Gaps and gray areas in federal training requirements wind up putting pressure on principal investigators when the burden rightly belongs on sponsors’ shoulders.

But in practice, says Jan S. Peterson, vice president of regulatory affairs and quality for Global Regulatory Partners, investigators may find themselves taking on responsibility for training the rest of the staff.

In the face of minimal guidance from the FDA or ICH, “the sponsor should be driving this training/training documentation issue using clear, written requirements,” Peterson says. Investigators and sites should be prepared to walk away if they don’t get sufficient guidance and time to train properly.

FDA regulations say only that sponsors must hire investigators “qualified by training and experience.” The ICH E6 GCP guideline says investigators must ensure that all trial staff are “informed about their obligations.”

“If the PI feels there’s inadequate training,” says Dalfoni Banerjee, CEO of 3Sixty Pharma Solutions, “that could mean there are systemic problems in the trial. A lot of systemic problems begin with a simple one: less than effective communication.”

Banerjee says sponsors can open up — and sustain — lines of communication by beginning a trial with a survey of the PIs. Questions such as, “What are your expectations for this trial?” or “What tools do you need for a successful trial?” can bring back see Staff Training on page 3

New Collaboration Aims to Use Advanced Data Analysis to Speed Trials

By Bill Myers

A Michigan CRO is teaming with MIT’s Computer Science and Artificial Intelligence Laboratory and the University of Maryland’s Center for Transitional Medicine (CTM) to create what organizers are calling “a supergroup” that will help speed drugs through the clinical trials pipeline.

Officials at MMS Holdings of Canton, Mich., MIT and Maryland’s CTM call their new venture the Health Analytics Collective. Its goal is to help use data — particularly real-world data — to help cut down on the time spent in trials, to augment label claims and to support new drug applications.

The group wants to merge real-world evidence and observational evidence from routine clinical practices with patient healthcare databases. The venture will rely on MIT’s Julia programming language, which is designed to whiz through complicated computational problems quickly.

Julia, organizers hope, will help the group sift through massive amounts of data quickly to help compare effectiveness claims of a given drug against similar compounds, to help put together efficacy or safety data on a drug or device, to assess treatments already on the market, to sniff out treatment gaps and to help evaluate patient risk quickly. It’s all to, as organizers say, “guide a company’s business decisions with insights into a potential asset’s life-cycle management and due-diligence efforts.”

see Speed Trials on page 4

Join the CenterWatch Community!
Genentech Pulls Plug on Two Alzheimer’s Trials
Genentech has closed two large Phase III trials for its once-hyped anti-Alzheimer’s drug crenzumab after an independent data monitoring committee warned the company that crenzumab wasn’t likely to hit its primary endpoint.

The CREAD 1 and CREAD 2 trials had enrolled 1,500 patients worldwide, all of them in the early stages of Alzheimer’s disease, and offered patients doses four times higher than in the Phase II trials that had showed promise in helping patients.

But Genentech, a subsidiary of Roche, announced last week that its IDM committee told them the drug didn’t seem to be improving patients’ scores on individual cognitive tests.

Genentech officials acknowledged the “disappointing” results but said that they’re still studying crenzumab in an ongoing trial of clinically healthy patients in Colombia who carry the genetic mutation associated with heritable Alzheimer’s.

J&J Scores on Phase III Metastatic Prostate Cancer Trial
Johnson & Johnson says it has scored another victory for its anti-cancer drug Erleada (apal tamide), this time in patients with metastatic prostate cancer.

The FDA approved Erleada for non-metastatic prostate cancer in February 2018. Last week, Johnson & Johnson subsidiary Janssen Pharmaceutical Companies announced that its Phase III TITAN trial of Erleada and a combination of androgen-deprivation therapy had met its two primary endpoints — radiographic, progression-free survival and overall survival.

The specific numbers weren’t released but Johnson officials promised to unveil them “at an upcoming medical congress.”

TITAN was a Phase III, randomized, placebo-controlled, double-blind study in men newly diagnosed with metastatic disease. More than 1,050 men were given either Erleada plus androgen depravation or a placebo with androgen depravation. The men were treated until the disease progressed, until they suffered from drug toxicity, or until they chose to stop treatments.

Erleada is an androgen receptor inhibitor and the first of its kind to win FDA approval for non-metastatic, castration-resistant prostate cancer.

Startup Launches Drug Development Program, Will Donate Rights to Nonprofit
Clinical trial service provider Notable Labs is making its first foray into research with a new investigational leukemia drug and plans to sign over rights to the pediatric treatment to the nonprofit group Cures Within Reach.

Notable has developed its own compound, ND-1000, as a treatment for adult and pediatric leukemia and blood cancers.

Under the FDA’s pediatric priority review voucher program, Notable will be able to donate its commercial rights to price, manufacture and distribute the pediatric form of ND-1000 to the nonprofit, whose mission is to match existing drugs and devices to applications for unsolved diseases.

Baylor Offers New Surrogate Endpoint for Prostate Cancer Survival
Researchers at Baylor University believe they’ve zeroed in on a surrogate endpoint for survival outcomes for prostate cancer patients: the time to biochemical failure in the disease.

The team analyzed data from the Phase III NRG Oncology/Radiation Therapy Oncology Group 9202 trial, which included about 1,500 men with localized, high-risk prostate cancer. The trial tested two treatments treatment — short-term and long-term androgen deprivation therapy.

Biochemical failure — defined as three consecutive rises in a patient’s prostate-specific antigens — seemed to track along four distinct time landmarks — 12 months, 24 months, 36 months and 48 months after the men completed radiation (or two years after the long-term group completed their androgen-deprivation). The trial found long-term androgen deprivation improved the men’s survival rates.

The 24-month biochemical failure status was an accurate predictor of the two different clinical outcomes. The predictive power was even stronger at 36 and 48 months.

Staff Training
continued from page 1

all sorts of useful data on PIs’ needs and concerns, especially regarding training gaps.

Sponsor training programs may not completely satisfy the FDA’s idea of adequate training, however. All parties involved in a trial should keep their eyes on that elusive definition, Peterson recommends. “Consider how regulators are likely to look at training documentation. Regulators, or trial monitors, or auditors, are likely to seek evidence that study employees were trained and qualified for their work,” he says. “It’s always a ‘show me the documentation’ world.”

David Borasky, vice president for IRB compliance at WCG Clinical, says most IRBs have “a baseline expectation” that site staff have at least a basic training on human subjects research.

“There are numerous options, and some IRBs will accept several, and others are more restrictive,” Borasky says. “This also goes for retraining requirements.”

He adds that “GCP training is similar, but with that different angle that ICH GCP is not the same as research ethics. It’s really about running a clinical trial to a certain standard, and the primary overlap is in requirements for IRB review and consent, which is covered in human subjects training. Human subjects training typically doesn’t linger on ICH GCP things like record keeping and documentation practices. In the world of sponsored research, this is really more of a sponsor or institutional prerogative than an IRB prerogative.

A growing number of investigators have expressed concern about the gaps in training requirements and training standards that may have a long-term effect on the industry. The constant back-and-forth among sponsors, CROs and sites on what and how to train is creating burnout that investigator advocates call “the one-and-done” problem — PIs that have a bad first trial experience aren’t willing to take on another.

The broader industry is taking notice of the problem. Late last year, the Association of Clinical Research Professionals announced it was drafting recommendations for clearer training rules. Days later, the Clinical Trials Transformation Initiative (CTTI) offered recommendations of their own. Both efforts carried the tacit approval of FDA officials (CenterWatch Weekly, Dec. 3, 2018).
Healthcare and pharma investments in Big Data are expected to reach $5.8 billion by the end of next year, MIT estimates.

The new collective was announced within days of a new trade group called Align Clinical CRO — consisting of most of the largest CROs in the market — offering up new operational data-sharing standards that the group hopes will simplify a traditionally thorny problem among sponsors, sites and CROs.

A typical trial spends between $50,000 and $200,000 just creating data extracts and data uploads — translating terms from site to sponsor and back again. Even a seemingly simple matter — such as determining when a site is “active” in a trial — can create complications.

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Exam for Continuing Education Research Practitioner 191, 3 Contact Hours

- **The issue of proper documentation in IRR liability**
- **Exam for Continuing Education**

**In this issue**

1. The undersecretary for Health Practices
2. The importance of proper documentation in IRR liability
3. The impact of IRR liability on research quality and integrity
4. The role of the IRB in ensuring proper documentation in IRR liability
5. The impact of IRR liability on research quality and integrity

- **Details**
  - Test: 20 multiple choices
  - Duration: 1 hour
  - Format: Multiple choice
  - Passing score: 70%
  - Exam fee: $191

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### Drug & Device Pipeline News

<table>
<thead>
<tr>
<th>Company</th>
<th>Drug/Device</th>
<th>Medical Condition</th>
<th>Status</th>
<th>Sponsor Contact</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dicerna Pharmaceuticals, Inc.</td>
<td>DCR-HBVS</td>
<td>chronic hepatitis B virus (HBV)</td>
<td>Phase I trial initiated enrolling healthy volunteers and subjects with non-cirrhotic chronic HBV</td>
<td>dicerna.com</td>
</tr>
<tr>
<td>Navitor Pharmaceuticals, Inc.</td>
<td>NV-5138</td>
<td>Treatment-Resistant Depression (TRD)</td>
<td>Phase Ib trial initiated enrolling up to 88 subjects, including healthy volunteers and those diagnosed with TRD</td>
<td>navitorpharma.com</td>
</tr>
<tr>
<td>Theravance Biopharma, Inc.</td>
<td>ampreloxetine (TD-9855)</td>
<td>symptomatic neurogenic orthostatic hypotension (nOH)</td>
<td>Phase III trial initiated enrolling 188 subjects with symptomatic nOH caused by primary autonomic failure associated with multiple system atrophy (MSA), Parkinson’s disease (PD) and pure autonomic failure (PAF)</td>
<td>theravance.com</td>
</tr>
<tr>
<td>Qualigen, Inc.</td>
<td>FastPack IP Sex Hormone Binding Globulin (SHBG) Immunoassay</td>
<td>diagnosis and treatment of men’s health</td>
<td>510(k) clearance granted by the FDA</td>
<td>qualigeninc.com</td>
</tr>
<tr>
<td>Merck</td>
<td>V114</td>
<td>prevention of invasive pneumococcal disease (IPD) caused by the vaccine serotypes in pediatric patients 6 weeks to 18 years of age</td>
<td>Breakthrough Therapy Designation granted by the FDA</td>
<td>merck.com</td>
</tr>
<tr>
<td>C2N Diagnostics</td>
<td>brain amyloidosis blood test</td>
<td>screening for brain amyloid pathology in individuals being assessed for an Alzheimer’s Disease diagnosis</td>
<td>Breakthrough Device Designation granted by the FDA</td>
<td>c2ndiagnostics.com</td>
</tr>
<tr>
<td>BiolInvnt International AB</td>
<td>BI-1206</td>
<td>mantle cell lymphoma (MCL)</td>
<td>Orphan Drug Designation granted by the FDA</td>
<td>bioinvent.com</td>
</tr>
<tr>
<td>Eureka Therapeutics, Inc.</td>
<td>ET140202 ARTEMIS T-cell therapy</td>
<td>AFP-positive patients with advanced hepatocellular carcinoma (HCC)</td>
<td>IND approval granted by the FDA</td>
<td>eurekatherapeutics.com</td>
</tr>
<tr>
<td>MGB Biopharma</td>
<td>MGB-BP-3</td>
<td>Clostridium difficile-associated diarrhea (CDAD)</td>
<td>IND approval granted by the FDA</td>
<td>mgb-biopharma.com</td>
</tr>
<tr>
<td>CorMatrix Cardiovascular, Inc.</td>
<td>Cor TRICUSPID ECM cardiac valve</td>
<td>adults with endocarditis and for pediatric patients with congenital heart valve disease</td>
<td>IDE approval granted by the FDA</td>
<td>cormatrix.com</td>
</tr>
<tr>
<td>Amerigen Pharmaceuticals, Ltd.</td>
<td>generic version of Shire’s Adderall XR (dextroamphetamine saccharate, amphetamine aspartate monohydrate, dextroamphetamine sulfate and amphetamine sulfate, extended-release capsules)</td>
<td>attention deficit hyperactivity disorder (ADHD)</td>
<td>ANDA approval granted by the FDA</td>
<td>amerigenpharma.com</td>
</tr>
<tr>
<td>Dr. Reddy’s Laboratories Ltd. and Promius Pharma, LLC</td>
<td>TOSYMRA (previously known as DFN-02)</td>
<td>acute treatment of migraine with or without aura in adults</td>
<td>NDA approval granted by the FDA</td>
<td>drreddys.com promiuspharma.com</td>
</tr>
<tr>
<td>AbbVie and Janssen Pharmaceutical Companies of Johnson &amp; Johnson</td>
<td>IMBRUVICA (ibrutinib) in combination with Roche’s obinutuzumab (GAZYVA)</td>
<td>adult patients with previously untreated chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL)</td>
<td>NDA approval granted by the FDA</td>
<td>abbvie.com janssen.com</td>
</tr>
</tbody>
</table>
Twice monthly, CWWeekly provides featured listings of clinical research job openings, upcoming industry conferences and educational programs from JobWatch, CenterWatch's online recruitment website for both clinical research employers and professionals.

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Jobs via Kelly Services

<table>
<thead>
<tr>
<th>Position</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research Associate</td>
<td>Gaithersburg, MD</td>
</tr>
<tr>
<td>Data Scientist I- Epidemiology and Health Economics</td>
<td>New Brunswick, NJ</td>
</tr>
<tr>
<td>Team Supervisor</td>
<td>Wilmington, MA</td>
</tr>
<tr>
<td>Senior Statistical Programmer</td>
<td>Seattle, WA</td>
</tr>
<tr>
<td>Clinical Data Associate I</td>
<td>Foster City, CA</td>
</tr>
<tr>
<td>Clinical Business Analyst</td>
<td>Lansdale, PA</td>
</tr>
<tr>
<td>Microbiologist</td>
<td>Miami Gardens, FL</td>
</tr>
<tr>
<td>CR45 - Medical Writer III</td>
<td>Pleasanton, CA</td>
</tr>
</tbody>
</table>

More Jobs

<table>
<thead>
<tr>
<th>Position</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manager, Clinical Operations</td>
<td>NantKwest, Cary, NC</td>
</tr>
<tr>
<td>Clinical Research Coordinator II</td>
<td>Emory University, Atlanta, GA</td>
</tr>
<tr>
<td>Clinical Trial Associate</td>
<td>TCR2 Therapeutics, Cambridge, MA</td>
</tr>
<tr>
<td>Clinical SAS Programmer</td>
<td>Lean-IT Solutions, Woodcliff Lake, NJ</td>
</tr>
<tr>
<td>Clinical Trials Assistant</td>
<td>Commonwealth Sciences, Canton, MA</td>
</tr>
<tr>
<td>Research Associate II</td>
<td>Kaiser Permanente, Fontana, CA</td>
</tr>
</tbody>
</table>

Academic Programs

<table>
<thead>
<tr>
<th>Program</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Boston College Clinical Research Certificate Program</td>
<td>Chestnut Hill Campus, Newton, MA</td>
</tr>
<tr>
<td>Drexel University College of Medicine Master's/Certificate Programs in Clinical Research Organization and Management</td>
<td>Online</td>
</tr>
<tr>
<td>University of North Carolina at Wilmington MS Clinical Research and Product Development</td>
<td>Online</td>
</tr>
</tbody>
</table>

Upcoming Event Highlights

Conferences

- **FEBRUARY 19-20, 2019**
  - Medical Device Risk Management
  - Atlanta, GA

- **MARCH 26-27, 2019**
  - Conducting Advanced Root Cause Analysis and CAPA Investigations
  - Raleigh, NC

- **MARCH 27-28, 2019**
  - ICH GCP E6 R2 Meeting CRO-Vendor Oversight Requirements
  - Raleigh, NC

- **APRIL 8-12, 2019**
  - FDA Compliance Boot Camp 2019
  - Frederick, MD

- **APRIL 15-18, 2019**
  - 18th Annual Design of Medical Devices Conference
  - Minneapolis, MN

- **APRIL 23-25, 2019**
  - Medical Device Quality Congress
  - Bethesda, MD

- **OCTOBER 23-25, 2019**
  - FDA Inspections Summit
  - Bethesda, MD

Webinars

- **FEBRUARY 13, 2019**
  - Building a World-Class Drug Supply Chain: Tips for Compliance and Digital Transformation
  - Evren Ozkaya — founder and CEO of Supply Chain Wizard, LLC — will discuss laying down a digital supply foundation with track-and-trace capabilities at the center of the systems and processes.
  - 2:30 p.m. – 3:30 p.m. EST