FDA Clarifies Stance on Clinical Trial Reimbursements for Patient Travel, Lodging

By Conor Hale

The FDA has updated its guidance to institutional review boards and clinical investigators clearly allowing reimbursements to patients in clinical trials for lodging and travel.

While paying subjects for participation in clinical research may raise difficult questions that should be addressed by an IRB, reimbursements for travel expenses to and from trial sites are not considered to raise issues regarding undue influence, according to the agency’s Office of Good Clinical Practice.

FDA Commissioner Scott Gottlieb highlighted the new passage in the guidance on travel reimbursement, saying the agency hopes “this clarity encourages recruitment in clinical trials.”

Contract Delays and Legal Negotiations Become a Growing Concern in Global Site Selection

The largest pain points in global clinical site selection no longer focus just around randomization times and patient recruitment, but have broadened to include slow contract turnaround and legal negotiations.

Total spending on study startups totals over $2.7 billion, and can account for around 19 percent of a sponsor’s expenditures, said Brooke Millman, WCG’s vice president of consulting solutions, during her webinar Strategies that Inform Investigator Selection and Enhance Enrollment.

Site contracting alone accounts for more than $350 million annually, making budget considerations a much larger sticking point in negotiations.

To help speed contract turnaround and site startup, Millman recommended that sponsors employ a team of global contract negotiators and develop site-specific contracts prepopulated with a range of applicable legal terms. In addition, country-based budget templates can be used to cover non-procedural items, such as overhead costs, site start-up fees and pharmacy setup and maintenance.

Millman identified the main methods that sponsors can employ to improve contract negotiation timelines: work with teams that have international regulatory expertise to deliver a legally sound site agreement; spending time prior to negotiations to build and capitalize on pre-existing relationships.
Gottlieb Outlines the FDA’s Future Approach to Precision Medicine in Davos

The FDA plans to base future approvals of precision medicines largely on clinical trials that examine long-term durability and safety issues, Commissioner Scott Gottlieb said during a panel discussion at the World Economic Forum in Davos, Switzerland. Gottlieb said the key regulatory issues will be less about determining efficacy, especially with products demonstrating a strong proof-of-principle and early observations of effectiveness in small trials — and instead more focused on product issues related to potential off-target effects and their implications. The agency will also seek accelerated approvals for precision medicines designed to optimize benefits for particular groups of patients, especially through genomic or molecular profiling. “I think we’re really at an inflection point right now, where we’re… defining the modern rules for how these technologies are going to be regulated,” he said. “We’re going to be looking at accelerated approval endpoints for earlier approval on questions of efficacy, with more vigorous long-term follow up in some of these constructs where we have authority to do that under accelerated approval.”

Federal Lawsuit Claims FDA Inspection Negligence Hurt Research Firm’s Reputation

A drug research firm is suing the FDA for $50 million in federal court, arguing an agency disciplinary letter led to the “annihilation” of the company’s reputation and finances, including the scuttling of the company’s potential sale, based on evidence fabricated by a rogue employee. In September 2015, FDA staff inspected Semler Research Center’s drug testing facility and corporate offices in Bangalore, India, finding a spreadsheet they described as evidence of data manipulation for five studies. According to the complaint, the FDA notified drugmakers in April 2016 that the company’s clinical and bioanalytical studies were “not acceptable as a result of data integrity concerns” and began requesting information from customers who had undertaken studies with Semler. These actions led the European Medicines Agency and the World Health Organization to withdraw approvals of generics whose studies were conducted by Semler, the complaint said, with the exception of drugs serving immediate needs such as HIV and malaria. Semler claimed the data was entered by an “unauthorized, unknown person,” and the information was “verifiably inaccurate and non-representative of the study data.” The lawsuit accuses the FDA of negligence for failing to properly investigate the spreadsheet’s authenticity.

FDA’s Oncology Center of Excellence Marks First Anniversary

In its first year, the FDA’s Oncology Center of Excellence (OCE) has worked to coordinate cancer treatment reviews across the agency’s product centers, centralizing clinical assessments to help expedite development and speed approvals as research advances. “In this new era of cancer therapeutics development, biologic products like gene and cellular therapies and vaccines, and devices like next-generation sequencing in vitro diagnostics, are increasingly being integrated with drug therapies into patient care,” wrote OCE Director Richard Pazdur on the center’s anniversary, following 16 new approvals in 2017, including the first cell-based gene therapies and tumor site-agnostic treatments, as well as 30 supplemental approvals, two biosimilars and multiple in vitro diagnostics. The OCE has scheduled a public listening session for March 15 to hear recommendations from the industry regarding their expectations of the center, specifically, what stakeholders desire in terms of structure, function, regulatory purview and activity.

FDA Says Sponsors Seeking QIDP and Fast Track Designations Must Apply for Both

Drug sponsors seeking the FDA’s Qualified Infectious Disease Product and Fast Track designations for antibiotics undergoing clinical trials must specifically request both designations, according to a new draft guidance from the agency. The QIDP designation makes a drug eligible for Fast Track and Priority Review, and also extends exclusivity for five years upon approval. Sponsors can request the designation prior to submitting an IND, but a request for Fast Track may only be made concurrently with or after an IND. An efficacy supplement to an NDA may also be granted the five-year exclusivity extension, if the supplement is for an indication that has already received a QIDP designation, and if the supplement qualifies for three-year exclusivity or orphan drug exclusivity. The FDA’s full question-and-answer guidance is available here: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm594213.pdf.
Patient Reimbursement (continued from page 1)

“IRBs should be sensitive to whether other aspects of proposed payment for participation could present an undue influence, thus interfering with the potential subjects’ ability to give voluntary informed consent.”

—FDA Guidance

for someone and their spouse and two nights in a hotel.”

For instance, a study on hypertension may have many potential participants available locally; studies in Duchenne muscular dystrophy patients carrying a particular genetic mutation, however, would require a larger recruiting footprint, she said, meaning a higher likelihood of paying travel expenses.

In contrast to reimbursement, the guidance states that ethics reviews should continue to examine how much compensation participants receive, including for reasons such as time, inconvenience or discomfort.

“IRBs should be sensitive to whether other aspects of proposed payment for participation could present an undue influence, thus interfering with the potential subjects’ ability to give voluntary informed consent,” the guidance said, adding that payments should be just and fair.

IRBs should receive the amounts and schedule of all payments, including end-of-study bonuses, during the initial review to ensure that they are not coercive according to federal regulations, including 21 CFR 50.20, the agency said. All information concerning payment should be spelled out in the informed consent document.

Credits for payment should accrue as the study continues, and not be contingent on study completion; however, a small proportionate payment to incentivize completion is acceptable, as long as it is not coercive, according to the guidance.

The question of what type of reimbursement crosses the line into undue influence or coercion has typically caused more stress for sponsors and researchers than IRBs, McNair said.

By comparison, IRBs — as well as Phase I research units with experience recruiting healthy volunteers to studies — all have a pretty good idea of what kind of compensation amounts will be considered appropriate.

“It's something they've been very used to considering,” McNair said. “We very rarely see anything come through where we need to push back on a payment plan,” especially in a study that an IRB has already decided has a reasonable risk.

Many research organizations and sponsors keep payment schedules — detailing how much they compensate for blood draws, nights spent in the clinic and other study procedures, for example — creating a guide to what they know IRBs have considered appropriate in the past.

But sponsors in all phases of clinical trials can be very concerned with the optics of offering patients money to participate in research, and often seek IRB input.

The FDA guidance is a welcome update, McNair said. “It’s nice to have them explicitly clarify the difference between compensation and reimbursement.”

“The previous guidance didn’t really separate those two things out, and I think it did cause some confusion to people in trying to plan what they wanted to do in a study,” she said, adding that it probably won’t change how IRBs weigh the issue.

When examining a submission, the boards typically break those two considerations apart to judge them individually, even if the two are not explicitly described by the sponsor in the protocol or consent form.

“We do think it’s generally appropriate for people not to have to pay out-of-pocket expenses to participate in research,” said McNair. “We don’t want the subject to incur those expenses, and we also look at it from the concept of justice and equitable subject selection.”

If only the people who can participate in research are those who can afford the travel expenses upfront, that could greatly limit who can be recruited into a study, she said.

The larger issue of research subject compensation has had a tremendous amount of discussion in the IRB space, and how study protocols should balance the issue of undue influence and respect for patients.

The full FDA guidance is available here: https://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm.
with sites; use harmonized tech solutions to track progress throughout the organization; and data-driven country selection.

“When we think about the consideration of which countries would be most impactful to our enrollment, there are a couple of different factors that we take into consideration,” added Suzanne Caruso, WCG’s vice president for clinical solutions. “One, of course, is how many investigators in the population of that particular country are able to enroll the particular study.”

Increasingly, however, sponsors are paying attention to the amount of time needed to settle on clinical trial agreement and any ancillary negotiations. “You cannot begin a study without a contract,” Caruso said.

For example, if it takes 130 days on average to open a site in Poland and 75 in Spain, with both offering the same patient population, “why wouldn’t you choose to go to Spain?” she asked. Other country-specific factors can affect the budget, such as requirements in Brazil that any woman of child-bearing age has to be on birth control for the duration of the study.

“Every single step we take together impacts the enrollment timeline, and impacts your time to database lock if you’re the sponsor,” Caruso said. “And for the site, it impacts how many patients potentially could get on a study, especially in situations that are life-threatening, where this may be a last resort for some of these particular patients.”

### New MIT Study Puts Clinical Research Success Rate at 14 Percent

**By Conor Hale**

Nearly 14 percent of all drugs in clinical trials eventually win approval from the FDA — a much higher percentage than previously thought, according to a new study from the MIT Sloan School of Management.

Approval rates ranged from a high of 33.4 percent in vaccines for infectious diseases to 3.4 percent for investigational cancer treatments. Previous estimates placed overall success rates, from Phase I through to FDA approval, between 9 and 11 percent.

In addition, the study found that trials that used biomarkers to stratify patients tended to be more successful than those that did not, pointing to the growing role of companion diagnostics in improving clinical trial success rates and future designs.

The MIT study, published in the journal Biostatistics, has broad implications for investors, regulators, policymakers and clinicians in calculating the probability of the success of investments in drug development programs.

“Without accurate and timely estimates, resources may be misallocated and financial returns may be misjudged, which leads to higher development costs, higher-priced drugs, and lost opportunities for investors and, more importantly, patients,” said study author Andrew Lo, director of MIT’s Laboratory for Financial Engineering.

While approval rates fell between 2005 and 2013, they have trended upward since. Oncology, for example, had the lowest overall approval rate, but estimates increased to 8.3 percent in 2015, partly due to progress in the development of immunotherapies, the university said.

The research was based on Informa’s Citeline dataset, which contains more than 400,000 entries corresponding to 185,994 unique clinical trials of over 21,000 compounds. Automated algorithms traced each drug’s development path, and determined the probability of success within a matter of hours, MIT said. By comparison, ClinicalTrials.gov contains over 217,000 clinical trial entries.

“We hope to provide this information on a regular basis — it’s not just a one-shot deal,” Lo said.

“As clinical trial success rates improve for certain diseases, it’s likely that more investment capital will flow into those areas.”

— Andrew Lo, MIT

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At some point, we have all had to make hard decisions to remedy an issue impacting an important process. Whatever the circumstance surrounding the decision, personal or professional, borne of opportunity or duress, the decision will create some degree of hope or discomfort for those involved.

The field of clinical research is no exception. Every study leader, clinical research associate (CRA), investigator or study coordinator who cared about making the right decision, has made that hard decision; whether to protect a study patient, to address conflict at study sites or within study teams, or when dealing with questionable data the decisions with consequence.

When I was a relatively new CRA, I was faced with a very difficult decision. It was the right decision, but there were consequences.

Over 10 years ago I was assigned to help monitor a global dermatology study that had experienced high CRA turnover. The investigational sites had continued to enroll patients without regular monitoring visits, and a large amount of screening/enrollment/visit data lay unreviewed. The imminent priority was to quickly retrieve the latent data and get the sites back on a regular monitoring schedule.

I completed a series of focused, one-off monitoring visits at sites that had not had a monitoring visit in months, and felt understandably neglected by the study team. Though they were bursting at the seams with accumulated data and study drug, they were not always motivated to fit me in for a last-minute monitoring visit.

I was instructed by the project manager to conduct a high-priority monitoring visit at a dermatology practice in the southeast. They had enrolled five new study patients and had replaced their study coordinator in the time period since their last monitoring visit. It was, therefore, critical to visit the site to review data and verify their continued capability for study conduct.

I contacted the study coordinator, introduced myself and apologized for the lack of appropriate monitoring. I explained the importance of visiting the site as soon as possible to retrieve the study data and assist the site with any issues or questions they had. The study coordinator was surprisingly sympathetic and accommodated a two-day monitoring visit for the following week.

When I arrived at the site, the study coordinator escorted me to a monitoring room overwhelmed with study records and disorganized regulatory binders. I began review to the informed consents and screening data for the newly enrolled patients. The central IRB approved consent form required investigator signature, in addition to signature of the “individual obtaining consent.” To my dismay I discovered that the investigator had neglected to sign any of the informed consents; this important action was overlooked for all new patients.

After reviewing patient data, and discovering many protocol deviations, I began the cumbersome task of drug accountability. The site had enrolled a total of 15 patients, and drug accountability had not been completed in months. Study drug and matching placebo were packaged in blister packs, and used/returned drug had been piled into a corner of the room. It was a daunting task to try and reconcile drug accountability log entries with returned study drug when the accountability logs were missing entries or had indecipherable data; some entries had been crossed out, or changed, but were missing the required initials and date of the individual making the change, and thus could not be authenticated.

The final straw was a missing shipment of study drug from a locked drug storage room. The study coordinator assured me that all used study drug was in the monitoring room and unused study drug was safely locked in the drug storage room. The site had received 10 kits of study drug that I could not locate. I checked every inch of the IP storage room and the box of returned blister packs with no success. I could not even find the drug requisition form to confirm the site had received the drug. Puzzled, I decided to ask the study coordinator for help, but when I called her she did not answer her phone. When I walked to the lobby to ask the receptionist to page her, I could not believe my eyes. The missing blister packs had been placed alongside the regular commercial drug samples, on open shelves in the practice lobby. There was no separation from investigational product and commercial drug and it was the antithesis of secure, limited access.

I left a note on the study coordinator’s desk, requesting her to find me upon her return, and returned to the monitoring room with a sinking feeling. This was the worst situation I had encountered as a CRA.
ever encountered as a monitor. It would take much more than a two-day monitoring visit to get this site back in shape. Though it was a difficult decision, I knew I had to speak to the investigator about the findings and escalate immediately to the project manager. I was not looking forward to the difficult conversations the severity warranted.

When the study coordinator returned, I informed her of the informed consent, and data and drug accountability findings. I showed her the location of the study drug shipment and advised her to move it to the storage room as soon as possible. Her defensive response lacked concern and initiative. She blamed her predecessor for the problems and even took a personal phone call in the middle of our conversation. So much for the anticipated teaching moment.

My discussion with the investigator was equally fruitless. He only had 10 minutes to spare between his afternoon clinic patients and maintained an unreadable expression while I recounted the findings. Before my recommendation for corrective action, his cell phone buzzed and he rushed out of the room with a patient emergency. He requested I email him the remaining items for discussion. While I had avoided an unpleasant conversation, his lack of response belied a level of apathy that was much more concerning than any confrontation would have been.

That was the moment I knew I needed to contact the project manager as soon as possible to escalate my findings. It would take two to three monitors and at least a week on site to get through the rest of the patient charts, drug accountability and issue resolution, and that was only if the site were not enrolling patients. The investigator was clearly an absent leader who left study conduct to an overwhelmed, inexperienced study coordinator. The sponsor could decide to halt enrollment at the site through the cleanup period, or close them altogether. I could survive the knot in my stomach, with potential site reaction. But making the easy choice to avoid the difficult conversations, and letting the project manager talk to the investigator, was no choice when it involved patient safety and data quality.

Elizabeth Blair Weeks-Rowe, LVN, CCRA, has spent nearly 14 years in a variety of clinical research roles including CRA, CRA trainer, CRA manager and clinical research writer. She also is author of the novella Clinical Research Trials and Triumphs. Currently she works in relationship development/study startup in the CRO industry. Email ebwcra@yahoo.com or tweet @ebwcra.

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## Drug & Device Pipeline News

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Elite Pharmaceuticals Reports Positive Topline Results From SequestOx Pilot Study

Elite Pharmaceuticals reported positive topline results from a pilot study conducted for SequestOx, Elite’s immediate release Oxydodon Hydrochloride product that incorporates its proprietary abuse-deterrent technology. An objective of the study was to assess whether the reformulated SequestOx could achieve a Tmax (the mean or median time to the maximum drug concentration in subjects) comparable to the reference drug, Roxicodone, when dosed with the standard high fat meal specified by the FDA. As opposed to the earlier formulation, based on pilot results, the modified SequestOx is expected to achieve bioequivalence with a Tmax range equivalent to the reference product when conducted in a pivotal trial under fed conditions. Elite intends to review with the FDA the study results and discuss the pharmacokinetic study requirements for a re-submission of the NDA. The study was a Phase I pilot, randomized, single-dose, single period, pharmacokinetic study in healthy male and female volunteers in the fed state.

Sunovion’s Parkinson’s Drug Succeeds in Late-Stage Trial

Sunovion Pharmaceuticals announced topline results from its pivotal Phase III, randomized, double-blind, placebo-controlled clinical trial, CTH-300, that evaluated apomorphine sublingual film (APL-130277) in patients with Parkinson’s disease (PD) who experience motor fluctuations (OFF episodes). The Phase III study met its primary endpoint, with initial results from 109 adults with PD showing that individuals with OFF episodes who received apomorphine sublingual film demonstrated a statistically significant mean reduction in the Movement Disorder Society Unified Parkinson’s Disease Rating Scale (MDS-UPDRS) Part III score from pre-dose to 30 minutes after dosing at week 12 compared with the placebo group, with effects persisting until the last observed time point at 90 minutes. The difference in MDS-UPDRS Part III score change from baseline 30 minutes after dosing between apomorphine sublingual film and placebo was 7.6 (p=0.0002). Apomorphine sublingual film was generally well-tolerated in the study population. The most commonly reported treatment-emergent adverse events during both the titration and maintenance treatment phases were nausea (27.0 percent), somnolence (14.9 percent), dizziness (14.2 percent), yawning (12.8 percent) and headache (9.2 percent).

Positive Data From Adocia’s Dose-Proportionality Study

Adocia announced positive topline results from a Phase Ib clinical trial evaluating the dose exposure and dose response relationships of BioChaperone Combo 75/25 at three different doses in people with type 2 diabetes. BioChaperone Combo is a proprietary formulation combining basal insulin glargine (active ingredient in Lantus, Sanofi and Basaglar, Eli Lilly) and prandial insulin lispro (active ingredient in Humalog, Eli Lilly and Admelog, Sanofi). This study aimed to document the dose exposure relationship of BioChaperone Combo in people with type 2 diabetes. In the double-blinded, randomized, four period cross-over trial, using automated 30-hour euglycemic clamp, 32 participants with type 2 diabetes mellitus were randomly allocated to a sequence of four treatments, i.e. one of three single doses of BioChaperone Combo 75/25 (0.6 U/kg; 0.8 U/kg or 1.0 U/kg) or one single dose of Humalog Mix25 at 0.8 U/kg. The primary endpoints were the assessments of dose-proportionality for total insulin exposure (AUCtotal_insulin 0-last) and maximal observed total plasma insulin concentration (Cmax) across three doses of BioChaperone Combo. Both primary endpoints were met (AUC0-last overall dose exposure slope 0.93; 95% confidence interval [0.58; 1.29]; Cmax overall dose exposure slope 0.80, 95%CI [0.43; 1.17]) and a dose-proportionality relationship was demonstrated for all exposure pharmacokinetic parameters assessed in the early, intermediate and basal phases.

Cerus Reports Results from INTERCEPT Study

Cerus reported that the primary efficacy and safety endpoints were successfully achieved in the company’s Phase III transfusion study of chronic anemia evaluating INTERCEPT-treated red blood cells (RBCs) in thalassemia patients, SPARC. A total of 86 patients were enrolled at three participating international sites in the double blinded, cross-over study. Subjects were randomly assigned to a sequential treatment period of either INTERCEPT-treated RBCs or conventional RBCs with cross over to the other treatment upon completion of the first treatment period. The study’s primary efficacy endpoint used a non-inferiority design to assess up to a 15% relative difference in the mean consumption of hemoglobin between INTERCEPT-treated RBC and conventional RBC.
Upcoming Event Highlights

Conferences
FEBRUARY 13-18, 2018
Scope Summit for Clinical OPS Executives 2018
SCOPE will offer three days of in-depth discussions in 18 different conferences, three plenary keynote sessions and interactive breakout discussions focused on advances and innovative solutions in all aspects of clinical trial planning, management and operations.
Orlando, FL
[ VIEW ALL CONFERENCES ]

Webinars
FEBRUARY 22, 2018
Improving Your Feasibility Selection
This session is perfectly suited to those dealing with site selection feasibility.
[ VIEW ALL WEBINARS ]

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MARCH 6-8, 2018
FDAnews ICH E6 GCP Interactive Workshops
Get all the ICH E6 (R2) training you need with three days of hands-on workshops aimed at helping you understand and comply with new requirements.
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Impel NeuroPharma
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The West Virginia University Research Corporation (WVURC)
Morgantown, WV

Clinical Trials Coverage Analyst
Rush University Medical Center
Chicago, IL

Experienced Research Coordinator
West Broward Research Institute, LLC
Ft Lauderdale, FL

Senior Clinical Research Coordinator
Elligo Health Research
Cincinnati, OH

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Leidos Biomedical Research, Inc.
Frederick, MD

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Apex Life Sciences
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Senior/ Clinical Data Coordinator
Loxo Oncology
San Francisco, CA

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Academic Programs

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