New Guidance for Multiregional Clinical Trials

By Bill Myers

The FDA has issued new guidelines designed to help researchers navigate sometimes conflicting regional requirements and differences in global clinical trials in an effort to pave the way for better cooperation and faster international drug development.

There is currently no single set of rules governing how multiregional clinical trials (MRCTs) should be conducted. However, the FDA is hoping to help make the road less bumpy with this fresh ICH E17 addendum.

Among its key recommendations: Plan ahead to make sure an international study is the best route to take. That is, assess potential challenges and regional differences — like environment, diet, cultural twists — to make sure they’re not too great to overcome or skew findings.

Consider all potential factors — and ways to account or adjust for them (by doing genetic testing, for example), the FDA advises, noting that “even in the case of expected major differences ... it may still be possible to conduct MRCTs by excluding some regions or a defined subgroup within a region.”

Your best bet for smooth sailing if you do opt for international probes? Design them with seven principles in mind, the FDA suggests:

- Identify early how different regional factors can affect drug trials.

see New Guidance on page 4 »

New Report: Improving Clinical Site Payment Practices

Paying sites on time is critical to a trial’s success, sponsors agree, and most believe they’re making the grade. So why are sites so frustrated with how they’re paid? Are their expectations unreasonable or are sponsors operating in the dark?

A recent survey by Metrics Champion Consortium (MCC) indicates the latter is true. More than 70 percent of trial sponsors who manage in-house payment procedures said they’re pleased with their processes; ditto 65 percent of CROs. But sites were overwhelmingly dissatisfied, with 70 percent expressing a negative view.

So what’s the deal?

The survey shows sponsors don’t pay attention to the kind of metrics that can help them solve payment woes. They may know they’re not ponying up promptly but they’re looking for answers in all the wrong places — if at all.

There are many details and data points that can help sponsors figure out how well their payment processes are (or aren’t) working, says Linda Sullivan, MCC’s executive director.

MCC discovered that sites aren’t the only ones unhappy. Sponsors that outsource payment to other entities (like CROs) have less control over the process and often have less insight into how it is working on the contractor’s end.

“Those who are running the process — a sponsor [managing payments] in house or a

see Improving Clinical Site Payments on page 5 »
FDA Issues New Guides on Use of Electronic Health Information in Clinical Trials

The FDA is urging researchers to work with electronic health record keepers to help improve clinical trial accuracy and efficiency. The agency doesn’t typically regulate companies or organizations that maintain electronic medical records (EMRs). But it says it’s weighing in to highlight and clarify ways electronic health record (EHR) systems can help clinical trials run more smoothly and use data from foreign studies conducted outside investigational new drug applications or device exemptions. In guidelines released July 18, the FDA encourages sponsors and investigators to use approved EHR or electronic capture data capture (EDC) systems to exchange key information, noting that doing so can dramatically speed up information sharing and precision.

Other FDA tips:

- Sponsors and investigators should use EHR systems endorsed by the Office of the National Coordinator for Health Information Technology (ONC). If they lack access to ONC-certified systems, they should make sure security measures are in place to protect study data.
- Study monitors should have easy access to “all relevant information” detailed in consent forms, including how long identifying records will be kept. (Federal law requires investigators to keep records from drug or human biological product trials for at least two years after marketing applications have been approved or trials have been scrapped and the FDA notified. Records relating to medical devices must be retained for at least two years after an investigation wraps up or after it’s determined they are no longer needed to support premarket approval applications or notices of completion.)


AbbVie Blood Cancer Drug Fails Phase III Trial

AbbVie has announced that ibrutinib doesn’t appear to enhance benefits for blood cancer patients being treated with the R-CHOP chemotherapy cocktail. Researchers at AbbVie subsidiary Pharmacyclics and Janssen Biotech had hoped that adding ibrutinib to R-CHOP — a mix of rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone — would improve outcomes for patients with untreated diffuse large B-cell lymphoma. But a Phase III study found it was no more effective than a placebo at improving event-free survival. Ibrutinib has been available in the U.S. since 2013. It’s approved for use in five different B-cell blood cancers and chronic graft-versus-host-disease.

NCI, VA Boost Veteran Access to Clinical Trials

The National Cancer Institute (NCI) and Department of Veterans Affairs are teaming up to make it easier for vets with cancer to get into clinical trials testing novel cancer treatments. The NCI and VA Interagency Group to Accelerate Trials Enrollment (NAVIGATE) is rolling out in a dozen VA centers around the country, boosting the ability of veterans to participate in NCI-sponsored trials and receive promising new treatments locally. “VA centers often face challenges initiating and completing externally-funded trials because of the need for partners to navigate the system,” the agencies said. “This program aims to overcome these challenges with dedicated staffing and a sustainable infrastructure, and to address existing barriers to trial enrollment that veterans, including minority patients, often experience.” NAVIGATE is being launched in VA centers in Atlanta; New York; Charleston, South Carolina; Denver; Durham, North Carolina; Hines, Illinois; Long Beach, California; Minneapolis; Palo Alto, California; Portland; San Antonio and West Haven, Connecticut.

Finnish Company Opens Phase III Trial of ALS Drug

Finnish drug company Orion has recruited its first patients for a Phase III trial to see if orally administered levosimendan can help ease ALS symptoms. Some 450 patients with the neurodegenerative disease Amyotrophic Lateral Sclerosis are set to participate in placebo-controlled trials at clinical sites in Europe, North America and Australia, the company announced last week. Orion said it plans to spend about 60 million euros (nearly $70 million) over the next three years to support its levosimendan research. ALS, also known as Lou Gehrig’s Disease after the New York Yankees’ beloved slugger who died from the illness, causes rapidly progressive muscle weakness. It specifically affects nerve cells (motor neurons) that control muscles that help us move, speak, breathe and swallow. There’s no cure for ALS but Orion researchers hope levosimendan — which helps strengthen respiratory muscle function — may help slow disease progression and keep patients breathing longer on their own.

see Industry Briefs on page 3 »
FDA Hopeful New Extended-Release Opioids Will Help Curb Addiction

The FDA has released more than two dozen new product-specific draft guidelines for generic drug trial designs and revised 17 others in a move aimed at getting less expensive drugs to market faster. The proposed guidelines cover a range of drugs from antibiotics such as ciprofloxacin to the antiretroviral drug ritonavir — and shed light on the FDA’s view of three different opioids (two of them extended release and a third that combines morphine with the opioid antagonist naltrexone) using so-called abuse-deterrent formulations. “We recognize that the science of abuse deterrence is relatively new and we need to continue to study and confirm the potential role of ADFs in reducing the rate of misuse and abuse via different routes when used in a population,” FDA Commissioner Scott Gottlieb said in announcing the new proposals. “Both the formulation technologies and the methods for evaluating those technologies are rapidly evolving. We believe that transitioning from the current market, dominated by conventional opioid analgesics, to one where most opioids have abuse-deterrent properties may have the potential to further reduce misuse and abuse.” Two of the revised opioid proposals deal with extended-release hydrocodone bitartrate (the generic name for Vicodin, among others) and extended-release oxycodone HCL tablets. Both encourage researchers to conduct two sets of studies (involving participants who either fast or eat before taking pills) to determine if the meds can help patients resist addiction: one in which participants chew pills and another in which they absorb the drugs through a nasal spray. The guidance urges researchers not to use naltrexone or other opioid antagonists in the trials. The third revised draft focuses on an extended-release capsule containing morphine sulfate and naltrexone hydrochloride. It urges researchers to conduct three bioequivalence studies: one in which participants fast before doses, another in which they eat first and a third in which fasting subjects take the drug sprinkled into applesauce. It also encourages investigators to conduct a pair of risk-abuse trials. Gottlieb said he’s optimistic the opioid tests will yield medicines that “can’t be easily abused” but cautioned it’s important to remember that no opioid is “abuse-proof.”

Feds to IRBs: Drop Grant Application Reviews

It’s not necessary for IRBs to review grant proposals or applications to ensure patient safety, the HHS says in a new draft guidance. “Experience suggests that review and approval of the application or proposal is not a productive use of IRB time,” say the proposals issued by HHS’s Office for Human Research Protection. Federal officials say the change won’t increase patient risks because IRBs will still have to review research protocols for any studies that seek federal funding. Read the draft guidance here: www.fdanews.com/07-23-18-IRB.pdf.

FDA Oks Breast Cancer Drug after Successful Trials Pilot

The FDA has greenlighted anti-breast cancer drug Kisqali, making it the first drug approved under a new pilot program designed to help bring cancer drugs to the market more quickly. The agency OK’d the use of Kisqali in combination with aromatase inhibitors to treat women with hormone receptor-positive, human epidermal growth factor receptor 2-negative advanced or metastatic cancer. It also approved using Kisqali with fulvestrant for postmenopausal women with the same cancers. The go-ahead gives Kisqali “the broadest first-line indications” of any drug in its class, drug maker Novartis said in a statement. The move comes less than a month after the company submitted its application for the FDA’s approval. The FDA credited the fast turnaround to two pilot programs it launched earlier this year — one in which regulators are given “real-time” review of data from oncology trials and another in which applicants work from a single template.

HHS Mulls Waiving Continuing IRB Review Rules

Federal officials are considering waiving rules that require continuing IRB review of a small sample of expedited and late-stage clinical trials. New regulations easing IRB review requirement are scheduled to take effect in January. But HHS’s Office for Human Research Protection last week issued a draft guidance to address studies pending the change. If the FDA adopts the recommendations, IRBs won’t have to continue monitoring trials in transition that are eligible for expedited federal review or in which data analysis is complete and participants are already in follow-up treatment. Nothing in the pending rules or the draft guidance exempts researchers from reporting problems or patient risks uncovered during studies. Read the draft guidance here: www.fdanews.com/07-23-18-ContinuingReview.pdf.
New Guidance (continued from page 1)

- Clear communication between sponsors, sites and regulators is a must.
- Make sure study designs meet all relevant international quality rules for trial planning, investigator training and monitoring.
- Stay focused on a single analysis so trials pass regulatory muster across regions.
- Make sure treatment is consistent across the board.
- Pre-plan pooling regions or subpopulations to provide flexibility in sample sizes.
- Strategically use trials to up drug development efficiency.

Multiregional trials have historically been used as a quick way to recruit participants with rare diseases or in special populations (like children or the elderly) or for large-scale studies (such as vaccine safety and effectiveness). But sponsors increasingly have found they’re an efficient way to get more drugs to more people — and they’re fast becoming the preferred choice for investigating new meds in today’s global market.

The difficulty is that disease definitions, diagnostic methods, medical practices, diet and other factors may vary from region to region, complicating global trials. Given all the potential differences at play, it’s vital to create an ongoing system of quality checks.

“Centralized and risk-based monitoring may be particularly useful for MRCTs to monitor and mitigate the impact of emerging regional difference in, for example, trial subject retention or adverse event reporting,” the FDA says. “Timely and accurate flow of information should occur between the sponsor, the trial management team and the participating sites.”

If investigators take the recommended steps and still notice different regional effects, the FDA suggests conducting “a structured exploration” to try to pin down potential culprits.

During their probe, researchers should consider the usual suspects first – things like disease severity and participants’ race, weight and lifestyle (smoker/non-smoker, for instance). If that fails to turn up answers, the FDA says, they may need to dig deeper — and perhaps call data from other clinical trials and sources.

Improving Clinical Site Payments  (continued from page 1)

CRO – think the process is going a lot better than those who are outside of the process,” Sullivan says.

One reason CROs like the process may be the fact that they use more metrics – nearly twice as many as sponsors – to evaluate it.

Understanding how well a process is working requires knowing all aspects of its operations. Tracking a simple metric of how many payments were made “on time” provides no information on why the other payments were not.

Fewer than 50 percent of survey respondents said they use the kind of metrics that provide insight into the root cause(s) of payment problems, such as the number of:

- Invoices submitted by sites with errors;
- Payments that are correct the first time;
- Outstanding invoices with queries;
- Days it takes to reconcile invoice discrepancies; and
- Site complaints about payment problems.

This kind of information allows payers to pinpoint areas that need improvement. Sponsors that manage their own payment processes should begin using such metrics; those that outsource payments should make sure their CROs do, too, and require them to share the information.

Sullivan says to truly grasp and fix payment problems, sponsors must shift their focus from overall performance to “quality metrics.” For example, a large number of invoices outstanding may signal glitches in the invoice reconciliation phase. Tracking the number and nature of payment complaints from sites paints a picture of the depth of the problem.

The survey recommends replacing out-moded clunky manual payment systems with speedy automated ones to eliminate time-consuming and error-prone procedures.

Another tip: Parties involved need to communicate more effectively to align expectations, improve transparency and develop solutions.


### Satisfaction with the Current Payment Model, by Organization Type

![Satisfaction with the Current Payment Model](image)

- **Satisfied**
  - Sponsors that manage the payment process internally (N=14)
  - CROs (N=14)
  - Sites (N=10)
- **Neither Satisfied nor Dissatisfied**
  - 7% 7% 7% 10%
- **Dissatisfied**
  - 65% 28% 70%

Source: Metrics Champion Consortium

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**Viking Therapeutics Announces VK5211 Phase II Study Results**

Viking Therapeutics announced results from the company's Phase II study of VK5211 in patients recovering from hip fracture. The Phase II clinical trial was a randomized, double-blind, placebo-controlled, parallel group, international study designed to evaluate the efficacy, safety and tolerability of VK5211 in patients recovering from hip fracture surgery. The top-line data from this study showed that the trial successfully achieved its primary efficacy endpoint, demonstrating statistically significant, dose dependent increases in lean body mass and less head, among patients treated with VK5211, as compared to placebo. The study also achieved important secondary endpoints, demonstrating statistically significant improvements in appendicular lean body mass and total lean body mass compared to placebo. Patients receiving VK5211 also demonstrated numerical improvements in certain exploratory assessments of functional performance. VK5211 demonstrated encouraging safety and tolerability, with no drug-related serious adverse events reported in this study.

**Ironwood Pharmaceuticals Initiates Phase IIIb Study of Linaclotide for Irritable Bowel Syndrome**

Ironwood Pharmaceuticals initiated a Phase IIIb clinical trial evaluating the efficacy and safety of linaclotide 290 mcg on multiple abdominal symptoms in addition to pain, including bloating and discomfort, in adult patients with irritable bowel syndrome with constipation (IBS-C). The randomized, double-blind, placebo-controlled, parallel-group study aims to enroll approximately 600 adult IBS-C patients in the United States. Eligible patients will be randomized to placebo or linaclotide 290 mcg once daily for 12 weeks, followed by a four-week randomized withdrawal period. The primary efficacy endpoint is a change from baseline in abdominal score based on daily patient assessments of abdominal bloating, discomfort, and pain at their worst, as reported on an 11-point numerical rating scale. Additional endpoints include change from baseline in spontaneous bowel movement (SBM) frequency, complete spontaneous bowel movement (CSBM) frequency, stool consistency and straining.

**Pfizer and Lilly Announce Positive Top-Line Results from Phase III Trial**

Pfizer and Eli Lilly and Company announced that a 16-week Phase III study in patients with osteoarthritis (OA) pain evaluating subcutaneous administration of tanezumab, an investigational humanized monoclonal antibody, met all three co-primary endpoints. The study demonstrated that patients who received two doses of tanezumab separated by eight weeks experienced a statistically significant improvement in pain, physical function and the patients’ overall assessment of their OA, compared to those receiving placebo. Preliminary safety data showed that tanezumab was generally well tolerated, with approximately 1 percent of patients discontinuing treatment due to adverse events. Rapidly progressive osteoarthritis was observed in tanezumab-treated patients at a frequency of less than 1.5 percent, and was not observed in the placebo arm. The Phase III OA study (A4091056) was a 16-week randomized, double-blind, placebo-controlled, multicenter, parallel-group trial evaluating the efficacy and safety of subcutaneous administration of tanezumab compared to placebo in patients with OA of the knee or hip. The trial included a 24-week safety follow-up period. In the study, patients were enrolled with moderate to severe OA pain who had experienced inadequate pain relief with other treatment options or OA pain who were unable to take other pain medications. A total of 698 patients were randomized to three treatment groups in a 1:1:1 ratio to receive two injections over the 16-week study, once every eight weeks. One group received two doses of placebo, the second group received two doses of tanezumab 2.5 mg, and the third group received one dose of tanezumab 2.5 mg followed by one dose of tanezumab 5 mg eight weeks later. The efficacy of tanezumab vs. placebo was measured by changes from baseline at 16 weeks.

**Phase III Data Show Vedolizumab Meets Primary Endpoint**

Takeda Pharmaceutical Company Limited announced top-line results from the VISIBLE 1 clinical trial evaluating the efficacy and safety of an investigational subcutaneous (SC) formulation of vedolizumab for maintenance therapy in adult patients with moderately to severely active ulcerative colitis (UC). VISIBLE 1 is a pivotal Phase III, randomized, double-dummy, double-blind, placebo-controlled study with a vedolizumab IV reference arm, to evaluate the safety and efficacy of an investigational SC formulation of vedolizumab for adult patients with moderately to severely active UC who have achieved clinical response at week six following two doses of open-label vedolizumab IV therapy at weeks zero and two. The study enrolled 384 patients, all of whom had inadequate response with, loss of response to, or intolerance to corticosteroids, immunomodulators or tumor necrosis factor-alpha (TNFα)-antagonist therapy prior to being enrolled. Patients who achieved clinical response at week six were randomized into one of three treatment groups, vedolizumab SC 108 mg and placebo IV, vedolizumab IV 300 mg and placebo SC or placebo SC and placebo IV. In the primary endpoint of the trial, a statistically significant proportion of patients receiving vedolizumab SC beginning at week six and every two weeks following achieved clinical remission at week 52 compared to placebo. The safety data were consistent with the known safety profile of vedolizumab, and no new safety signals were identified.
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Conflict of Interest Disclosures

The authors reported no conflict of interest.

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Q-Pharm
Herston, Queensland, Australia
+61487166677
enquiries@qpharm.com.au

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CLINICAL TRIALS MONITORING SERVICES

**Emericlin**
Scotch Plains, NJ
(908) 603-1316
dberk@emericlin.com

---

**Confidence Pharmaceutical Research**
Russia
+1 401 965-3377
anna.ravdel@confidenceresearch.com

---

**Criterium, Inc.**
Saratoga Springs, NY
(518) 583-0095
rkschnel@criteriuminc.com

---

**Juno Clinical Research Services LLP**
Houston, TX
(713) 882-6857
miguel_posada@junoresearch.us

---

**Q-Pharm**
Herston, Queensland, Australia
+61487166677
enquiries@qpharm.com.au

---

**WCCT Global**
Costa Mesa, CA
(657) 229-6907
mgr@wcct.com

---

**Vascular Imaging Solutions and Clare Diagnostic Echo & Research**
Surprise, AZ
(623) 262-7199
eileen.spengler@gmail.com

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**Evolution Research Group, LLC & Thievon-Wright Consulting Group, LLC**
Watchung, NJ
info@cnssites.com

---

**LabConnect LLC**
Seattle, WA
(206) 322-4680
info@labconnectllc.com

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**Splash Clinical**
Wauwatosa, WI
(414) 443-3280
matt@splashclinical.com

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