FDA Unveils Guidelines on Innovative Trial Design

By Bill Myers

The FDA late last week issued two new draft guidances — one on adaptive clinical trials and the other on master protocol designs — that it hopes will help sponsors innovate and get treatments to market more swiftly and efficiently.

“The standard approach to generating evidence — a series of clinical trials, each investigating one or two interventions in a single disease — has become more expensive and challenging to execute,” FDA Commissioner Scott Gottlieb said in announcing the guidances.

“Adaptive clinical trials can give sponsors the flexibility to react to clinical evidence as it’s being collected, and modify the design and enrollment in trials by including more patients with characteristics that help predict that they’re more likely to derive a benefit,” he added.

The FDA for months has been signaling interest in creative trials that stray from the traditional Phase I, II and III model. The 36-page guidance on adaptive design, which replaces a 2010 document, recommends the following approaches:

- Group sequential designs, which can reduce the sample size and length of a clinical trial by setting, in advance, the criteria for stopping the trial if it hits its goals or seems destined to flop.
- Sample size adaptations, in which investigators lay out in advance a plan to adjust sample size depending on what they learn from ongoing data. These types of trials might be best seen in Trial Design on page 4.

CTTI: New Recommendations for Decentralized Trials

By Bill Myers

Decentralized clinical trials offer a chance to expand patient pools, obtain more data and — ultimately — move medicines and treatments to market faster. But sponsors worried about risks behind the technology driving decentralization don’t have to completely abandon traditional trials, according to CTTI.

“There is a broad continuum of hybrid approaches that provide sponsors and CROs with varying opportunities to implement decentralized trials, even if it is their first time doing so,” the group says in new recommendations urging drug developers to absorb fresh technologies into trials.

FDA officials sit on the board of CTTI, headquartered at Duke University — and its recommendations are often curtain-raisers for FDA guidance. The group’s latest recommendations aren’t exactly revolutionary — most can be distilled down into the phrase “think ahead.” But they’re an effort to reassure a skittish industry that it’s possible — and even encouraged — for them to think creatively about clinical trials, CTTI Executive Director Pamela Tenaerts tells CenterWatch.

“There is this perception — and I think we’ve debunked that — that if you do trials in a decentralized way, there’s somehow a higher standard,” she says. “You just have to plan ahead.”

Trial costs have continued to grow — it now costs nearly $2.6 billion to get a single drug to market — even as information and communication technologies have gotten cheaper and better. This indicates the current clinical trial see Decentralized Trials on page 5.
FDA Lifts Holds on Trials
The FDA has lifted holds on two sets of clinical trials, one for an experimental treatment of several cancers and the other a gene therapy targeting Duchenne’s muscular dystrophy.

Epizyme announced last week that the agency is allowing six U.S. trials for its drug tazemetostat to resume after stopping them in April because a child in one of them developed secondary T-cell lymphoma. The child stopped taking tazemetostat and underwent treatment for the new cancer.

The FDA OK’d restarting the trial after Epizyme turned over all efficacy and safety trial data and convened a panel of experts to validate the drug’s safety.

Tazemetostat – which was granted orphan status in June 2017 – is being tested to treat several cancers, including non-Hodgkins lymphoma.

Sarepta Therapeutics last week announced the FDA had also greenlighted its request to continue a clinical trial on an early-stage gene therapy program for Duchenne’s, which it paused in July after finding trace amounts of DNA in the treatment. The company said it never gave the compromised therapy to any patients in the Columbus, Ohio-based trial but switched suppliers just in case.

Duchenne’s is a rare disorder that mostly affects boys. The rapid decline in muscle strength and mass usually means victims don’t survive to adulthood.

The hope is that Sarepta’s gene therapy will boost the amount of microdystrophin to stem muscle loss. Microdystrophin is a smaller version of the protein dystrophin missing in Duchenne’s sufferers.

The company says it hopes to re-open clinical trials by the end of the year.

FDA: $18M for Rare Disease Trials
The FDA is doling out more than $18 million in grants to support clinical trials for rare diseases, the agency has announced.

The grants will roll out over the next four years and be given to 12 principal investigators, a mix of major academic institutions and private companies. The money comes from the FDA’s Orphan Products Clinical Trials Grants Program.

Here’s the list of grant recipients:
- Leonide Saad of Alkeus Pharmaceuticals in Cambridge, Mass., $1.75 million over four years for a Phase II study of experimental drug ALK-001 to treat Stargardt disease, which causes macular degeneration in children and adolescents;
- Keith Lindor of Arizona State University-Tempe, $2 million over four years for a Phase II trial of oral vancomycin for the treatment of primary sclerosing cholangitis, a potentially fatal liver disease;
- Shlomo Melmed of Cedars-Sinai Medical Center in Los Angeles, $2 million over four years for a Phase II trial of seliclib to treat Cushing disease, a non-cancerous tumor that affects the pituitary gland;
- Yvonne Saenger of New York City’s Columbia University, $750,000 over the next three years for a Phase I trial of talimogene laherparepvec to treat advanced pancreatic cancer;
- Eric Sorcher of Emory University in Atlanta, $1.5 million over three years for a Phase I/II study of Ad/PNP Fludarabine to treat head and neck squamous cell carcinoma;
- John Maslowski of Fibrocell Technologies in Exton, Pa., $1.5 million over four years for a Phase I/II study of gene-modified fibroblasts to treat dystrophic epidermolysis bullosa, a genetic disorder that leaves the skin fragile and easily blistered;
- Amy Dezem of Johns Hopkins University, $750,000 over three years for a Phase I/II study of T cell treatments of myelodysplastic syndrome, a group of blood disorders;
- Yang Liu, of Oncolimmune in Rockville, Md., $2 million over four years for an experimental drug called CD24Fc to prevent graft versus host disease, a potentially fatal side effect of stem cell transplants;
- Zachary Rome of Patagonia Pharmaceuticals in Woodcliff Lake, N.J., $1.5 million over three years for a Phase II study of isoretinoin for treatment of congenital ichthyosis, a skin disorder that affects newborns;
- Stephanie Seminara of the General Hospital in Los Angeles, $2 million over four years for a Phase II study of kispeptin for dopamine agonist intolerant hyperprolactinemia, a disorder that causes the body to over-produce the hormone prolactin, which stimulates breast milk production;
- Kyriakie Sarafoglou of the University of Minnesota, $1.4 million over three years to study a hydrocortisone pump to treat congenital adrenal hyperplasia, an adrenal gland disorder; and
- Matthew Laughon of the University of North Carolina, $2 million over four years for a Phase II study of sildenafil to prevent bronchopulmonary dysplasia, which affects the lungs of newborns.

Heart Clamp Scores Big in Trials
A small clip attached to a heart valve significantly helped heart failure patients in clinical trials, researchers report.

Abbott’s MitraClip, fastened to the “leaflets” of the heart’s mitral valve, is designed to help prevent mitral regurgitation, which occurs when the mitral valve doesn’t completely close allowing blood to flow backward into the heart, forcing it to work harder to pump blood.

Mitrval regurgitation is the most common heart valve disease, affecting nearly one in 10 older Americans that — left untreated — kills nearly 57 percent of its sufferers within a year.

Here’s the list of grant recipients:
Researchers enrolled 614 heart failure patients at 78 trial sites in the U.S. and Canada to see if the MitralClip could help improve or slow symptoms. All took their regular heart meds and 302 also received MitralClips.

The findings, published in the *New England Journal of Medicine*: There were 47 percent fewer hospitalizations and 38 percent fewer deaths among the MitralClip patients during the two-year study. Patients who received the clip also reported “significant” improvements in their quality of life and daily activity, the research team reported.

People who suffer from severe heart failure are often too sick to undergo open heart surgery and have their mitral valves replaced.

The clamp, which first obtained FDA pre-market approval in 2013, is threaded through a blood vessel in the groin.

Lead researcher Gregg W. Stone, a cardiologist at New York-Presbyterian/Columbia University Irving Medical Center, said the surgery offers heart failure patients “substantially more hope.”

**UK Allows E-Consent in Trials**

Regulators in the UK and Northern Ireland will allow researchers to collect electronic signatures for informed consent in clinical trials, officials announced last week.

Health agencies in England, Scotland and Northern Ireland say most trials can get by with “simple” electronic signatures — a stylus or finger-drawn signature, a tick box and consent declaration, a unique representation of characters or a finger-print scan.

Higher risk trials, including Phase I healthy volunteer studies, can also use simple signatures but it’s recommended they stick with finger- or stylus-drawn signatures so they can be compared with previous patient signatures in audits.

Remote clinical trials, however, may need to use “advanced” or “qualified” e-signatures, regulators said.

Advanced signatures are more akin to passwords. They’re uniquely linked to the signer, can identify him or her and are tied to data within the signature that can detect any variations or changes. Qualified signatures are uniquely linked to the signer and are created by a special, certified electronic device.


**Getting Closer to a TB Vaccine**

An experimental tuberculosis vaccine protected participants in a large clinical trial 54 percent better than those who took a placebo, GlaxoSmithKline reported last week.

The drugmaker recruited nearly 3,600 patients in Kenya, South Africa and Zambia who tested positive for latent TB but weren’t yet symptomatic.

About half were given the experimental vaccine M72/AS01 and the rest received a placebo during trials held between August, 2014 and November 2015.

Nearly three years later, 10 people in the vaccine group and 22 who received the placebo developed full-blown TB, researchers reported.

The World Health Organization estimates close to a quarter of the world’s population is infected with tuberculosis. Only a handful of people who carry the germs — between 5 percent and 15 percent — will develop TB but it remains the world’s leading cause of infectious death and there are more than 10.4 million new cases each year.

**ACRP: Sites Rate Sponsors, CROs**

Clinical site employees say they have better relationships with drug sponsors than with CROs, a new survey finds.

The Association of Clinical Research Professionals and the Avoca Group surveyed 281 site staffers online between January and March 2018 to gauge their satisfaction with sponsor/CRO colleagues and protocol designs – and how likely they were to recommend a sponsor or CRO to others.

Sponsors scored higher overall on questions relating to their protocol knowledge, responsiveness to questions or concerns, communication style, clarity of instructions and the ability to manage time efficiently.

Staffers ranked “communication style” as the most important factor in their attitude toward clinical relationships.

Sites also seemed to have more confidence in sponsors’ ability to execute trials, rating them above CROs on questions such as reliability of clinical supplies, initiation or training, support for patient recruitment and retention and setting realistic goals.

Link to the survey here: https://www.acrpnnet.org/resources/white-paper-site-perspectives-on-becoming-a-sponsor-or-cro-of-choice.
“Adaptive clinical trials can give sponsors the flexibility to react to clinical evidence as it’s being collected, and modify the design and enrollment in trials by including more patients with characteristics that help predict that they’re more likely to derive a benefit.”

—Scott Gottlieb, FDA Commissioner

Features

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“when there is considerable uncertainty about the true treatment effect size,” the FDA says.

- Adaptive enrichment, where investigators can change their patient pool to focus on a subgroup in response to early results.
- Treatment arm selections, in which investigators can either add or end an experimental treatment depending on data.
- Patient allocation adjustments. There are two kinds of these, according to the guidance. The first, a covariate-adaptive treatment assignment, puts a patient in a treatment arm based on his or her baseline characteristics and how they compare to those of earlier patients. The second, a response-adaptive randomization, allows patients to be moved from one treatment arm to another over the life of the trial.

The key to making any of the methods work, suggests the FDA, is careful planning and communication with regulators.

The biggest danger is the risk of false positives, the agency says. But it’s also clearly worried about bias creeping into adaptive trials. In an effort to prevent this, the document “strongly” recommends that access to interim trial data be limited.

One way to keep interim data under wraps is to create a separate “adaptation body” outside of the usual data monitoring committee — although that approach might work best for group sequential designs or other trial designs that have “simple adaptation algorithms.”

“Regardless of the chosen approach, the committee tasked with making adaptation recommendations should have members with the proper expertise, including a statistician or statisticians who are knowledgeable about the adaption methodology, the monitoring plan, and the decision rules,” the guidance states.

Sponsors and their employees or agents, too, should “generally” be kept away from interim data. But the FDA says it can envision situations — dose selection, for instance, which could “have important long-term implications for the drug development program” — where a sponsor’s staff might be entitled to a “limited” briefing.

The guidance on master protocols is similar in spirit but focuses on cancer trials.

It lays out a brief definition of the three main types of master protocols: platform trials, in which researchers study multiple, targeted therapies for a single disease more or less perpetually, with treatments allowed to drop in or out of the platform depending on how well they perform in the trial; umbrella trials, which study several therapies for a single disease but focus various subgroups (usually determined by biomarkers) of a disease; and basket trials, in which researchers zero in on a single, targeted therapy for several diseases or disease subtypes (for instance, by focusing on a cancer mutation and seeing how a given drug treats the mutation when it appears in different types of cancers).

It also acknowledges that some clinical trials may combine the different approaches.

Whatever tack they take, sponsors conducting master protocols should create a separate safety or data monitoring committee responsible for gathering and disseminating urgent safety information as part of a “systemic approach that ensures rapid communication of serious safety issues to clinical investigators and regulatory authorities,” the guidance says.

The safety plan, as well as the committee’s make-up, should be part of the sponsor’s IND application. The FDA also urges a central IRB, which meets frequently to review the trial’s safety, to oversee master protocols. Institutions should also consider creating a “specialty” IRB to meet “on short notice to review new information and/or modifications to trials with master protocols” just in case there’s an urgent need and the central IRB can’t gather a quorum for a meeting.

In trials involving children, at least one person on the IRB should be an expert in “managing pediatric oncology patients and have experience with the regulatory requirements, including parental permission and assent requirements.”

Among the FDA’s other recommendations:

- Those conducting umbrella trials should probably use a common control arm (in most cases the disease’s currently accepted standard treatment) “to improve efficiency.”
- In platform trials testing more than one investigational drug, sponsors will probably have to offer “strong scientific rationale” to create a combined drug regimen; the FDA “strongly recommends” that the recommended Phase II dose for each drug has already been established.
- If a master protocol is trying to find an appropriate dose for novel combinations, the FDA will require safety data for a proposed dose from at least six patients before allowing researchers to test the combo’s efficacy.
- If protocols have substudies that target multiple biomarkers, sponsors must come up with a plan on how to assign patients potentially eligible for more than one of them.
- Trials focused on patients’ biomarkers should not only explain why a given biomarker is worthy of study, but also be careful to use blood or tissue tests “that are analytically validated.”


Decentralized Trials
continued from page 1

model simply isn’t sustainable, Tenaerts and her colleagues argue.
That doesn’t mean sponsors and CROs have to surrender their old ways completely, though. A traditional trial, for instance, might use local nurses or doctors to visit patients in remote areas, videoconferencing technology to talk to them or wearable devices to remotely monitor participants.
There’s a real potential for patients with rare diseases to participate in clinical trials, Tenaerts says. That said, sponsors and CROs will have to seriously consider which activities have to be done at sites, CTTI says. They’ll also have to make sure they comply with state and local licensing and telecom regulations, the groups adds, urging them to “invest in appropriate legal resources.”
For those sponsors or CROs who make use of local health aides, it’s also extremely important to consider — and to lay out early — which areas of care locals should oversee and which principal investigators should control.
“You probably want to be more conservative about that, especially early on in a trial,” Tenaerts says.
CTTI’s recommendations are a good first step, says Jill Johnston, president for site activation solutions at WCG.
Decentralized trials “are such a new thing for most of the industry” that most sponsors “are very hesitant to take a risk on their own studies,” she says. “They typically have a wait-and-see attitude when it comes to new thinking in this industry, especially in Phase II and III studies. They want to see proof that it works, ensure it will hold up to regulatory scrutiny.”
For now, sponsors are more likely to consider decentralized trials in post-market studies, Johnston notes. Nonetheless, the signs are unmistakable: clinical trials are moving toward decentralized trials, “albeit slowly,” she adds, stressing there’s no shame in them taking their time.
“In a traditional clinical study, there are literally 1,000-plus things that are all happening concurrently and need to be set up/standardization,” Johnston says. “Having to think through a new approach, as in a decentralized trial, would be very difficult if it is done within the confines of an individual study.”

Pivotal Clinical Trial Costs Estimated at $19 Million

By Bill Myers
It cost an average of $19 million to get new drugs through their pivotal clinical trials and onto the market, a new analysis has found.
Researchers at the Institute for Safe Medication Practices and Johns Hopkins University reviewed 99 separate drugs or therapies approved between 2015 and 2016 and analyzed their costs based on estimates from IQVIA software. In what may be the first study of its kind, they found costs varied widely, from $12 million to $33 million per trial. A glaring exception: cardiovascular drug trials, which averaged more than $157 million.
The researchers said one lesson learned is that trials for novel drugs don’t have to break the bank.
“For years, there have been discussions about how expensive clinical trials are and can we afford to keep doing them at this level but no one had any price tags,” lead study author Thomas J. Moore told CenterWatch. This “actually puts a price tag on what it costs to run these trials.”
Tufts University’s Center for the Study of Drug Development periodically reviews the costs for all — including failed — clinical trials. Its most recent estimate, published in 2016, was that it took nearly $2.6 billion to get a single treatment to market.
Moore and his colleagues focused only on studies — most of them Phase III trials — that led directly to FDA approval.
Moore says he was motivated in part by critics urging regulators to trim the length of time of clinical trials, noting he was concerned that pressure to cut costs might lead policy makers to sacrifice scientific rigor.
But it turns out the cost of pivotal trials are relatively reasonable.
“This is the price of evidence,” he says. “That’s telling me that you wouldn’t gain much by reducing requirements for approval and you might lose a lot.”
Moore and his colleagues identified three key elements likely to drive up costs. If a trial:
- Needs large patient pools;
- Requires the control group to take an active drug not a placebo; and
- Focuses on clinical rather than on surrogate endpoints.
The most expensive trials involved cardiovascular drugs, the research team found. Those were followed by cancer drugs (more than $45 million), digestive system drugs (more than $29 million), central nervous system drugs (nearly $26 million) and dermatology drugs (nearly $25 million).
“The most striking finding we saw was that the most expensive trials were conducted because the drug under study was similar to an already proven drug for a similar ailment,” Moore says.
One such drug, the combo sacubitril-valsartan for chronic heart failure, checked in at nearly $347 million, Moore and his colleagues found.
Researchers not only had to prove the drug’s clinical benefit but that it was no worse than rival warfin. That meant more complicated trial designs and more patients, Moore said.
The team’s findings were published in JAMA Internal Medicine.
Setting you Up for Success from the Start.

At WCG, we use our evidence-based insights to help set you up for success from the start. From strategic site selection to accelerating enrollment, our solutions empower you to anticipate problems, make better decisions and gain greater control over the key elements of your clinical study startup.
## Drug & Device Pipeline News

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Upcoming Event Highlights

Conferences

OCTOBER 9-10, 2018
Medical Device Complaint Management
Waltham, MA

OCTOBER 23-25, 2018
FDA Inspections Summit – 13th Annual
Bethesda, MD

NOVEMBER 1-2, 2018
SOPs and Policies for the 21st Century: Why Less is More
Washington, DC

DECEMBER 10-12, 2018
Design of Medical Devices Conference, China 2018
Beijing, China

Training Programs

NOVEMBER 1-31, 2018
Phlebotomy Training — Two Day Training
Various locations

Webinars

OCTOBER 16, 2018
Pharmacy Compounding Regulation: Deconstructing Latest Guidance, Compliance & Enforcement Activities

OCTOBER 17, 2018
Quality Metrics Redux: Taking Advantage of FDA’s Renewed Focus

OCTOBER 18, 2018
The CDER Reorganization: What it Means for Drugmakers

Jobs via Kelly Services

Sr. Clinical Documentation Specialist
San Francisco, CA
Sr. Clinical Portfolio Specialist
East Hanover, NJ
Clinical Research Global Studies Leader
New York, NY
Medical Device Systems Engineer and Agile Scrum Master
Deerfield, IL

SE14 - Scientist
Cincinnati, OH
Biomedical Engineer
Englewood, CO
Quality Control Inspector
Los Gatos, CA
Clinical Trial Manager/Senior Manager
Seattle, WA

More Jobs

Pharmaceutical Teaching
International Education Services
Tokyo, Tokyo

Experienced Clinical Research Coordinator
M3 Wake Research, Inc.
Raleigh, NC

Clinical Data Project Coordinator
ProClinical
Boston, MA

Contract Clinical Research Coordinator
Elligo Health Research
Boca Raton, FL

Research Associate I
Kaiser Permanente
Pasadena, CA

Clinical Research Coordinator II
Medical College of Wisconsin
Milwaukee, WI

Academic Programs

Boston College
Clinical Research Certificate Program
Chestnut Hill Campus, Newton, MA

Drexel University College of Medicine
Master’s/Certificate Programs in Clinical Research Organization and Management Online

University of North Carolina at Wilmington
MS Clinical Research and Product Development Online

More Jobs

Pharmaceutical Teaching
International Education Services
Tokyo, Tokyo

Experienced Clinical Research Coordinator
M3 Wake Research, Inc.
Raleigh, NC

Clinical Data Project Coordinator
ProClinical
Boston, MA

Contract Clinical Research Coordinator
Elligo Health Research
Boca Raton, FL

Research Associate I
Kaiser Permanente
Pasadena, CA

Clinical Research Coordinator II
Medical College of Wisconsin
Milwaukee, WI

Academic Programs

Boston College
Clinical Research Certificate Program
Chestnut Hill Campus, Newton, MA

Drexel University College of Medicine
Master’s/Certificate Programs in Clinical Research Organization and Management Online

University of North Carolina at Wilmington
MS Clinical Research and Product Development Online

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