FDA Seeks $100 Million for Real-World Databank

By Bill Myers

The FDA has asked Congress for $100 million to help build an advanced analytics system the agency says will help it, at long last, master real-world evidence.

The funding, part of President Trump’s fiscal year 2019 budget request, would go toward building a database of at least 10 million patients and provide regulators with “near real-time evidence” on “a broad range of medical products, including drugs, biologics and medical devices,” the FDA says.

Drug sponsors and regulators have long been hopeful that real-world evidence — electronic health records, insurance claims, product and disease registries, mobile health apps — might offer shortcuts through the clinical process and bring safe, cheap drugs to market more quickly by allowing researchers to scale up their trials. But industry leaders and policymakers are still feeling their way forward.

It’s easy to see the appeal of folding real-world evidence into clinical trials. Traditional clinical drug or diagnostic trials have necessarily kept a narrow focus — excluding whole swaths of potential participants in the hope that no other possible variables could cloud results. In practice, though, that means researchers and drug sponsors run the risk of finding out only after the fact — sometimes even after a med has been approved — that a drug may not perform as well as or as safely in the real world as it did in a controlled clinical setting.

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FDA Suggests Endpoints for Opioid Treatments

By Bill Myers

Sponsors may not have to prove a proposed therapy helps addicts totally kick opioids to win FDA approval. But they will have to show it significantly cuts dependence on the potent pain meds, the agency says in new draft guidance.

The majority of clinical trials for proposed medicine-assisted treatments for opioid addiction focus on how well they curb use. But “sponsors and other stakeholders often mistakenly believe that using a change in drug use patterns as an endpoint always requires complete abstinence,” the FDA says, noting it’s not always possible to “have absolute confidence” someone has completely kicked the habit.

So the agency says it may be open to other endpoints for medicine-assisted therapy. Among those suggested in the draft guidance:

- Adverse outcomes such as deaths, emergency room trips and hepatitis C outbreaks. (The agency acknowledges that, to capture this kind of data, trials may need to study a large number of patients for a long period of time — and may make such studies impractical to support initial marketing approval.)
- Whether a medicine can help change a patient’s official diagnosis (as laid out by the Diagnostic and Statistical Manual

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FDA: Focus on Hardest to Treat in Cohort Cancer Trials
The FDA says sponsors considering adaptive studies for early phase cancer treatments should focus on patients with no other options. The agency notes that so-called expansion cohort trials — which start out relatively small but expand if a potential treatment shows promise — can be a way to get a treatment to market more quickly. The thinking is, the more participants in earlier trials the more likely it is to find and fix (if possible) glitches — ensuring faster approval or scrapping the potential treatment in its infancy if it doesn’t work or if risks outweigh benefits. “A lot of time and cost of clinical development is spent waiting in between the start and end of the phases of trials,” FDA Commissioner Scott Gottlieb said in a statement. “Expansion cohort trials can bring efficiency to drug development, potentially reducing development costs and time.” In a 17-page draft guidance released last week, the FDA says it wants to “establish an infrastructure” designed to help sponsors use cohorts to speed drug approvals without compromising safety. Its top recommendation: Focus on patients who are most seriously ill and don’t have any other treatment options. The agency also encourages researchers to hire centralized data management committees and IRBs and have them meet regularly to discuss latest findings and best next steps. “It is critical that investigators, IRBs and regulators are updated with new safety information so that they can provide the necessary oversight for the protection of human subjects and so that investigators can ensure that patients can provide adequate informed consent,” the draft document says. The jury’s still out on the effect of expansion cohorts. A 2017 study by Texas researchers, published in the Journal of the American Association for Cancer Research, analyzed 533 Phase I cancer trials between 2006 and 2011. They found the ones that used expansion cohorts went on to have successful Phase II trials at nearly twice the rate (48 percent) as studies that didn’t (27 percent). But just a year earlier, a team of Cleveland researchers analyzed 252 cancer trials conducted between 2004 and 2014 and found expansion cohorts made little or no statistical difference between success or failure in Phase II trials. Read the FDA’s draft guidance here: www.fdanews.com/08-10-18-DraftGuidance.pdf.

Drug Companies to FDA: Iron Out Rules for Teens in Cancer Trials
The FDA has proposed allowing adolescents to join adult oncology clinical trials as long as their disease or the drug target is the same. Under proposed guidelines, teens would make the cut if the agency approves the pharmacokinetic and toxicity data for adults and sponsors adjust dosing for patients’ body size. Drug giant PhRMA in comments urged the FDA to work with global regulatory agencies “to promote adoption of similar pragmatic approaches.” PhRMA also encouraged the agency to discuss its recommendations with institutional review boards to ensure they’re aware of them. “In order to fully realize the benefits of adolescent participation in adult trials, input from the IRB community and acceptance of the draft guidance will be necessary,” the industry group wrote. GlaxoSmithKline, meanwhile, suggested the FDA clarify a provision on teens in clinical trials of 522 malaria patients in eight sites in Asia, Africa and Latin America showed that taking Krintafel along with anti-malarial tafenoquine, in 21 clinical trials involving 3,100 U.S. Army to test Arakoda, the brand name for 60 Degrees said it worked with the agency approved GlaxoSmithKline’s Krintafel after clinical trials of 522 malaria patients in eight sites in Asia, Africa and Latin America showed that taking Krintafel along with anti-malarial drug chloroquine for three days kept patients malaria-free for up to six months. The FDA last week also greenlighted 60 Degrees Pharmaceuticals’ Arakoda tablets. It’s the first preventive malaria medicine to win federal approval in two decades. 60 Degrees said it worked with the U.S. Army to test Arakoda, the brand name for tafenoquine, in 21 clinical trials involving 3,100 subjects. Both companies will have to conduct post-marketing studies to make sure that their drugs are safe and effective for children, elders and the obese.

Rules for Teens in Cancer Trials
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Anti-Malaria Drugs OK’d
The FDA has signed off on two malaria treatments, one designed to help prevent relapse of the disease, the other a preventive measure. The agency approved GlaxoSmithKline’s Krintafel after clinical trials of 522 malaria patients in eight sites in Asia, Africa and Latin America showed that taking Krintafel along with anti-malarial drug chloroquine for three days kept patients malaria-free for up to six months. The FDA last week also greenlighted 60 Degrees Pharmaceuticals’ Arakoda tablets. It’s the first preventive malaria medicine to win federal approval in two decades. 60 Degrees said it worked with the U.S. Army to test Arakoda, the brand name for tafenoquine, in 21 clinical trials involving 3,100 subjects. Both companies will have to conduct post-marketing studies to make sure that their drugs are safe and effective for children, elders and the obese.
Real-World Evidence (continued from page 1)

The explosion of relatively inexpensive, powerful technology — everything from Fitbits to artificial intelligence algorithms — offers sponsors a chance to manage multiple variables through data that, in many cases, has already been collected and, also, is continually updated. Considering using an approved drug for a new indication but worried about its side effects? What could be easier than tapping into a health outcomes database of thousands of patients who took the med to assuage or confirm concerns? “That data helps you identify down to the personal level who will be eligible for a certain trial and who won’t be eligible,” says Joe Selby, executive director of the Patient-Centered Outcomes Research Institute (PCORI), a Washington, DC, nonprofit that funds trials. “We can identify almost exactly the people we would like to invite to a trial before we ever put a stamp on the postcard or send an email. That’s a huge advance.”

For the FDA, the challenge is to find a way to use that data to speed up approvals without risking public health or safety. Some researchers aren’t waiting for the FDA to catch up. They’re already doing their own large-scale, real-world trials. Russell Rothman, vice president for population health research at Vanderbilt University Medical Center, says a trial he’s conducting (on the effect of aspirin doses on people with high risks for heart disease or stroke) is about to enroll its 10,000th patient. The five-year study, called ADAPTABLE and funded by PCORI, plans to enroll 15,000 people — and researchers are trying to make it all as “real-world” as possible. “We have very broad inclusion criteria,” Rothman says. “We take almost all comers out there.”

Patients are randomly assigned either a daily baby (81 mg) or regular strength (325 mg) dose of aspirin. Participants are being enrolled through some 30 healthcare systems around the country linked by PCORnet (PCORI’s analytic system). The data is collected automatically whenever patients visit their doctors for checkups and researchers check in with study subjects every three-to-six months for a brief survey. After that, researchers basically sit back and wait, Rothman says. “We don’t give the doctors treatment algorithms. We really try to leave these patients in the real-world setting as much as possible. All sorts of things that happen in the real world, we let them happen in the trials,” he says.

The FDA’s budget request suggests the agency is taking real-world evidence seriously — and wants to get the show on the road. It’s the second major step the FDA has taken on the issue in the past year: It also published guidelines on the use of real-world evidence in medical device approvals.

The proposed new data analytics bank would build on the agency’s Sentinel and National Evaluation System for Health Technology (dubbed “NEST”) and represents “the next evolution” in the FDA’s role as Big Data manager, Commissioner Scott Gottlieb said in a recent blog. Used properly, the proposed database could become “a national utility,” he added.

Used properly, the proposed database could become a “national utility.” —Scott Gottlieb, FDA Commissioner

But the budget proposal also illustrates how much work is yet to be done. Sentinel and NEST relied on healthcare payer claims. The new system will rely on electronic health records. Whether or not Congress approves the budget request, the FDA still has to standardize language and measurements across millions of different data points, Gottlieb noted. For example, should patients’ temperatures be recorded in Celsius or Fahrenheit? That may seem like a tiny detail but it’s the kind of thing that can throw off an entry and create cascading errors in a database. That’s partly why some experts are on the fence about real-world data, especially in a drug’s pre-approval phase.

“It’s impossible to learn everything there is to know about a new drug in the pre-marketing phase,” says James Bannon, CEO of Vigilare, a consulting company that helps sponsors and sites manage risk. “The reason for that is because good clinical trial design requires you to eliminate compounding variables.” Real-world evidence, Bannon says, has become a “buzz term” that means different things to different people. He is open to the possibility that advanced analytics might help shorten trials but says their most important role comes after a drug has already gone through regulatory approval. “The major issue becomes, ‘Is it safe? And the primary mechanism for proving that it’s safe is the adverse event reporting mechanism that all the regulators can use’ after a drug comes to market, he says.

Annette Stemhagen, senior vice president at United BioSource Corporation, is more sanguine about the prospects for real-world evidence in clinical trials. “Epidemiologists have been doing real-world evidence for years. That part is not novel. It’s bigger data now, but the strategies, the techniques are the same,” she says.

It’s not just that there’s already a ton of data out there that can help inform a trial, Stemhagen says. It’s that there’s a seemingly limitless capacity to gather even more information before a drug or diagnostic hits the market. “Really, every company ought to be thinking about natural histories,” Stemhagen says. This kind of deep data dive “improves your development program whether or not it saves your drug,” she adds.

For now, even the most aggressive advocates of real-world evidence are only talking about it augmenting or supplementing clinical trials, not replacing them. Rare diseases, novel treatments — they’ll likely continue to need close observation with a narrow focus. But even in these cases, technology can help researchers do a lot more with a lot less, a lot faster, PCORI’s Selby says. “It’s a great way to find all 20 of them instead of six of them.” In fact, he adds, the enormous scale that modern technology offers probably means we’ll see more not fewer clinical trials.

“The truth is many trials get dragged out longer than necessary because they’re so small,” he says. Modern technologies “make it really feasible to think about faster, larger trials. Given the level of uncertainty in medicine, we should be doing an order of magnitude — 10 times, 100 times — more trials than we’re currently doing.”

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Opioid Treatments (continued from page 1)

- Patient-reported outcomes. Are patients (or their family) telling researchers that they’re sleeping better or that their mood has improved after taking a new medicine for opioid addiction? Sponsors could also use patient reports to come up with a concrete measure for cravings.

The FDA stresses that researchers should not focus on whether a med helps addicts stay in treatment. “Many features of trial design can produce incentives to remain in treatment without accruing clinical benefit,” the draft guidance states.

The FDA has only approved three medicines — methadone, buprenorphine, and naltrexone (most commonly known by its brand name, Vivitrol) — to help treat addiction. Methadone and Suboxone are themselves derived from opioids and Vivitrol can be very expensive — up to $1,300 per monthly injection.

FDA records show there are currently 161 open clinical trials dealing with medication-assisted therapy in which drugs such as methadone are used in combination with a broader treatment plan. Most of the trials focus on the non-medicinal side of treatment. Only two — a British Columbia study testing the effects of opium tincture against methadone and a nationwide study by Kaiser Permanente on the best way to manage Suboxone treatments for addicts — are testing the impact of the drugs themselves.


Sponsors and other stakeholders often mistakenly believe that using a change in drug use patterns as an endpoint always requires complete abstinence.”

—Food & Drug Administration
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<td>Elite Pharmaceuticals, Inc.</td>
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Vivitrol Helps HIV Patients Reduce Alcohol Intake

Monthly injections of the anti-addiction drug naltrexone (brand name Vivitrol) may help HIV-positive patients cut down on heavy drinking but it doesn’t help them stick to their med schedules, Yale researchers found. Researchers recruited 51 HIV patients for a four-year trial; all were heavy drinkers and strayed from their daily treatment plans. During the trial, patients received monthly naltrexone injections and regular counseling. The findings, published in the journal AIDS and Behavior: Naltrexone helped patients reduce heavy drinking days. But it didn’t improve their antiretroviral adherence. Antiretroviral drugs have converted HIV and even AIDS from deadly diseases into chronic ones. But they only work if patients take them at least 95 percent of the time, researchers said.

Are Crickets Good for You?

Researchers may have found a healthy new addition to a complete breakfast: crickets. In what may be the first trial of its kind, University of Wisconsin researchers studied the effects of eating cricket and found it may help humans produce a key probiotic and reduce inflammation. Nearly 2 billion people worldwide eat insects as part of their everyday diet and the habit is slowly spreading to Europe and the U.S. Advocates of a bug diet say it’s a good way to get relatively cheap, high-density protein without the harmful health and environmental effects of livestock farming. But until now, no one had ever studied it in clinical trials. For their study, researchers split 20 healthy participants, ages 18 to 48, into two groups. One set ate a controlled breakfast and the other a breakfast of muffins or shakes made with 25 grams of powdered crickets for two weeks. All participants then reverted to regular, cricket-free diets for two weeks during what researchers called the “washout period.” Finally, over two more weeks, the groups swapped menus: Those who initially ate breakfasts of bug bits switched to the cricket-free meals and vice versa. The findings, published in the journal Nature: At the end of the six-week trial, participants had significantly higher levels of the probiotic Bifidobacterium animalis and lower levels of TNF-α — a cell-signaling protein linked to inflammation. Researchers caution the trial was small and say more study is needed. But the results are no doubt good news for the growing bug protein industry: According to the study, commercial bug farming is a $33 billion industry that’s expected to jump 40 percent over the next five years.

Phase II Trial of OV101 Promising

Ovid Therapeutics announced that the Phase II STARS trial of OV101 for Angelman syndrome achieved its primary endpoint of safety and tolerability. The study met its primary endpoint of safety and tolerability given that the adverse events (AEs) with OV101 treatment were similar to placebo treatment, with the majority of AEs being mild. The investigational medicine showed a favorable safety profile and was well-tolerated in adults and adolescents with Angelman syndrome. The Phase II STARS international study is a 12-week randomized, double-blind, placebo-controlled clinical trial, which randomized patients across three groups: a once-daily or twice-daily dose of OV101, or a placebo. Some 88 patients, aged 13 to 49, diagnosed with Angelman syndrome were randomized at 13 clinical trial sites in the U.S. and Israel. The study randomized patients to one of three arms: once-daily (QD) dose of OV101 at night (15mg), twice-daily (BID) dose of OV101 (10mg in the morning and 15mg at night), and a placebo at the pre-specified efficacy analysis. After 12 weeks OV101 showed a statistically significant improvement compared to placebo in the physician-rated clinical global impressions of improvement (CGI-I). CGI-I was ranked first in the topline statistical plan. The STARS trial explored the clinical utility of OV101 on improvements in clinical global impressions, maladaptive behavior, sleep, and gross and fine motor skills.

Positive Colitis Trial Results

Protagonist Therapeutics announced results from an independent blinded re-analysis of the Phase II PROPEL study of oral alpha-4-beta-7 integrin antagonist PTG-100 for the treatment of patients with ulcerative colitis (UC). The Phase IIb PROPEL trial was a global, randomized, double-blind, placebo-controlled, two-stage adaptive clinical trial to assess the safety, efficacy, and dose-optimization of three doses (150 mg, 300 mg, or 900 mg) of PTG-100 compared to placebo for 12 weeks in patients with moderate to severe ulcerative colitis. The primary efficacy endpoint of the study was the proportion of patients who achieved clinical remission as defined by rectal bleeding, stool frequency, and endoscopic subscores of the Mayo score. No safety concerns were noted with PTG-100. The data from blinded endoscopy re-reads and a comprehensive data review provide signals of clinical efficacy and support further development of PTG-100. Results showed independent, blinded histological scores favor PTG-100 over placebo and correlate with the clinical remission and endoscopic response outcomes from the re-analysis.

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