By Brandon May

Collaboration, integration and data-sharing are popular concepts in a life sciences industry focused on finding novel treatments to meet critical healthcare needs. But are clinical trials really ready to “walk the walk” when it comes to making their data accessible to other sponsors and researchers? Not just yet, say industry experts.

“The industry is a long, long way off from standardizing and collecting and sharing data,” says April Mulroney, chief data officer at WCG Clinical. “Standardizing the collection will enable the standardization of sharing, and I think we have a long way to go.”

What is needed are methods of data collection and management that are recognized by the entire clinical research field, agrees Rebecca Kush, chief scientific officer at Elligo Health Research.

Kush points to the work of the Clinical Data Interchange Consortium (CDISC) as an example. CDISC’s Clinical Data Acquisition Standards Harmonization effort features global and consensus-based data standards available for clinical trials data collection and electronic submission.

CDISC’s approach, which was developed with the encouragement of the FDA as part of its Critical Path Initiative, “streamlines the generation of tables and analysis datasets that meet global regulatory requirements for data,” Kush said. The FDA requires the use of CDISC standards in the electronic submission of applications and data.

By Leslie Ramsey

Patient involvement shouldn’t end when a trial closes. If you really want subjects to feel they are part of the team, you need to share the results with them, says one cancer survivor turned trial advocate.

Mary Elizabeth Williams, who wrote about her clinical trial experience in her book A Series of Catastrophes and Miracles: A True Story of Love, Science and Cancer, says sharing trial results with participants builds a sense of pride and accomplishment that can translate into a more positive public view of clinical trials.

Unfortunately, that doesn’t typically happen, Williams said.

“Everything I know about my clinical trial comes from basically my own initiative and from my work as a journalist, and from my research,” Williams told WCG Clinical Chief Medical Officer Lindsay McNair in a recent interview. And what information she did receive was hard to understand.

“I had to have people explain to me what endpoints are and what... the charts were and the data was. I wouldn’t have understood it myself, and I don’t think any layman would.”

A summary of the trial written for the layman would be “amazing,” she said. “To have your hospital or your facility communicate with you, and say, ‘If you would like to read some of the study results, here is where it was published [and] here’s what that means,’ how fantastic would that be?”
Trials Still in Limbo

The UK has won a further delay from European leaders on its exit from the EU, leaving drug sponsors no clearer about the ultimate impact of Brexit on their clinical trials. The departure, originally scheduled for March 29 and then moved to April 12, now is slated for October 31.

UK regulators — who have promised to implement European drug guidelines even if the UK crashes out of Europe without a deal — would be excluded from Europe’s centralized IT portal for clinical trials and Europe’s single assessment model.

Drug Industry Asks FDA for Clarity on Natural Histories for Rare Disease Trials

The drug industry is asking the FDA for more clarity around whether natural histories should be included in rare disease trials — and two of the nation’s largest drug trade groups appear to be at loggerheads over the issue.

Among the proposals the FDA is kicking around is allowing natural history studies to substitute as control arms in special cases. Many commenters urged the agency to expand the idea beyond natural histories and to consider such things as patient registries as another way to speed drug development.

Roche, Takeda and BioMarin, among other drugmakers, suggested the agency be more specific about the ways in which natural histories can help speed a drug to market.

But BIO and PhRMA were split on the issue. BIO says it’s worried that the guidance will harden into a requirement that will stall life-saving drugs. Properly done natural histories, the group says, can take several years to complete.

PhRMA, on the other hand, said the draft guidance doesn’t go far enough. Natural histories “should not be the exception but rather common practice” in rare disease trials, the group said.

Read the full comments here: https://bit.ly/2v0aOEd.

Drugmakers Question Exclusion Criteria for Rare Esophageal Disease Trials

Two drug companies are pushing back against a proposed FDA guidance that would require drug sponsors to screen out patients in esophageal swelling trials who would respond to an alternate therapy.

The FDA’s draft guidance on eosinophilic esophagitis, published in February, would require clinical trials to exclude subjects who could benefit from proton pump inhibitor (PPI) therapy by holding a two-month pre-trial of PPI dosage.

In comments made public Monday, Adare said the proposal flies in the face of the most recent diagnostic consensus and suggested the agency require trials to examine patient histories to identify and assess those who already have tried PPI.

AstraZeneca noted that the scientific consensus on PPI was still “evolving.” The company currently is working with Children’s Hospital Medical Center in Cincinnati to recruit 26 esophagitis patients for a trial of Fasenra that’s scheduled to wrap up by next year. AZ won orphan disease status for Fasenra from the FDA last fall.

Read the full comments here: https://bit.ly/2GfWmhH.

continues on next page »
Industry Briefs

**Histogenics and Ocugen Agree to Merge**

A merger agreement has been inked between cell therapy company Histogenics and eye disease drug developer Ocugen, the two companies jointly announced.

The merger would result in a new, clinical-stage biopharmaceutical company under the Ocugen name, with former Ocugen stockholders holding around 90 percent of the common stock of the combined company. Current Histogenics stockholders would retain the rest, the companies said.

Ophthalmology programs Ocugen currently has in development include a modifier gene therapy platform, ocular surface disease programs and retinal disease programs.

Histogenics’ technology platform, which has focused on restorative and pain relief cell therapies, has the potential to be used for a broad range of restorative cell therapy indications.

The merged companies will be headquartered in Malvern, Pennsylvania, under the leadership of Ocugen’s current management team.

**New Jersey Site Network Acquires CNS Research Group**

New Jersey-based sites company Evolution Research Group has acquired Finger Lakes Clinical Research, Evolution officials have announced.

Evolution already owns 13 sites and has a network of affiliates. The company focuses much of its work on early-to-late stage neuroscience drugs. Finger Lakes specializes in central nervous system trials.

Terms of the deal were not disclosed.

**J&J Partners with Children’s Research Hospital in D.C.**

Johnson & Johnson’s life sciences startup subsidiary JLABS has paired up with Children’s National Health System (CNHS) to develop a large pediatric research facility in the nation’s capital, the two announced last week.

The 32,000-square foot JLABS site will be located on the former Walter Reed Army Medical Center campus — which serves as CNHS’s Research and Innovation Campus — placing it close to academic research centers, universities, federal research institutions and government agencies.

The facility will be open to pharmaceutical, medical device, consumer and health tech companies working on new drugs, medical devices, precision diagnostics and health technologies.
Data-Sharing
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According to Mulroney, there are a bevy of technologies in the start-up phase that may help facilitate greater data-sharing in clinical trials. The costs and hurdles associated with getting these technologies approved and adopted may be the leading reasons why the clinical trials industry has been so slow.

“The biggest barrier for us is who is going to pay for that,” she says. “Pharma has been typically unwilling to pay for data standards and platforms like this because they typically hold their cards close to their chest, and they’re not willing to share their information. I think pharma should treat their scientific IP that they have as private, but I think that the hoarding of information as it relates to sites and patients is just not helpful.”

Despite these sentiments, Mulroney doesn’t believe it’s entirely impossible. “It’s definitely been achieved in other industries that are equally regulated as ours,” she adds, “but the challenge in our industry is that we haven’t even begun scratching the surface.”

The first step is to admit that there is a problem, Mulroney says, and everyone agrees that drug development can be accelerated if data are shared. “The second step is sharing in any form or fashion,” she says, “and the third step is to create the standards that make it easier to share.”

“I think the standards for sharing have to be done as an entire industry.”

But it may be up to individual companies to lead the way. “There are a couple of companies stepping forward that would like to start sharing results from their clinical trials,” Mulroney says. “The challenge is that it’s one of those things where ‘if everybody doesn’t do it, we’re not going to do it’ This industry is also a ‘pack mentality,’ and no one wants to be first. Everyone agrees on the value of data-sharing, but no one wants to put their chips on the table.”

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- Benchmark data for small sites
- Benchmark data for large sites
- Comparison data showing differences and similarities between small and large sites

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Empower Trial Participants
continued from page 1

“We live in a culture where all we want to do is know about ourselves.”

Understanding the implications of your trial participation gives you a sense of pride in being part of medical advancements, Williams stressed. “I know how proud I feel of the little teeny, tiny part I played in medical science. I am really proud of that. I am really excited about that,” she said. “To just feel that little bit of my research that my genes, that my DNA, that my blood and my urine all became part of really scientific history, medical history, is an amazing feeling.”

“I had to have people explain to me what endpoints are and what … the charts were and the data was. I wouldn’t have understood it myself, and I don’t think any layman would.”

—Mary Elizabeth Williams

“… knowing how their experience was used to help others would change how people look at clinical trials. The result, Williams said, is that more people would be interested in participating. “In a few years, that next patient’s coming down the line who understands more about clinical trials,” and can go into it with a sense of being part of a research team, not just a passive subject. “You’re part of a team,” Williams said. “That is really empowering, really cool, I would love that. Maybe someday.”

For the rest of the interview, please go to WCG’s website: https://bit.ly/2U9qqu.
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# Drug & Device Pipeline News

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For news on trial results, FDA approvals and drugs in development, Join the LinkedIn Drug Research Updates group!
## Upcoming Event Highlights

| May 5-9, 2019 | MAGi East | Boston, MA |
| June 23-27, 2019 | DIA 2019 | San Diego, CA |
| September 4-5, 2019 | Clinical Trial Risk & Performance Management Summit | Philadelphia, PA |
| October 23-25, 2019 | FDA Inspections Summit | Bethesda, MD |

## Webinars

**April 24, 2019**

**Clinical Trial Billing Documentation Best Practices: Optimize Reimbursement**

11:00 a.m. – 12:30 p.m. EDT

- Relationship between documentation of medical necessity & billing compliance
- Importance of complying with Medicare diagnostic & procedural codes
- Connection between the language used in the informed consent form & billing compliance
- And more.

**June 11, 2019**

**Using KPIs to Improve Site Performance**

1:30 p.m. – 3:00 p.m. EDT

- Improve your business development chances by illustrating turnaround times & other KPI metrics when communicating & selling services to potential clients
- Utilize more productive tools to better centralize & streamline your processes
- And more.

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**Upcoming Event Highlights**

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.

**Jobs via Kelly Services**

| Clinical Trial Associate | Sr Clinical Research Associate (CRA) |
| San Francisco, CA | Cupertino, CA |
| Lab Assistant - Clinical | Clinical Research Consultant |
| Austin, TX | Malvern, PA |
| Clinical Research Project Manager / Clinical Research Scientist | Project Manager |
| Raynham, MA | Sunnyvale, CA |
| Medical Officer (Clinical Trials) - NIH | Clinical Study Assistant |
| Rockville, MD | Jacksonville, FL |
| Clinical Research Coordinator (Oncology) | Clinical Trial Assistant |
| Phoenix, AZ | Andover, MA |
| Clinical Assistant | Clinical Data QC Specialist |
| Rock Hill, SC | Malvern, PA |
| Clinical Protocol Coordinator - NIH | Clinical Trial Assistant |
| Bethesda, MD | San Francisco, CA |

**More Jobs**

| Clinical Trials Administrator II | Clinical Research Coordinator |
| United Therapeutics | Northwest Neurology, Ltd. |
| Silver Spring, MD | Rolling Meadows, IL |
| Clinical Trial Manager | Clinical Research Coordinator |
| Oyster Point Pharma, Inc. | Massachusetts General Hospital (MGH) |
| Princeton, NJ | Boston, MA |
| Clinical Operations Program Manager | Clinical Trial Specialist |
| Battelle | PRA Health Sciences |
| Baltimore, MD | Blue Bell, PA |
| Lead Project Data Manager | Program Coordinator |
| Covance | BJ&J HealthCare |
| Research Triangle Park, NC | St. Louis, MO |

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