Protocol Problems Continue to Trip Up Investigators, FDA Data Show

By Leslie Ramsey

The most pressing compliance problem clinical trials have, data from the FDA show, continues to be following their protocols to the letter.

The agency’s report on inspection findings in fiscal year 2019 places “failure to follow investigational plan” at the top of the list of most frequently cited observations, a spot it has held for the past five years. But the numbers are dropping, from 171 citations in 2015 to 108 in inspections conducted in 2019.

Good news for trial staff is the fact that informed consent observations have dropped out of the top five entirely. “Consent form not approved/signed/dated” citations decreased by two-thirds since 2015 (15 citations), falling to only five in 2019 and dropping to the tenth most-frequent citation, according to data analyzed by CenterWatch.

Case history records also have proven problematic over the past five years, consistently holding the number two spot, but again falling in total numbers from 2015 (92 citations) to 2019 (54 citations).

Appearing in the top five for the first time in 2019 is “general responsibilities of sponsors,” an observation that encompasses failure to select or adequately prepare principal investigators, ensure proper monitoring of the trial or report adverse effects to the FDA and investigators. And while the “failure to follow investigational plan” observation is directed primarily at sites and investigators, this citation dings...

see Protocol Problems on page 5 »

Half of EU Cancer Trials Show Bias, Study Says

By Colin Stoecker

Half of all cancer drugs approved by the European Medicines Agency (EMA) from 2014 to 2016 were the result of trials that exhibited a high risk of bias and even exaggerated treatment effects, a new research study says.

Researchers at seven institutions in the U.S. and UK examined data from 39 studies resulting in EMA approvals following concern that new drug submissions in Europe lack enough scientific evidence to support approval. According to the study, risk of bias was seen in 19 of the oncology drug trials — in 10 trials owing to missing outcome data and seven due to the way outcomes were measured.

The study was tasked with examining the design characteristics, risk of bias and reporting adequacy of trials of oncology drugs approved by EMA in the three-year period. Oncology is the single largest category of drug approval in the EU. More than one-quarter of EMA approvals in 2017 were for cancer drugs.

Randomized control trials (RCT) comprised 76 percent of the study sample. Only seven approvals were supported by two or more RCTs. Researchers found an increasing percentage of cancer drugs are approved based on findings from non-randomized or single-arm trials, which made up 24 percent of the study sample.

Of the RCTs, 23 trials demonstrated deviations from intended interventions due to either lack of blinding or risk of compromised blinding...

see Half of EU Cancer Trials on page 5 »
First Right-to-Try CRO Launches

Florida-based Beacon of Hope is the first CRO to focus solely on right-to-try activities.

Launched this month, Beacon of Hope will help companies provide safe, ethical and legal patient access to their investigational treatments outside of traditional clinical trials. The CRO also will work with patients, support advocacy groups and educate the community on right-to-try issues.

The Beacon of Hope Patient Database will help match patients with sponsors conducting clinical trials on ALS and other life-threatening diseases.

The privately held CRO is headed by CEO Richard Garr.

Biogen Halts Another Trial Over Safety Concerns

Biogen continued its run of bad luck this week, halting another drug trial over safety concerns.

The termination of its human monoclonal antibody trial of BG00011 comes just days after the company closed three of its Alzheimer’s disease trials last week.

The trial of the drug to treat idiopathic pulmonary fibrosis was in phase 2 and was halted because it did not outperform the placebo arm.

New COA Development Projects in the Works

Three universities and one technology partnership are working on separate projects to increase the availability of clinical outcome assessments (COA).

The FDA has awarded a $4 million grant to the Albert Einstein College of Medicine, Duke University and Northwestern University to conduct projects on using patient input to inform selection of clinical outcomes.

The Einstein College of Medicine and Vector Psymetric Group will use their $1.29 million to standardize a set of endpoints and related COAs for migraine clinical trials.

Duke University will use their $1.4 million grant to identify COAs and endpoints for use in developing acute pain therapeutics in infants and children under two years old.

Northwestern will use $1.4 million to develop COAs across various chronic conditions that assess physical function severity.

In the corporate sector, tech company Medidata is partnering with Icon’s Mapi Research Trust (MRT) to add MRT’s library of COAs to a new collection of electronic questionnaires that will save trials the time required to create their own COAs.

The company estimates its Medidata Rave eCOA will help trials cut startup timelines by 50 to 60 percent by providing ready-made COAs in multiple languages.

The nonprofit MRT provides patient-reported outcomes data and has assembled a library of more than 470 eCOA forms and 7,000 translations representing 190 instrument developers.

Developer agreements in the database will be pre-approved so sponsors don’t have to seek approval to use a COA for each individual study.

Public Trust in Pharma at an All-Time Low, Says Gallup Poll

Americans feel that pharma is the least trustworthy industry, according to a new poll.

Pharma came in dead last on the 2019 Gallup Work and Education poll, which asks respondents to rate the trustworthiness of 25 business sectors. Even government, the traditional holder of last place, scored higher.

According to the report, Americans are more than twice as likely to rank pharma negatively than positively, with 58 percent expressing negative opinions and only 27 percent viewing the industry in a positive light. Fifteen percent of respondents had no opinion.

The new low accompanies public criticism of an industry that generates the highest-cost drugs in the world and has spent large amounts of money on lobbying in the wake of the U.S. opioid crisis.

Few industries have ever received as low a score in the poll, including the federal government, which spent the first month of 2019 shut down.

Gottlieb Joins Aetion Board to Advance RWD Platform

Former FDA Commissioner Scott Gottlieb will advise healthcare startup Aetion on developing its tool to assess treatment safety, effectiveness and value of using real-world data.

The Aetion Evidence Platform is part of the RCT Duplicate project, a partnership with the FDA and Brigham and Women’s Hospital that will use real-world data to replicate the results of 30 completed randomized clinical trials and predict the results of seven ongoing Phase 4 trials (CenterWatch Weekly, April 15, 2019).

Sindh Healthcare Starts IRB in Pakistan

The Sindh Healthcare Commission of Pakistan announced the formation of its first IRB to review clinical research and promote responsible ethics in life sciences.

The new IRB is welcoming research projects and investigators willing to initiate research in the region and is setting up five district offices and a divisional office.

The move is in response to the commission’s closure of 2,148 non-compliant clinics, including 28 in one week.
Up and Coming

This feature highlights changes in clinical research organizations’ personnel.

Adamas Pharmaceuticals
Neil McFarlane was named chief executive officer at Adamas Pharmaceuticals. McFarlane most recently was chief operating officer at Retrophin.

AIM ImmunoTech
AIM ImmunoTech has appointed Ellen Lintal chief financial officer. Lintal was previously senior vice president of finance and control for Hemispherx BioPharma, Inc.

Alexion Pharmaceuticals
Aradhana Sarin has been named chief financial officer at Alexion Pharmaceuticals. Sarin most recently served as chief strategy and business officer at Alexion.

Almirall
Almirall has appointed Mike McClellan chief financial officer. McClellan is currently group CFO at Teva in Tel Aviv, Israel, and will accept the new position Nov. 11.

Bayer
Daniella Foster has been named head of public affairs and sustainability for the consumer health division at Bayer. Foster led Global Corporate Responsibility at the Hilton Corporation.

Dexcom
Quentin Blackford was named chief operating officer in addition to his role as chief financial officer at Dexcom. Previously, Blackford was the executive vice president and CFO at the company since 2017.

Encoded Therapeutics
Andrew Stober has been appointed chief manufacturing officer and David McNinch has been named chief business officer at Encoded Therapeutics. Stober was a leader in gene therapy manufacturing for Novartis and McNinch was a consultant with Encoded Therapeutics.

Everest Medicines
Jason Brown has been named chief business officer, Frank Grams has been named senior vice president of alliance management and head of business development in Europe, Sophia Zhu has been named senior vice president of portfolio management and strategic planning, Alex Wang has been named head of international business and Daniel Weng has been named vice president of finance at Everest Medicines. Brown founded the company and previously served as senior vice president of business development at Everest. Grams previously served as vice president and global head of alliance management for general medicines and emerging markets and global head of research and development alliance management at Sanofi. Zhu joined Everest from Sanofi China, where she was head of strategic portfolio development and specialty care. Wang was previously general manager of Abbott’s Singapore-based point of care division in the Asia Pacific. Weng previously served as head of finance for Amgen China.

Foghorn Therapeutics
Foghorn Therapeutics has named Samuel Argesta chief medical officer and Allan Reine chief financial officer. Previously, Argesta served as CMO at Infinity Pharmaceuticals and Reine served as CFO at Pieris Pharmaceuticals.

Gemini Therapeutics
Gemini Therapeutics has named Jason Meyenburg chief executive officer. Meyenburg joined Gemini from Orchard Therapeutics where he was chief commercial officer.

Insitro
Insitro has added to its leadership with Matthew Rasmussen named vice president of data engineering. Rasmussen most recently served as vice president of software engineering at Myriad Genetics.

Lyra Therapeutics
Lyra Therapeutics has appointed Vineeta Belanger senior vice president of clinical affairs. Belanger held the position of vice president of clinical affairs at Avedro.

Lytx Biopharma
Oystein Rekdal has been named chief executive officer at Lytx Biopharma. Previously, Rekdal served as head of research and development at Lytx Biopharma.

Medisafe
Sean Markey has been named chief business officer and Jennifer Butler has been named chief marketing officer at Medisafe. Markey previously was head of business development at Phreesia and Butler led marketing at New Century Health.

Menarini Group
Florence, Italy-based Menarini Group, named Elcin Ergun chief executive officer. Ergun most recently served as executive vice president and head of new businesses at Merck.

Opiant Pharmaceuticals
Aziz Mottiwala has been named chief commercial officer at Opiant. Mottiwala most recent appointment was with Avanir Pharmaceuticals as senior vice president and head of commercial.

PhRMA
PhRMA has named Lori Reilly the company’s first chief operating officer. Previously, Reilly served as executive vice president of policy, research and membership at PhRMA in her 20 years with the company.

Medispend
Medispend has named Diana Borges as vice president of compliance solutions and Francoise Renaud as vice president of client operations. Borges was previously director of corporate compliance for Merz North America and Renaud served as program manager for Nuance.

Menarini Group
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Rallybio
Douglas Sheridan has been named research and development leader at Rallybio. Sheridan was the executive director and global program team leader at Alexion Pharmaceuticals.

Regenix
Regenix has named Robert Wasserman chief medical officer. Previously, Wasserman served as chairman of the clinical biomarker leadership team and the global head of oncology translational medicine and early clinical development for Roche Pharma.

Salarius Pharmaceuticals
Salarius Pharmaceuticals has appointed Scott Jordan as chief business officer and Mark Rosenblum at executive vice president finance and interim chief financial officer. Previously, Jordan was the chief financial officer at Salarius since 2016, and Rosenblum was a financial consultant assisting in the recent merger of Flex Pharma at Salarius.

Solgenix
Solgenix has named Daniel Ring president of business development and strategic planning. Ring most recently served as vice president of business development at Exela Pharma Sciences, LLC.

twoXAR
Allen Poirson has been named senior vice president of biopharmaceutical business development. Poirson was previously a partner with Mighty Capital, a venture capital firm.

WindMIL Therapeutics
WindMIL Therapeutics has named Urvashi Patel vice president of regulatory and quality systems. Patel was previously senior director of regulatory affairs at Precision for Medicine.

Worldwide Clinical Trials
Worldwide Clinical Trials has named Aman Khera global head of regulatory strategy for the scientific solutions team. Khera was most recently the head of Americas for the regulatory strategy and agency liaison team with PRA Health Services.

X4 Pharmaceuticals
Renato Skerlj has been named senior vice president of research and development at X4 Pharmaceuticals. Skerlj previously served as a leader in drug development and discovery at Lysosomal Therapeutics.

Xenon
Xenon Pharmaceuticals has appointed Shelley McCloskey senior vice president of human resources. Previously, McCloskey was vice president of human resources and administration at Aquinox Pharmaceuticals.

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Protocol Problems
continued from page 1
sponsors for not making sure their trials are protocol-compliant.

The number of citations in this category generally have been consistent from 2015 to 2018 (average of 10 citations a year), but a four-point rise in 2019 (14 citations) is enough to take over the number three rank. Citations for inadequate drug distribution records, formerly in third place, have been cut in half since 2016, when they totaled 26.

IRBs also have improved their inspection performance, with citations for insufficient meeting notes more than cut in half, from 29 in 2015 to 11 in 2019.

FDA released its fiscal 2019 data on Sept. 17, two weeks before the end of the fiscal year, so the dataset is not complete for the entire year.

To view previous years’ metrics, click here: https://bit.ly/2kTQraq.

Most Frequent Inspection Observations, FY 2015-2019

<table>
<thead>
<tr>
<th>Observation</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigation not conducted</td>
<td>171</td>
<td>140</td>
<td>108</td>
<td>82</td>
<td>120</td>
</tr>
<tr>
<td>according to protocol</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Failure to maintain case history</td>
<td>92</td>
<td>76</td>
<td>69</td>
<td>54</td>
<td>120</td>
</tr>
<tr>
<td>records</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>General responsibilities of sponsors</td>
<td>10</td>
<td>11</td>
<td>11</td>
<td>14</td>
<td>14</td>
</tr>
<tr>
<td>Inadequate drug distribution records</td>
<td>24</td>
<td>26</td>
<td>18</td>
<td>13</td>
<td>20</td>
</tr>
<tr>
<td>Insufficient IRB meeting minutes</td>
<td>21</td>
<td>14</td>
<td>11</td>
<td>12</td>
<td>16</td>
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<tr>
<td>Consent form not approved/signed/dated</td>
<td>24</td>
<td>26</td>
<td>18</td>
<td>13</td>
<td>20</td>
</tr>
</tbody>
</table>

Source: FDA

Half of EU Cancer Trials
continued from page 1
Researchers found that trials evaluating overall survival were at lower risk of bias than those that evaluated other endpoints, such as surrogate measures of clinical benefit for cancer patients. However, overall survival, or the length of time from either the date of diagnosis or start of disease treatment to present, was used as a primary endpoint in only 26 percent of trials.

Other trials evaluated indirect measures of clinical benefit, such as disease response, event-free survival or safety endpoints, which are not always a reliable predictor of whether a patient will live longer and have a better quality of life.

“Researchers found that trials evaluating overall survival were at lower risk of bias than those that evaluated other endpoints…”

Researchers also identified 10 trials with concerns resulting from inappropriate comparators and non-preferred study endpoints. Findings of bias differed, the study said, between trials relying on information available from scientific literature as opposed to regulatory documents, such as European Public Assessment Reports (EPAR), indicating that the information being communicated by these different sources is being interpreted differently by sponsors and can result in confusion and misconception.

For example, researchers found in the case of one study, that scientific literature was missing some outcomes data, but the related EPAR provided more information about study and treatment discontinuations. Taken together, the two sources provided a more accurate picture of study results.

“Because cancer drugs are responsible for most of the recent increases in pharmaceutical spending,” the study concludes, “the evidence base that supports their market entry warrants close scrutiny.”

Read the full report here: https://bit.ly/2mjr2qT.

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<table>
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<tr>
<th>Company</th>
<th>Drug/Device</th>
<th>Medical Condition</th>
<th>Status</th>
<th>Sponsor Contact</th>
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<tr>
<td>Clover Biopharmaceuticals, Inc.</td>
<td>SCB-313</td>
<td>peritoneal carcinomatosis</td>
<td>Phase 1 trial initiated enrolling subjects in China</td>
<td>cloverbiopharma.com</td>
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<tr>
<td>Immunic</td>
<td>IMU-935</td>
<td>various inflammatory and autoimmune diseases</td>
<td>Phase 1 trial initiated</td>
<td>immunic-therapeutics.com</td>
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<tr>
<td>Benitec Biopharma</td>
<td>BB-301</td>
<td>Oculopharyngeal Muscular Dystrophy (OPMD)</td>
<td>Phase 1 trial initiated</td>
<td>benitec.com</td>
</tr>
<tr>
<td>Transgene</td>
<td>TG4050</td>
<td>HPV negative, squamous cell carcinoma of the head and neck (SCCHN)</td>
<td>Phase 1 trial initiated enrolling subjects that have received an adjuvant (first line) therapy in the UK and France</td>
<td>transgene.fr</td>
</tr>
<tr>
<td>Transgene</td>
<td>TG4050</td>
<td>ovarian cancer</td>
<td>Phase 1 trials initiated enrolling subjects after first-line surgery and chemotherapy in France and the U.S.</td>
<td>transgene.fr</td>
</tr>
<tr>
<td>Poxel SA</td>
<td>PXL065</td>
<td>Non-alcoholic steatohepatitis (NASH)</td>
<td>Phase 1b trial initiated enrolling 30 healthy subjects</td>
<td>pixelpharma.com</td>
</tr>
<tr>
<td>Applied Molecular Transport</td>
<td>AMT-101</td>
<td>Ulcerative Colitis</td>
<td>Phase 1b trial initiated enrolling 20 adult subjects in Europe</td>
<td>appliedmt.com</td>
</tr>
<tr>
<td>NOXXON</td>
<td>NOX-A12 in combination with radiotherapy</td>
<td>Brain cancer</td>
<td>Phase 1/2 trial recruiting newly diagnosed patients with brain tumors who would not benefit from the current standard of care of chemoradiotherapy and whose tumors cannot be fully resected by surgery in Germany</td>
<td>noxxon.com</td>
</tr>
<tr>
<td>REVOLUTION Medicines</td>
<td>RMC-4630 in combination with cobimetinib (Cotellic)</td>
<td>relapsed/refractory solid tumors harboring specific genomic mutations</td>
<td>Phase 1b/2 trial initiated</td>
<td>revolutionmedicines.com</td>
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<tr>
<td>Momotaro-Gene</td>
<td>MTG201 in combination with PD-1 inhibitor nivolumab (Opdivo)</td>
<td>relapsed malignant pleural mesothelioma</td>
<td>Phase 2 trial initiated enrolling 12 subjects with malignant mesothelioma who have failed front-line systemic platin-based chemotherapy at Baylor College of Medicine in Houston, Texas</td>
<td>mt-gene.com/en/</td>
</tr>
<tr>
<td>Pulmatrix</td>
<td>Pulmazole</td>
<td>Allergic Bronchopulmonary Aspergillosis (ABPA)</td>
<td>Phase 2 trial initiated enrolling 64 subjects with asthma</td>
<td>pulmatrix.com</td>
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<td>Graybug Vision, Inc.</td>
<td>GB-102</td>
<td>macular edema (ME) secondary to Diabetic Macular Edema (DME) or Retinal Vein Occlusion (RVO)</td>
<td>Phase 2a trial initiated enrolling 20 subjects at six centers in the U.S.</td>
<td>graybug.com</td>
</tr>
<tr>
<td>Alnylam Pharmaceuticals, Inc.</td>
<td>patisiran</td>
<td>transthyretin amyloidosis (ATTR amyloidosis) with cardiomyopathy</td>
<td>Phase 3 study initiated enrolling 300 adult subjects with ATTR amyloidosis (hereditary or wild type) with cardiomyopathy</td>
<td>alnylam.com</td>
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<tr>
<td>Apollo Endosurgery, Inc.</td>
<td>Polypropylene Suture-Anchor Assembly</td>
<td>pass and anchor suture in the gastrointestinal tract</td>
<td>510(k) Clearance granted by the FDA</td>
<td>apolloendo.com</td>
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<td>Janssen</td>
<td>Erleada</td>
<td>metastatic castration-sensitive prostate cancer (mCSPC)</td>
<td>Supplemental New Drug Application granted by the FDA</td>
<td>janssen.com</td>
</tr>
<tr>
<td>Merck</td>
<td>Keytruda in combination with Lenvima</td>
<td>advanced endometrial carcinoma</td>
<td>Approval granted by the FDA</td>
<td>merck.com</td>
</tr>
<tr>
<td>Eisai</td>
<td>GVOKE (glucagon) injection</td>
<td>severe hypoglycemia</td>
<td>Approval granted by the FDA</td>
<td>xerispharma.com</td>
</tr>
</tbody>
</table>

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Click on any provider to view the company’s complete online profile or click here to search more profiles.

<table>
<thead>
<tr>
<th>CONTRACT RESEARCH ORGANIZATION</th>
<th>INVESTIGATIVE SITE NETWORKS (NON SMO)</th>
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<tbody>
<tr>
<td><strong>Accell Clinical Research, LLC</strong>&lt;sup&gt;®&lt;/sup&gt;</td>
<td><strong>Summit Research Network Management, Inc.</strong>&lt;sup&gt;®&lt;/sup&gt;</td>
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<tr>
<td>Culpeper, VA</td>
<td>Portland, OR</td>
</tr>
<tr>
<td>+7 981 844 10 48</td>
<td>(503) 972-9818</td>
</tr>
<tr>
<td><a href="mailto:svetlana.kazanskaya@accellclinical.com">svetlana.kazanskaya@accellclinical.com</a></td>
<td><a href="mailto:jhockley@summitnetwork.com">jhockley@summitnetwork.com</a></td>
</tr>
<tr>
<td>ACCELL has been providing clinical CRO services to pharmaceutical and biotechnology companies since 2007. They are a full-service CRO specializing in Phase I-IV clinical trials in Eastern Europe, Russia and the CIS.</td>
<td>Since 1976, Summit Research, an independent medical research organization with an outpatient facility, has worked in cooperation with pharmaceutical companies to develop medical treatments for a variety of conditions.</td>
</tr>
</tbody>
</table>

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