FDA Urges More Valid HCT/P Research with Agency Assistance

By Colin Stoecker

To help increase the number of effective trials of regenerative medicine therapies, the FDA will work with researchers and sponsors to focus on the populations, endpoints and designs best suited to prove success.

Approximately 5,000 regenerative medicine trials are being conducted under the watch of the Center for Biologics Evaluation and Research (CBER) and Center for Device and Radiologic Health, but the agency is working to encourage more legitimate research in the area to combat the rise of untested treatments that put the public at risk.

The agency’s overall goal is to protect the public against bogus therapies that have not been proven in a clinical setting, such as the accidental blinding of two patients after an untested HCT/P was injected into their eyes in March 2017.

To help allay HCT/P manufacturers’ fear of rejection by the FDA, the agency in June started the Rapid Inquiry Program for HCT/Ps, which gives manufacturers a “rapid, preliminary, informal, non-binding assessment” of how their research could be regulated.

To further encourage clinical research, the agency issued a draft guidance in February that promotes the use of innovative regenerative medicine trial designs (CenterWatch Weekly, Feb. 18, 2019).

Despite the encouragement, the agency has seen only modest progress among sponsors.

Expert Q&A: Site Feasibility Factors

Diane Carozza, WCG vice president of clinical strategic services, and Danya Kaye, director of business development for R&D and innovation at Inspire, share their thoughts on a variety of issues related to successful site feasibility practices.

Question: What are the pros and cons of conducting blinded versus unblinded initial site feasibility studies?

Carozza: When we begin speaking with either the steering committee members or key opinion leaders or thought leaders that sponsors tend to work with going through the protocol feasibility process, my answer is 100 percent that the unblinded outreach yields the better. But when we actually do site feasibility within WCG, we see a difference in months when we had those blinded outreach efforts versus the ones where the sponsor is identified. We just recently had an instance where we were able to begin and end a whole site feasibility outreach effort in a matter of two weeks, and it was because we knew that the sites were very interested in working with this sponsor that they know is doing very novel research in their area of expertise.

Kaye: At Inspire, as an online social health network that partners with pharma and CRO organizations and research services, we’re not doing site feasibility, but we do a lot of protocol feasibility, and from a protocol feasibility perspective, it’s kind of the opposite. We’re typically doing blinded outreach to collect unbiased patient perceptions of a protocol design. So, we don’t want the biases...
FDA Cautions on Use of ‘Bayesian’ Statistics in Complex Trials

Sponsors of trials using complex innovative designs (CID) should carefully consider the statistical approaches they use and discuss them with the FDA, a new draft guidance issued last week says.

The benefits and risks of using novel statistical approaches — especially Bayesian analysis — in CID trials must be weighed carefully.

“The use of Bayesian methods can increase the chance of erroneous conclusions,” the agency says, adding that discussions between sponsors and the agency are “critical to the FDA’s evaluation of Bayesian proposals.”

It also warns about leveraging outcome data from the phase 2 to the phase 3 stage by making projections about outcomes, noting that “borrowing the prior data could increase the chance of a false conclusion of effectiveness.”

Comments on the draft guidance are due Dec. 23.


ALS Guidance Embraces Regulatory Flexibility to Speed Treatments

Sponsors of treatments for amyotrophic lateral sclerosis (ALS) will benefit from increased FDA regulatory flexibility, according to final guidance released last week.

The agency recognizes that scientific progress has been “particularly lagging” for complex neurological diseases such as ALS, said acting FDA Commissioner Ned Sharpless in a joint comment with Center for Drug Evaluation and Research Director Janet Woodcock. “[W]e stand ready to use the expedited development and approval programs available to help bring new treatments for ALS to patients as quickly as possible.”

The agency suggests decentralizing trials and broadening inclusion criteria to include as many different types of subjects as possible in trials. It also encourages the use of novel technologies for conducting ALS trials, such as wearables and biosensors.


Patient Advisors Can Expedite Device Trials, FDA Says

The FDA is urging sponsors of medical device trials to involve patient advisors in the design and conduct of their trials, according to a draft guidance released last week.

The guidance defines the term “patient advisors” as “individuals who have experience living with a disease or condition” but who are not study participants themselves.

Companies can work with patient advisors to improve informed consent, follow-up visits, endpoints and patient-reported outcomes. Input from patient advisors also can reduce protocol violations and revisions, and streamline data collection, resulting in better data, the agency says.

The FDA’s goal in issuing this guidance is to help sponsors find ways to combat the challenges and misperceptions involved in patient engagement, including the perception that the agency does not allow patient engagement in the design and conduct of clinical investigations, and patient perceptions that their input is not valued.

Because patient advisors primarily serve in a consulting or advisory capacity, the guidance says, the FDA does not consider these types of activities to “constitute research or an activity subject to FDA’s regulations” and so don’t require IRB approval.

Comments for the draft guidance close Nov. 25.


Mass General Develops New Trial Design for ALS

The Sean M. Healy Center for ALS at Massachusetts General Hospital will launch the first clinical trial platform for amyotrophic lateral sclerosis (ALS).

The innovative platform trial, a partnership with biotech company Prilenia, aims to accelerate the development of effective treatments by evaluating three drugs at the same time.

Prilenia’s ALS drug Pridopidine will be the first treatment tested. Two additional compounds will be added to the trial at a later date.

Conflict of Interest Oversight Lacking at NIH, IG Says

The National Institutes of Health does not supervise its grantees’ financial conflicts of interest closely enough, especially when it comes to involvement with foreign entities, according to recent inspector general reports.

While the HHS Office of Inspector General (IG) commended NIH for establishing a database of financial conflict of interest (FCOI) reports, it noted that there is no quality assurance procedure for reviewing the reports before awarding grants. Only 3 percent of NIH’s 2018 grants — totaling $1 billion — went to investigators with FCOI statements on file.

continues on next page »
In addition, HHS regulations do not require FCOI statements to identify whether conflicts involve an entity outside the U.S., leaving NIH-funded research open to potential foreign influence, the IG says.

The agency watchdog also took issue with NIH’s oversight of its grantees’ FCOI policies. Of the 1,875 institutions receiving NIH grants in 2018, 1,013 did not post the required FCOI policy on their websites.

The IG reports make several recommendations for improving NIH handling of conflicts of interest, including making periodic quality assurance reviews of its online system, enhancing its FCOI monitoring program to ensure that institutions resolve identified deficiencies and reviewing all grantee websites to ensure that FCOI policies are publicly accessible.

NIH also should “use information regarding foreign affiliations and support that it collects during the pre-award reporting process to decide whether to revise its FCOI review process to address concerns regarding foreign threats,” the IG says.

NIH concurred with all IG recommendations but noted that the institutions that failed to post their FCOI policies in 2018 represent only 4 percent of its grants that year.

Read the IG reports here: https://bit.ly/2nQKyMm.

**University of Maryland Receives NIH Grant for Flu Vaccine Research**

The University of Maryland Center for Vaccine Development and Global Health (CVD) will receive an NIH grant of up to $200 million to develop a universal flu vaccine.

In the first stage of the seven-year grant, the center will use $2.5 million for clinical testing aimed at improving seasonal influenza vaccines and conducting challenge studies for the National Institute for Allergy and Infectious Diseases’ Collaborative Influenza Vaccine Innovation Center (CIVICs) program.

**Bayer Joins AI Data Management Collaboration**

Bayer has joined the Life Sciences Cloud Coalition, which uses Accenture Life Sciences’ artificial intelligence platform for clinical data collection and management.

Accenture’s Intient platform uses a cloud-based technology developed by Oracle to collect internal and external clinical data in a single data management system.

The coalition, which enables collaboration among biopharmaceutical companies, also includes Pfizer, Eli Lilly, Merck, Novo Nordisk and GlaxoSmithKline.

**Elligo Partners with Canadian Walmart Clinics**

Elligo Health Research is partnering with Jack Nathan Health in Canada to provide clinical research as a care option for its Walmart clinics.

The partnership expands on Elligo’s research network, with an added $20 million in funding to connect physicians and their patients to clinical trials. The partnership will draw on the two million patients the Walmart clinics see annually.

**WCG KMR Opens New Trial Cost Benchmark Study**

Enrollment in the WCG KMR 2019 Clinical Trial Cost Study is now open to pharma companies. WCG KMR collects data validated directly with clients to ensure integrity in the results. Findings from the study will be presented to senior leadership teams of participating organizations.

To apply to participate in the study, click here: https://bit.ly/2l92a50.
AGC Biologics
Naofumi Kagami was named site head and general manager of the Chiba, Japan facility at AGC Biologics. Previously, Kagami was head of bioprocess solution sales with Sartorius Stedim Japan and marketing manager with Roche.

Adicet
Adicet has appointed Francesco Galimi senior vice president and chief medical officer. Galimi was most recently with Amgen where he held the position of global program general manager of early development.

Aperio
Aperio Clinical Outcomes has appointed Jennifer Hodak director of talent acquisition. Hodak was most recently with SRG Woolf Group where she served as senior director.

Artois Pharma
Tania Dimitrova was named chief business officer, New York, as part of expansion efforts to the U.S. for Artois Pharma Limited. Previously, Kagami was a director in worldwide business development, leading partnership, licensing, M&A and externalization transactions at Pfizer.

Beam
Beam Therapeutics has named Brian Riley senior vice president of technical operations. Previously, Riley was vice president of operations at Catalent.

Biom’up
Biom’up SA has named Patrice Ferrand chief executive officer and Evelyne Nguyen group chief financial officer. George Makhoul has been appointed chief executive officer of Biom’up USA, Inc. Ferrand was previously CEO at Unilabs France, Nguyen is the founder and general director at ANMPARTNERS SAS and Makhoul was formerly chief compliance officer with the company.

Black Diamond Therapeutics
Christopher Roberts has been named chief scientific officer at Black Diamond Therapeutics. Roberts was previously an entrepreneur in residence for SR One, the corporate venture capital arm of GlaxoSmithKline.

CANbridge Pharmaceuticals
CANbridge Pharmaceuticals has named Lisa Li vice president of rare disease and Lily Liu as head of market access. Li was most recently the commercial director for Rheumatology in the Japan-Asia Pacific region at AbbVie. Liu was previously head of central market access for oncology and rare disease products at Novartis Oncology China.

CASI Pharmaceuticals
CASI Pharmaceuticals has named Larry Zhang president. Previously, Zhang served as president of CASI Pharmaceutical’s Beijing, China operating subsidiary since 2018.

Catabasis Pharmaceuticals
Andrew Komjathy has been named chief commercial officer at Catabasis Pharmaceuticals, Inc. Komjathy is the former vice president, commercial sales at Alkermes, Inc.

Cerebral Therapeutics
Cerebral Therapeutics has added to its leadership with John Foster named president and chief operating officer. Foster previously founded CNS Therapeutics and served as chief executive officer before it was bought by Mallinckrodt Pharmaceuticals.

ENYO Phamra
ENYO Pharma has named Johnathan Lieber chief financial officer. Lieber is currently managing director of Danforth Advisors and most recently served as chief financial officer at Histogenics Corporation.

Fluid Analytics
Joe Keegan has been named chairman at Fluid Analytics. Keegan was previously chief executive officer at ForteBio.

FogPharma
FogPharma has appointed Fang Wang as vice president of biology and Nancy Wilker as vice president and lead IP counsel. Wang was most recently director of biology at Agios Pharmaceuticals and Wilker was IP counsel at Biogen.

FORMA Therapeutics
FORMA Therapeutics has appointed Todd Shegog senior vice president and chief financial officer and Patrick Kelly senior vice president and chief medical officer. Shegog was most recently CFO for Synlogic. Kelly lead translational clinical activities for FORMA’s portfolio of small molecule therapeutics since 2016.

Healthstat
Warren Hutton has been appointed president at Healthstat. Hutton was the general counsel and chief operating officer at the company for the past 15 years.

HemoShear Therapeutics
Brian Johns has been appointed chief scientific officer at HemoShear Therapeutics, LLC. Johns is the former director, HIV medicinal chemistry at GlaxoSmithKline.

Illumina
Illumina named Joydeep Goswami senior vice president of corporate development and strategic planning. Goswami was previously president of the clinical NGS and oncology division at Thermo Fisher Scientific.

IntuitiveX
IntuitiveX has named Desney Tan senior advisor and chief technologist. Tan joined from Microsoft where he was general manager of Microsoft Healthcare.
Up and Coming (continued from page 4)

**Inversago**
Inversago Pharma, Inc. named Caroline Fradette vice president, clinical research. Fradette was previously director, clinical research at ApoPharma.

**JenaValve Technology**
JenaValve Technology has named Vinny Podichetty vice president of clinical affairs and Jeff Thiel vice president of operations. Previously, Podichetty served as vice president of global clinical and regulatory affairs at IRRAS; Thiel was president and chief executive officer of Devax.

**Mitsubishi Tanabe**
Gustavo Suarez Zambrano has been named vice president of medical affairs at Mitsubishi Tanabe Pharma America, Inc. Previously, Suarez Zambrano served as the lead medical director, U.S. clinical development and medical affairs for Novartis.

**Neurogene**
Christine Mikail has been named president at Neurogene. Previously, Mikail served as the principal for Ferndale Advisors and an adjunct professor at Rutgers Business School.

**Nimbus Therapeutics**
Nimbus Therapeutics has appointed Christine Loh senior vice president, head of biology. Previously, Loh was vice president of translational medicine at Kymera Therapeutics.

**Noven Pharmaceuticals**
Noven Pharmaceuticals has named Ruhito Higo as chief executive officer. Higo most recently served as head of research and development at Hisamitsu, Noven’s parent company.

**Omega Therapeutics**
Mahesh Karande has been named president and chief financial officer at Omega Therapeutics. Karande most recently served as president and chief executive officer of Macrolide Pharmaceuticals and as an executive at Novartis AG.

**OnKure**
James Winkler has been named vice president of discovery and translational biology and Michael Carruthers has been named chief financial officer at OnKure. Winkler was vice president of discovery and translational biology at FORMA Therapeutics. Carruthers was previously with Nivalis Therapeutics where he served as interim president, chief financial officer and secretary.

**OS Therapies**
Robert Petit has been named chief medical and scientific advisor. Petit most recently served as chief science officer for Advaxis.

**Oyster Point Pharma**
Dan Lochner has been named chief financial officer and John Snisarenko has been named chief commercial officer. Lochner was most recently managing director at Goldman Sachs; Snisarenko was group vice president and head of ophthalmic business at Shire, now Takeda.

**Passage Bio**
Gary Romano has been named chief medical officer at Passage Bio. Romano previously led Janssen research and development as the head of clinical development for neurodegenerative disease and deputy leader of the neurodegenerative disease therapeutic area.

**Precision BioSciences**
David Thomson was named chief operating officer at Precision BioSciences. Thomson most recently served as chief development officer at the company since 2017.

**SOPHIA Genetics**
Gaëtan Fraikin and Sergei Yakneen have been named chief marketing officer and chief information officer at SOPHIA Genetics. Fraikin’s most recent appointment was with Roche where he was head of global marketing, digital & brand, clinical sequencing solutions. Yakneen was previously senior technical officer with EMBL in Germany.

**Thrive Earlier Detection**
Thrive Earlier Detection has named Seema Bhan senior vice president of public policy and external affairs. Bhan most recently served vice president and head of public policy for Foundation Medicine.

**Vivex Biologics**
Peter Wehrly has been named chief executive officer of Vivex Biologics. Wehrly was previously executive chairman of the board at Synaptive Medical.
Features

FDA Urges More
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sors, says Barbara Blumenfeld of Buchanan Ingersoll & Rooney PC.

“There’s understandably been some hesitation from what I have heard from some entities to come forward to FDA,” she said, because “sometimes you might be afraid to hear the answer.” Sponsors should view the FDA as a partner in their development plans, rather than see the agency as a watchdog.

Clinics and physicians using regenerative medicine therapies should think about starting their own investigator-initiated research projects, applying to the FDA for an investigational drug or biologics license and actually conducting a clinical trial, Blumenfeld says. “I think really what it boils down to is that anyone involved, including physicians, have to take an honest look at the practices that they’re engaged in.”

In addition to promoting valid regenerative medicine trials, regulators are concerned that the term “clinical research” may be misused to market untested treatments that don’t meet regulatory standards, Blumenfeld says. The federal database ClinicalTrials.gov is considering changing the way it characterizes its listings to clarify the difference between listings of legitimate trials that are part of an FDA-granted investigational new drug or biologics license application and listings by for-profit stem cell clinics that aren’t conducting sanctioned research.

Some clinics may submit listings to the database just to say that “Hey, we have a trial listed here, and therefore, it’s great,” Blumenfeld says. The concern is that such listings on a federally sponsored database could imply federal government endorsement or approval.

“What it boils down to is that anyone involved, including physicians, have to take an honest look at the practices that they’re engaged in.”

—Barbara Blumenfeld, Buchanan Ingersoll & Rooney PC

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Expert Q&A  
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or perceptions associated with a specific pharmaceutical company to be masking the types of data that we collect on the actual protocol. The exception to that is if you’re looking to collect perceptions on competitive trials and you know, for example, that a patient community is very well aware of maybe just a few pharmaceutical companies working in that space, then maybe it makes sense to unblind it to understand where their perceptions are of your pharmaceutical organization versus some of the competitor trials.

Question: Beyond feedback on patient perspectives that you receive from sites, what other insights can be garnered from doing a more general patient insights initiative?

Kaye: When you’re collecting patient perspectives, in terms of hearing directly from sites what patients are saying, you’re really only getting one part of the story because you’re only getting a small percentage of patients that actually even make it to the site or are under the care of the specific investigators that you might be working with. There’s a whole community, globally, that can really be leveraged to understand patients in a more holistic way.

There are a couple of different common initiatives or themes of data that we collect. One is collecting patient feedback on protocol design. How do you minimize the patient burden? How do you ensure that patients are going to be willing to enroll in this study?

We can also look at a patient insights initiative as it relates to patient relevant trial endpoints. So, identifying information that is most important to patients related to treatment, benefits, risk, burden and how to best communicate information to them to support their decisionmaking. This, along with all of the patient voice insights projects or patient voice incorporation, is something that the FDA is now looking for in developing guidelines.

Question: What are the most important questions to include in the site feasibility questionnaire?

Carozza: The complexity of protocols these days really necessitates that we look at experience in a different way. It’s no longer just about how many trials you’ve done, but really which ones you have done relative to the study that you are being evaluated for.

Of course, we do want to be asking about depth and breadth of experience within the therapeutic area and indication, but we also need to be thinking about expanding our pool of potential investigators and sites with personnel who are really passionate about the research and the patients, especially in some of these novel approaches.

But if we’re talking about the questionnaire itself, use the site profile information that you have with whatever partner you are working with. Here at WCG, we’re working very hard to expand the data that we’re collecting on our investigators and our institutions and facilities so that the questionnaires can really be very focused on just the study-specific information that we would need to ask in the moment.

So, of course things like estimated enrollment on the patient funnel for the target population, any concerns about the study design or how much work that a site does in the indication annual basis — those would definitely be the objective questions that I would always want to see asked in an operational feasibility process. Use and reuse as much as you can when it is facility and investigator profile-related. Consider it more of data collection than question asking.

Question: What is the best way to get a site to give actual data on their feasibility questionnaire and not just guess?

Carozza: An important aspect of this is for sites to know that, more and more, their qualification is being targeted based on the historical performance metrics that may exist in a public forum. We need to move in the direction of having sponsors come prepared to discuss the expectation based on that enrollment projection that they have worked out. I think the site has to be prepared then to be able to show evidence through their access to their EHR or to their locally kept databases. I just think there’s a risk for the site to guess, because we’re starting to all get more informed. And so now, maybe, we have to start to shift the way we ask the question, where sponsors have to share what their knowledge is, that sites may not have that perspective.

So, I challenge sponsors to be more transparent about the methodologies that they’re using to come up with their enrollment targets, and sites to be extremely honest and transparent. Because I’ve been doing this a very long time, and I will tell you, every time the sponsor will say they would rather have a site say that they can get five patients, and they turn out to be five valuable patients that will make it to the end of a trial, than for them to claim that they can get 10.
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<td>Neuralstem Inc.</td>
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<td>Oragenics, Inc.</td>
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