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INSIDE THIS ISSUE

Approval for Beckman troponin tests delayed by slow trials.....[Page 2](#)

FDA's Temple: Larger trials needed to better predict adverse events.....[Page 3](#)

ACTION initiative offers grant to improve pain drug trials.....[Page 3](#)

Sponsor Best Practice: Audit trails, SOPs key to passing electronic records inspections.....[Page 5](#)

Advisory committee recommends Afinitor, Sutent despite trial issues.....[Page 6](#)

Site Best Practice: Segmenting, goals key to recruiting through social media networks.....[Page 7](#)

Executives: New legislation, regulation needed for orphan drug trials.....[Page 8](#)

Comments: Guidance Ignores eSource System Capabilities, Current Practice

Drugmakers commenting on an FDA draft guidance addressing electronic data from clinical trials say the guidance is out of sync with current capabilities and practices for data capture and lacks information about the sponsor's role in reviewing data.

Released in January, the guidance describes recommended procedures for the collection, transfer and review of electronic source (eSource) data. Comments were due earlier this month.

One of the biggest concerns raised in industry comments was an apparent lack of understanding of the capabilities of most electronic data capture (EDC) systems. The guidance describes a model where electronic data flows from various locations and devices directly into electronic case report forms (eCRFs), but several drugmakers

(See [eSource Guidance](#), Page 2)

FDA Rules Could Expand Investigator Disqualification

A proposed rule would beef up the FDA's policy on investigator disqualifications so that individuals disqualified by any one of the agency's centers would be ineligible to conduct research on any FDA-regulated product.

The new rule proposes "that a clinical investigator disqualified by the FDA commissioner's decision will be ineligible to receive any test article under the disqualification regulations in parts 312, 511, or 812, and, in addition, the investigator will be ineligible to conduct any clinical investigation that supports an application for a research or marketing permit for products regulated by FDA."

Comments on the proposed rule are due July 11. Any final rule will go into effect 30 days after it is published in the *Federal Register*.

Under current regulations, an investigator who is disqualified by the FDA commissioner's decision becomes ineligible to conduct research

(See [Clinical Investigator](#), Page 4)

eSource Guidance, from Page 1

pointed out that current technology doesn't support this plan.

A variety of EDC methods are used at sites, and these programs do not have the same compatibilities, Biogen Idec writes.

Most devices and diagnostic tools that produce electronic data are similarly incompatible, Novo Nordisk points out. These data require manual input, for which the guidance should address procedures, Biogen says.

The described flow of information, too, raised concern for many companies. According to the guidance, investigators review and sign off on all data and forms before submitting them to sponsors or monitors (*CTA*, Jan. 20).

"One of the advantages of eCRFs as compared to paper CRFs in current use is that the sponsor has immediate access to the data ... and can therefore better fulfill the sponsor responsibility of monitoring progress of the study and safety of the patients," Sanofi-Aventis writes.

Sponsor Role

Novo Nordisk echoed this concern, adding that sponsors can report serious adverse events and product quality complaints more quickly when they have access to data before investigator sign off.

In current industry practice, review of data is a "collaborative" and "iterative" process shared by investigators, sponsors and monitors, which yields "the most accurate data for analysis," according to Amgen.

However, the "role of the sponsor ... is notably absent" in the guidance, Amgen says in its comments.

In addition to clarifying the role of sponsors, the guidance should address more specifically what sort of data is considered "eSource," Biogen says.

Despite its title — "Electronic Source Documentation in Clinical Investigations" — the guidance focuses mostly on eCRFs, the company says.

The real confusion, though, is in the terminology and procedures surrounding the creation and transfer of data from electronic sources, not the forms.

The guidance "offer[s] a novel approach" to a complex subject, Merck says, but "as written, there appear to be misconceptions."

"We believe this model, even as an example, is flawed because it is not based on current EDC capabilities and the process by which electronic data are sourced in clinical studies," the company continues.

Before any new guidance is implanted, the FDA should host a public forum or workshop to discuss these issues, Merck says.

The draft guidance is available at www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM239052.pdf. — Wilson Peden

Beckman Troponin Tests Delayed by Slow Trials

Beckman Coulter is delaying two 510(k) submissions covering changes to its cardiac troponin test kits because of slow clinical trial progress.

The submissions, now scheduled for the third quarter, cover the troponin assay's use with Beckman's Access instruments and its DxI instruments, according to an April 18 SEC filing.

However, the new deadline is not firm, the company adds. Beckman had previously hoped to submit the applications in the first half of the year.

Beckman has seen ongoing regulatory problems with the assays. It contacted customers in February 2010 about discrepancies between results for troponin on its UniCel DxI platform versus the Access or Access 2 platforms.

The company then made uncleared changes to the diagnostics, leading to a March recall. Beckman said it would submit new 510(k)s for the AccuTnI tests, used with both the DxI and Access systems.

But the uncleared changes still landed the company a warning letter last June. — Virgil Dickson

FDA Official: Larger Trials Needed To Better Predict Adverse Events

Larger clinical trials are needed to determine additional adverse events for heart drugs that may lead to non-cardiovascular complications, according to a senior FDA official.

During a presentation April 15 at a cardiovascular (CV) safety in drug development conference hosted by the Drug Information Association in Washington, D.C., Robert Temple, deputy center director for clinical science at the Center for Drug Evaluation and Research pointed to an increase in asthma, breast cancer, tumor promotion, valvulopathy and suicidality associated with drugs in recent years.

Because heart drugs may lead to additional adverse events, the FDA requires “new drugs ... to show, prior to approval, they do not cause increased CV mortality,” Temple said. “That’s been the position for many years now: whatever good you do, you have to show you don’t make something else worse.”

ACTION Initiative Offers Grants To Improve Pain Drug Trials

The FDA has announced the formation of the Analgesic Clinical Trials Innovation, Opportunities, and Networks (ACTION) Initiative, which will offer grant money for conducting research on ways to improve clinical trials for new pain drugs.

However, the agency expects to offer only one grant, which will not exceed \$1 million.

While other therapeutic areas have seen rapid advancements over the last 30 years, analgesic drugs have lagged behind, the FDA says. In order to compensate for this lapse, the agency is offering a grant to institutes of higher education or nonprofit organizations for research into study design for the class.

The difficulty of proving the efficacy of analgesics makes industry reluctant to invest in the class, leaving the public with access to treatments such as opioids, acetaminophen, and non-steroidal anti-inflammatory agents, “all of which

To discover adverse events earlier, Temple called for longer clinical trials with more people.

Heart drug studies “will have little chance of showing anything unless they are enormous. Studies have to be long, but that is hard in symptomatic conditions where dropouts are common,” Temple said.

But opportunities to conduct larger trials, possibly with a health maintenance organization that would also provide older patients, would greatly enhance the ability to do such trials, Temple said.

Meanwhile, Temple added there is an increasing interest “in cardiovascular effects of non-heart drugs.”

In the past, trials aiming to show a particular benefit from a drug ended up showing CV outcomes. For instance, Temple said that despite the benefit of raising high-density lipoprotein, cholesterol that fights heart disease, Pfizer’s torcetrapib also increased mortality based on cardiovascular effects. — Molly Cohen

have serious, potentially life-threatening toxicities,” the FDA says.

But the high failure rate of analgesics is belied by “literally thousands of years of clinical experience” demonstrating the efficacy of these drugs, the agency says, and many experts believe the fault lies in trial design.

Institutions that receive grants will be asked to design research projects that, at a minimum, address the following three areas:

- Data analysis of group trials, with an emphasis on identifying relationships between assay sensitivity and metrics;
- Alternative means of analyzing pain score that consider variables; and
- Methods for executing and transforming pooled trial data from multiple trials.

For details and application information, view the *Federal Register* announcement at www.fdanews.com/ext/files/2011-9650.pdf.

— Wilson Peden

Clinical Investigator, from Page 1

in a particular area and to receive test articles of the type under study when the violation occurred.

As the rule stands now, a researcher investigated by Center for Devices and Radiological Health and subsequently disqualified by the commissioner for violations during a device study would still be eligible to conduct drug studies, and vice-versa with a Center for Drug Evaluation and Research-initiated disqualification.

The proposed rule would also harmonize the language in disqualification provisions for different FDA-regulated products and clarify the procedures for disqualification by a commissioner decision.

Hearing Procedures

Under the proposed rule, the applicable FDA center would notify in writing any investigator suspected of repeatedly or deliberately failing to comply with regulations or of deliberately submitting false information to the FDA or a sponsor.

The investigator would be given the opportunity to offer an explanation in writing or during an informal conference with the center. If the center does not accept the explanation, disqualification procedures proceed and the investigator may request a regulatory hearing.

The final decision to disqualify an investigator remains with the FDA commissioner, who may also withdraw approval or rescind clearance of products whose data is deemed insufficient once the disqualified investigator's data is removed.

The new rule would also contain an explicit reference concerning notification of investigator disqualifications and instructions for notifying sponsors concerning ongoing studies or approved products that include or have made use of the disqualified investigator's data.

The impetus for the rule comes from a 2009 Government Accountability Office (GAO) report.

GAO noted consent agreements reached between the FDA and investigators may contain

“more extensive restrictions by disqualifying the investigator from receiving any FDA-regulated products,” and suggested that similarly broad restrictions should apply to disqualifications coming from commissioner decisions.

The report also recommended the FDA take measures to speed up the process of disqualifying or debaring investigators (*CTA*, Oct. 29, 2009). Debaring is a separate process in which the agency may also ban, or “debar” from the drug industry individuals and companies convicted of certain felonies or misdemeanors related to drug products (*CTA*, June 10, 2010).

The FDA says “there is little, if any, evidence that an investigator ... later conducted a clinical investigation of a different type of test article,” but agrees with GAO's recommendations, saying explicitly extending disqualifications “would help to reduce the risk of additional violations.”

The proposed rule is available at www.fdanews.com/ext/files/2011-08786_PI.pdf. — Wilson Peden

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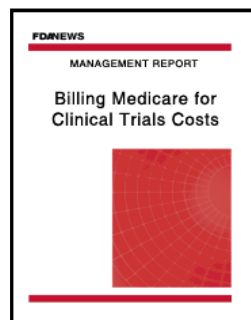
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SPONSOR BEST PRACTICES

Audit Trails, SOPs Key to Passing Electronic Records Inspections

In order to make sure their electronic records systems pass inspection, sponsors should clearly document any changes to the systems and the personnel that access them, according to an FDA official.

Speaking at the FDA's Small Business Assistance Clinical Trials Forum April 21, Sean Kassim, a pharmacologist in the FDA's Part 11 work group, explained that implementation and documentation of the system are just as important as the parameters of the system itself.

There is still a great deal of confusion about the FDA's enforcement of Part 11 — the federal guidelines for ensuring the accuracy of electronic records and signatures — despite the publication of a number of draft and final guidances.

Industry Concerns

Industry comments on the most recent draft guidance, concerning electronic sourced data documentation, showed a great deal of concern with the FDA's proposed model for how electronic information should flow between sponsors, sites and regulators (*see story, page 1*).

In particular, the companies that commented felt the guidance did not address the role of sponsors in overseeing electronic recordkeeping and data transfer.

Kassim addressed the issue by stressing that sponsors should keep in mind that Part 11 compliance is based on the implementation and use of the system, not some intrinsic aspect of the system itself.

“Just because the box says it's Part 11 compliant, that doesn't mean anything,” Kassim said. The key is in the operation of the system and the documentation of those operations.

One of the most important issues FDA inspectors will look for is access.

“I can't stress the issue of access enough,” Kassim said, adding this is where inspectors often find violations.

Often companies will use one access account that is shared by multiple users, but “that's a big no-no for the FDA,” Kassim said. All personnel who access data should have their own login so inspectors can see exactly who has accessed the system when and what changes they made.

Weak passwords are also an issue. Kassim noted that he has seen companies use passwords that are only two characters long, or that were written down on Post-it notes attached to computer monitors.

Sponsors should also make sure their settings are configured so that a system that stands idle for a certain period of time will automatically log users off, preventing workers from leaving sensitive data open and unattended.

Employees who no longer work for the company, or whose work has taken them to different projects, should have their access removed immediately, Kassim said.

“The last thing you need is a disgruntled former employee” with access to records, he said.

Documentation

Documentation is also crucial to passing inspections, with perhaps the most important documentation being the record of what aspects of Part 11 the sponsor is choosing not to follow.

While the FDA has stressed that all predicate guidelines and regulations for paper data still apply to electronic data, the agency has announced a policy of “enforcement discretion” with regards to Part 11-specific guidelines.

However, sponsors must provide a risk-based justification, in writing, of any aspects of Part 11 they feel are not necessary with regards to a particular investigation or recordkeeping system.

Sponsors should also be able to produce documentation showing their personnel have been trained on the systems, as well as investigators

(*See Sponsor BP, Page 6*)

Committee Recommends Afinitor, Sutent Despite Trial Issues

Despite reservations related to adverse events and clinical trial issues, the FDA's Oncologic Drugs Advisory Committee (ODAC) April 12 recommended the approval of sNDAs for Novartis' Afinitor and Pfizer's Sutent to treat a rare type of tumors.

ODAC members agreed that Afinitor's (everolimus) benefits outweighed its risks, voting unanimously to recommend the drug to treat neuroendocrine tumors (NET). The committee said it was moved to support the Novartis drug partially because of the "unmet need" for additional NET treatments.

Members also recommended Sutent (sunitinib), overcoming concerns about its clinical trial and voting 8–2 that sunitinib's benefits outweighed its risks.

Adverse Events

However, due to everolimus' toxicity and adverse event history, ODAC members cautioned that the drug's labeling should be restrictive. In addition, patients with carcinoid tumors should avoid the drug, they suggested.

The panel also took issue with the fact that Pfizer prematurely stopped its sunitinib trial after enough positive results were received. They were concerned the trial's early cessation — which meant the drug's performance was judged on a relatively small sample size — might have led to an overstatement of its efficacy.

The drugs are already approved to treat renal cell carcinoma.

Because both drugs are known to be toxic, the FDA asked ODAC to assess whether the drugs' efficacy and safety outweighed their risk.

Afinitor and Sutent are associated with a number of adverse events, including diarrhea, nausea, dysgeusia, pneumonitis, renal failure and intracranial hemorrhage.

In briefing documents released prior to the meeting, FDA reviewers gave a tepid assessment of both drugs, noting NET can have a relatively

indolent natural history, and cited the "uncertain clinical benefit" of treating the disease with everolimus and sunitinib.

However, patient advocacy groups lobbied for both drugs' approval during the hearing, citing a need for additional NET treatments.

Many NET treatments are only available outside the U.S., and making a new drug available to patients would give NET patients hope, said Grace Goldstein, chief operating officer of the Carcinoid Cancer Foundation.

Afinitor was granted priority review and Sutent is already approved in Europe to treat some patients with pancreatic NET. — Kevin O'Rourke

Sponsor BP, from Page 5

and even patients, in the case of studies that require direct subject input.

Standard operating procedures (SOPs) related to use of electronic systems should be clearly written and available for inspectors.

In addition, the agency will also look for documentation of system validation, especially if changes are made in the middle of a study, as this may necessitate revalidation.

That said, there are certain requirements for the system itself the FDA will also be looking for.

Audit trail capabilities are crucial, Kassim said — the record system must be able to record what changes have been made to data, and by whom.

Other system aspects are not required, but would be beneficial.

One of the benefits of using electronic records is that their operational limits can be set to eliminate common mistakes. An electronic system should be able to recognize the error when someone enters a subject date of birth that is in the future, Kassim said.

Catching those "dumb, common data entry" mistakes is one of the reasons to move to electronic systems to begin with, he added. — Wilson Peden

CLINICAL SITE BEST PRACTICES

Transparency, Segmentation Key In Social Media Trial Recruitment

Social media can be a powerful tool for recruiting human subjects, but sites should target specific audiences and make sure they are transparent about the parameters of the study, according to one researcher.

“I think more and more you’re going to see consumers are having a large impact on each other in terms of clinical trials,” Alexandra Hughes, an account supervisor in public relations firm Ogilvy’s social marketing practice, told *CTA*.

However, it’s important that sites are upfront about what exactly is involved in the trial and who is sponsoring it.

“Patients in the social media space almost have higher expectations than they might in the regular space,” and sites need to respond to that, Hughes said.

Segmenting

That said, social media offers many potential benefits for recruitment, especially if sites take the time to tailor recruitment materials to particular segments of the public.

Mid-life women — those in their 40s, 50s and 60s — are an especially important segment because they are frequently “wellness gatekeepers” of health information and the primary healthcare decision makers for their families, Hughes says.

Women in this segment tend to prefer large networking sites like Facebook and Myspace, Hughes says, but recruiters are more likely to see gains from posting on niche sites and blogs.

Websites such as PatientsLikeMe feature user groups of women talking to each other, sharing information about their conditions or those of their family members and passing along information about clinical trials, Hughes says.

Sites can also make contact with influential bloggers and find out what kind of information their followers are looking for, she added.

Providers such as primary-care physicians and nurses can also be very influential in encouraging trial enrollment, but their role in social media networks “is a huge question mark right now,” Hughes says.

Providers may be less likely to see the value of social media, she says and suggests approaching providers in person first to convince them of the value of these platforms.

Social media content, like all promotional materials for recruitment, must be approved by IRBs. The FDA has not released guidance about using social media for patient recruitment, but regulations for print and broadcast materials still apply.

Approving Content

Sites can facilitate the process by getting marketing material approved by IRBs and out to potential subjects much more quickly by using social networks to link back to existing, approved content on static web pages.

“We try to use as much content that has already been IRB-approved as possible,” said Jennifer Texada, digital and new media program manager at the University of Texas’ MD Anderson Cancer Center. “We try to link back to resources as opposed to reinventing the wheel” (*CTA*, Dec. 9, 2009).

“If you’re trying to write a tweet and take it through the approval process [individually], by the time it’s sent out, it might not be relevant anymore,” she added.

However, marketers of all kinds should keep in the mind the “one-click rule,” Hughes says — users should be able to access detailed content, tailored to their interests, through one link.

Research shows patients prefer to stay within a single social network when following links, Hughes says.

However, given the uncertainty about social media regulations, and the length and format restrictions of many platforms, linking back to static websites may be the best way to provide detailed information. — Wilson Peden

New Legislation, Regulation Needed for Orphan Drug Trials

A new regulatory paradigm is needed to make it easier for drugmakers to conduct clinical trials for treatments of rare diseases, the CEOs of two Dutch biotech companies said.

Legislators and regulators in the U.S. and EU are going to have to tackle tough questions about trial design, approval timelines and reimbursements, Jorn Aldag, CEO of Amsterdam Molecular Therapeutics (AMT), and Hans Schikan, CEO of Pronsensa, told attendees at the Orphan Drugs World Congress USA April 18.

Dealing with these issues is going to require greater flexibility from regulators, Aldag said, and that's why legislators need to get involved and make sure regulatory agencies have the tools necessary to make decisions about orphan drugs.

To begin with, the type of clinical trials typically approved pose problems for orphan diseases, Aldag said. "How do you conduct a randomized trial for 50 patients?" he asked.

In addition, trials with small populations, and the degenerative nature of the diseases AMT is working with, may necessitate different endpoints.

A "legality of flexibility" is needed, Aldag said, to allow more regulatory acceptance of different endpoints and trial timelines.

Schikan agreed. He compared applying current regulatory timelines to orphan drugs to forcing an ambulance to abide by posted speed limits.

We allow the ambulance to drive faster, he said, because the patient's need to reach the hospital quickly outweighs the need to regulate traffic speed.

Unfortunately, "the rules are piling up," Schikan said, and they're threatening to slow down approvals even further.

Pricing and reimbursement is also a serious issue for orphan drugs, both men said.

Aldag suggested more government payers should consider reimbursing during Phase III clinical trials. In France, patients can receive payment for orphan medications in trials if they are shown to need immediate treatment.

The larger question, though, is where to set prices. "If you have a thousand patients, you can't sell for \$1,000 per patient," Aldag said.

Furthermore, venture capital is hard to come by for orphan treatments, Aldag said, so pricing is particularly important for companies to see revenue.

These are just a few of the hurdles orphan drugs face trying to make it through trials and onto the market, Schikan said. Drugmakers are still struggling to locate patients, identify the faulty genes that cause many orphan diseases, and design processes to manufacture the complex molecules required for treatments.

People say drug development isn't rocket science, Schikan said, "but I think it is rocket science."

Companies and regulators alike still have a lot to learn about the "orphan space" — a space that is still largely "untapped and undeveloped," he added. — Wilson Peden

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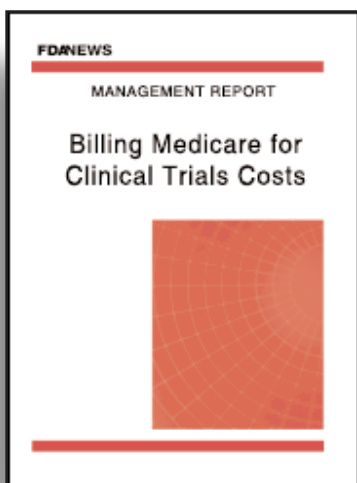
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