailored alert system?
Last year, Roche saved a hefty $65 million
by personalizing its alert system, Beales
says.

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FDA Guidance
continued from page 1

“This is the consistent message from FDA since the Common Rule revisions were published almost two years ago,” he tells CenterWatch.

The bottom line is that FDA regulations for human subject protection and IRBs won’t change when the Common Rule revisions take effect in January, Borasky says.

That means clinical investigations regulated by both the FDA and the Common Rule will still have to comply with agency regs if they’re more stringent. “The FDA still has an expectation that institutions, IRBs, sponsors, etc., continue to follow the FDA regulations as written, even when their requirements go beyond what is required by the revised Common Rule.”

—David Borasky, VP of quality management, WIRB

“The FDA still has an expectation that institutions, IRBs, sponsors, etc., continue to follow the FDA regulations as written, even when their requirements go beyond what is required by the revised Common Rule,” Borasky says.

He adds that the real question is how soon the agency will release more “substan tive” guidance on its harmonization plans and what it will allow IRBs to implement between the time the Common Rule revisions go live and it harmonizes its regulations (set to be completed in December 2019) as part of the 21st Century Cures Act.


A Host of Challenges Strain Clinical Trial Site Viability

Clinical trial site finances are a problem and sites are hiring extra staff to chase down funding opportunities. And sites are hiring extra staff to chase down funding opportunities. And sites are hiring extra staff to chase down funding opportunities. And sites are hiring extra staff to chase down funding opportunities. And sites are hiring extra staff to chase down funding opportunities.

Start-up Costs Can Be an Uphill Slog in Need of Change

FDA Guidance, continued from page 1

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<td>TEGSEDI® (inotersen)</td>
<td>Polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults</td>
<td>Granted approval by the FDA</td>
<td>TEGSEDI.com</td>
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<td>Akcea Therapeutics</td>
<td>AKCEA-APO(a)-LRx</td>
<td>Cardiovascular disease (CVD) and elevated levels of lipoprotein(a), or Lp(a)</td>
<td>Positive topline results from a Phase II clinical trial</td>
<td>akceatx.com</td>
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<td>Bausch Health Companies, Inc.</td>
<td>BRYHALI™ (halobetasol propionate) Lotion, 0.01%</td>
<td>Plaque psoriasis in adults</td>
<td>FDA tentatively approved New Drug Application; final OK pending expiration of exclusivity for related product</td>
<td>bauschhealth.com</td>
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<td>Eximo Medical Ltd</td>
<td>B-Laser™ Atherectomy System</td>
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<td>Granted 510(k) clearance by the FDA</td>
<td>eximomedical.com</td>
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<td>YiSheng BioPharma Co.</td>
<td>PIKA® rabies vaccine</td>
<td>Rabies</td>
<td>Granted clearance by the China FDA to proceed with a clinical trial</td>
<td>yishengbio.com</td>
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<td>Genentech</td>
<td>Hemlibra</td>
<td>Hemophilia A patients without factor VIII inhibitors</td>
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<td>gene.com</td>
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<td>Leadiant Biosciences, Inc.</td>
<td>Revcovi™ (elapegademase-lvlr) injection</td>
<td>Adenosine deaminase severe combined immune deficiency (ADA-SCID) in children and adults</td>
<td>Granted approval by the FDA</td>
<td>leadiantbiosciences.com</td>
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<td>Breckenridge Pharmaceutical, Inc.</td>
<td>Roflumilast Tablets, 500mcg (generic for Daliresp® Tablets)</td>
<td>COPD</td>
<td>Abbreviated New Drug Application approved by the FDA</td>
<td>bpirx.com</td>
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<td>Valneva USA</td>
<td>IXIARO® (Japanese Encephalitis Vaccine, Inactivated, Adsorbed)</td>
<td>Japanese encephalitis</td>
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<td>PreventJE.com</td>
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<td>Eidos Therapeutics, Inc.</td>
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<td>Granted Orphan Drug designation by the FDA</td>
<td>eidotx.com</td>
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<td>Paratek Pharmaceuticals, Inc.</td>
<td>NUZYRA™ (omadacycline)</td>
<td>Community-acquired bacterial pneumonia; acute skin infections (ABSSSI) in adults</td>
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<td>ParatekPharma.com</td>
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<td>Poxel SA</td>
<td>Imeglimin, an investigational therapeutic agent</td>
<td>Type 2 diabetes</td>
<td>Patient enrollment completed in the TIMES 2 trial of the Phase III registration program</td>
<td>poxelpharma.com</td>
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<td>Chugai Pharmaceutical Co., Ltd</td>
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<td>Genentech</td>
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<td>Influenza type A/H3N2 and type B</td>
<td>Phase III CAPSTONE-2 trial showed symptoms improved significantly faster in patients at high risk of serious flu who took the drug v. a placebo</td>
<td>gene.com</td>
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<td>Zealand Pharma A/S</td>
<td>Glepaglutide</td>
<td>Short bowel syndrome (SBS)</td>
<td>First patient enrolled in a global Phase III trial</td>
<td>zealandpharma.com</td>
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Jobs via Kelly Services

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More Jobs

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<td>Clinical Research Coordinator</td>
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Upcoming Event Highlights

Conferences

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<tr>
<th>OCTOBER 23-25, 2018</th>
<th>FDA Inspections Summit – 13th Annual</th>
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<td>Bethesda, MD</td>
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<td>NOVEMBER 1-2, 2018</td>
<td>SOPs and Policies for the 21st Century: Why Less is More</td>
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<td>Washington, DC</td>
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<td>NOVEMBER 14-15, 2018</td>
<td>Conducting Advanced Root Cause Analysis &amp; CAPA Investigations</td>
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<td>Princeton, NJ</td>
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<td>NOVEMBER 14-15, 2018</td>
<td>Clinical Trial Risk and Performance Management Summit</td>
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<td>Princeton, NJ</td>
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<td>DECEMBER 10-12, 2018</td>
<td>Design of Medical Devices Conference, China 2018</td>
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Training Programs

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<tr>
<th>NOVEMBER 1-31, 2018</th>
<th>Phlebotomy Training — Two Day Training</th>
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<td>Various locations</td>
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Webinars

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<tr>
<th>OCTOBER 18, 2018</th>
<th>Retooling Risk-Based Quality Management Approaches in the Era of ICH EG(R2)</th>
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<tr>
<td>OCTOBER 30, 2018</td>
<td>Understanding ISO 19011:2018 The Path to Better Medical Device System Audits</td>
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