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TRIBUNE

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Pandemic Trials

COVID-19 Forces Adaptations in Race for Treatments

In his keynote presentation, Chris Lindsell, Ph.D., said the idea of addressing so many COVID-19-related challenges in a single clinical trial protocol was like asking if unicorns exist. He and his team ultimately generated a master protocol for a multi-site clinical trial that has provided the platform for other trials.

"Every day you waste, thousands of people will die."

Chris Lindsell, Ph.D., from Vanderbilt University, told a UAMS audience that the motivational statement was voiced multiple times a day as researchers ramped up the national effort in 2020 to find treatments for COVID-19.

Lindsell, who is director of the Vanderbilt Institute for Clinical and Translational Research Methods Program and a professor of Biomedical Informatics and Biostatistics, was a keynote speaker at TRI's recent Research Regulatory Conference, Virtual Research in a Complicated World. He presented, "ACTIV6, TREAT-NOW and Other Stories: Lessons Learned from Running Decentralized Platform Trials during a Pandemic."

Lindsell said the pressure to move quickly with COVID-19 clinical trials has raised ethical questions for

Letter from the Director

Dear Colleagues,

In this issue of The TRIbune we highlight the presentations of two national speakers who provided the keynotes at our annual Research Regulatory Conference – Virtual Research in a Complicated World. Both Chris Lindsell, Ph.D., from Vanderbilt, and Erin Rothwell, Ph.D., from the University of Utah, provided great perspective on the major clinical trial issues across the country in this pandemic environment. COVID-19 has forced some significant changes in the way we consent participants and follow them in trials, and it has raised thorny ethical and regulatory challenges. We posted the conference on YouTube, and I would encourage everyone to watch.

The end of the year is always a great time for reflection and gratitude. As we close out 2021, I want to acknowledge the hard work and strong collaboration across UAMS and our partner institutions. I think this Henry Ford quote expresses it well: "Coming together is a beginning, staying together is progress, and working together is success."

You have seized on new research, education and training opportunities available through our CTSA and have made UAMS a stronger research institution.

You can be proud, as I am, of all that we are accomplishing, despite the challenges of the pandemic. Our work together is improving the lives of Arkansans now and in the future, and it is being recognized across UAMS and at the national level.

Sincerely,

Laura James, M.D.
Director, UAMS Associate Vice Chancellor for Clinical and Translational Research

Pandemic Trials

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Erin Rothwell, Ph.D.

Research participants scored much higher in comprehension of consents that used a comic/graphic novel style, Rothwell said.

consenting and other issues. In one example, he said a trial was designed and running with the first patient in in 12 days, but it took some three months to get the data published.

"Because there was no test, and because there was no vaccine, the early emphasis of all of the clinical trials work was to go fast to find treatments," said Lindsell, who worked with a large consortium of research institutions and regulators across the United States to streamline the research. "It gave us a common purpose to solve problems, and with that common purpose to solve problems, we were able to move rapidly from a pre-COVID era of very traditional trials to a post-COVID era of decentralized virtual trials."

"This awakening story of, 'We can do research differently; we can do it fast,' still has a fair way to go to overcome some of the challenging timeline pathways on the back end," Lindsell said. "The story in here is that the publication processes on the back end really don't tie nicely to the way we design and innovate in trials."

The conference also featured Erin Rothwell, Ph.D., associate vice president for Research at the University of Utah and a professor in the Department of Obstetrics and Gynecology School of Medicine.

Rothwell, a bioethicist, presented, "Promoting Informed Decision Making for Consent in Virtual Research."

Rothwell has been tackling big questions around how to create more equitable and sustainable consenting platforms in a virtual world – using remote or e-consents. She has compared consent approaches using game technology, brochures, videos, smartphone apps and comics/graphic novels.

"How do we create a process that's sustainable that goes beyond just one project for improving virtual consents," she said. "I do think this is the academic medical centers' responsibility."

She has found that a comic/graphic novel consent vastly improves participant comprehension of consent information, much more than videos and smartphone apps, when compared to a brochure.

"When we looked at a comic, we have ten to 12 questions correct for those that got the comic versus the brochure. That is huge … almost perfect scores every single time," Rothwell said.

She is part of a national CTSA working group to better understand the challenges of consent that resulted from COVID-19. The effort has included discussions with 15 CTSA IRB directors and a white paper on the different types of consent.

The group has worked on definitions for electronic consents, virtual consents and remote consents.

An **e-consent**, she said, has the same information as provided in person but can include images, audio or other multi-media components, and the signature is obtained digitally. It also requires validation of the person's identity. REDCap is the most used platform for acquiring e-consents.

Virtual consent may be conducted with technology or telephone, email, teleconference, text and paper-based mail.

Remote consent is conducted without in person contact and may include telephone, email, teleconference, text and or mail, but the signature is captured by the person signing the consent document.

Video recordings of the conference presentations by Lindsell, Rothwell and others can be found on YouTube and at TRI.uams.edu.

TRI Offers New $75,000 Team Science Champion Award

TRI is now seeking applicants for a new Team Science Champion Award that will support early stage, cross-disciplinary collaborations.

One-year grants of up to $75,000 will be awarded to up to two cross-disciplinary teams. The funded research will involve telemedicine, digital health or other innovative technologies, and it will address rural health. Proposed projects will involve a collaboration with a rural provider, such as the UAMS Rural Research Network or similar located outside of the UAMS Little Rock campus catchment area.

TRI is particularly interested in projects that forge new collaborations across multiple disciplines that directly support its mission to develop new knowledge and novel approaches that will measurably address the complex health challenges of Arkansas' rural and underrepresented populations.

Champion Award information sessions will be offered on 12/16/21, 01/06/22, and 01/27/22. Please email Adam Kleinerman (akleinerman@uams.edu) or Paul Duguid (pduguid@uams.edu) if you would like to attend one of these sessions.

Letters of Intent are due Feb. 7, 2022. All applications must be received no later than March 14, 2022.

Get the details at TRI.uams.edu.

TRI Study of the Month

Sisira Yadala, M.D., (right) an epileptologist, is assisted on the study by TRI's Renee Shaide, M.N.Sc., APRN, FNP-BC, clinical research coordinator.

- **Principal Investigator:** Sisira Yadala, M.D., Director, Division of Epilepsy; Director, Clinical Neurophysiology Lab, Assistant Professor, Department of Neurology; College of Medicine.
- **Summary:** A phase 3 clinical trial evaluating the efficacy and safety of intravenous Ganaxolone as a potential treatment for refractory status epilepticus, uncontrolled seizures that do not respond to typical first and second line seizure medications.
- **Significance:** Status epilepticus is a serious condition that requires immediate intervention to stop the seizures and prevent permanent brain damage.
- **TRI Services:** Budget development, Medicare coverage analysis, regulatory and research nurse coordinator services.
- **Sponsor:** Marinus Pharmaceuticals Inc.

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ARresearch Offers More to Researchers

The ARresearch registry of potential research participants now enables a much richer dataset for the researchers who use it. On the upgraded platform established last year, the TRI program provides a more efficient way to generate reports and a simplified process for researchers to communicate with registrants. This includes easier dissemination of surveys to registrants and the ability to contact them about participating in other research.

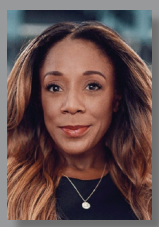
The number of ARresearch registrants had reached 8,196 by Dec. 1, 2021, an increase of nearly 10% over the last eight months.

The platform also includes functionality using REDCap that allows registry data to be uploaded by researchers for analysis. In addition, researchers who use ARresearch now receive a CLARA report from the IRB that includes reminders to ask their study participants to consider joining the registry.

ARresearch.org

A 10-minute tutorial video on the TRI website shows researchers how they can maximize the registry's new capabilities.

Carolyn Greene, Ph.D., Joins TRI as Associate Director



UAMS researcher Carolyn Greene, Ph.D., joined TRI full-time on Dec. 1 as associate director of Programmatic and Strategic Planning.

Greene, an associate professor in the Department of Psychiatry, has been a member of TRI's Leadership Council, serving as director of TRI's Team Science Program, co-director of the Mentored Research Career Development Scholars Program, and as liaison to the UAMS Institute for Digital Health and Innovation. She will continue to provide her expertise to these programs in a variety of ways.

"I am thrilled to have Dr. Greene on our team full-time," said TRI Director Laura James, M.D. "Not only is she a nationally recognized expert in digital health technologies, she brings a wealth of knowledge, experience and enthusiasm to our translational research mission."

Greene's research has focused on using mobile apps to deliver care to underserved Arkansans, using innovative technologies to increase access to evidence-based health care. She spent over 10 years developing and implementing a national digital health program and has been recognized as an Innovation Leader by the American Psychiatric Association.

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