Newly integrated tool enables better tracking of clinical trial metrics

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Before new treatments can reach the clinic, they must be tested in clinical trials to see if they are safe and effective. Trials that do not enroll enough participants present roadblocks for advancing care to the

clinic because they offer no scientific insight, waste money and time and inflate the costs of new treatments.

Improving clinical trial efficiency—ensuring robust patient enrollment while minimizing costs and waste—is a high priority for the Clinical and Translational Science Awards (CTSA) consortium, which serves as a laboratory for testing new ways to speed the translation of care into the clinic.

In a recent article in the *Journal of Clinical and Translational Science* (*JCTS*), a team at the Medical University of South Carolina (MUSC), which is the academic home of the South Carolina Clinical & Translational Research (SCTR) Institute, describes an integrated tool that is helping them to track clinical trial enrollment and cost effectiveness across the MUSC Health System. The tool integrates a commercial clinical trial management system (CTMS), with the MUSC-created Research Integrated Network of Systems (RINS), which tracks study-level data across otherwise siloed systems. The integration enables study teams, administrators and evaluators to ensure that the trials are the best fit for the enterprise and to track the progress of their studies.

"We needed a platform where we could track all of our studies that were recruiting patients, all the patients who were enrolled in research and whether they were also clinical patients at MUSC. Additionally, bringing a clinical trials management system into RINS will allow us to really look at financials, particularly for industry trials," said Royce Sampson, lead author of the JCTS article. Sampson is the director of the Office of Clinical Research (OCR) and chief operations officer and associate director of SCTR.

RINS was created by SCTR and the Biomedical Informatics Center (BMIC) team to capture protocol-level data across systems. None of the existing systems were capturing patient associations, so a CTMS was

identified to fill that gap. Integrating a CTMS provided the missing piece of the puzzle, according to Jillian Harvey, Ph.D., senior author of the JCTS article. Harvey is the evaluation director for SCTR and an associate professor in the College of Health Professions.

"In the past, we've had challenges accessing the data needed to track clinical trial metrics," said Harvey. "CTMS/RINS allows us to get our hands around tracking and reporting our outcomes and being efficient with our data and evaluation."

Previously, tracking clinical trial metrics too often meant manually pulling and calculating data. Teams would pass on whatever data sets they had. Leila Forney, DNP, an associate director in the OCR, recalls the arduous job of pulling together data for a CTSA grant renewal, which took nine months. Now, the process is much easier.

"Having an electronic platform for clinical trial data really helps you think about the metrics you're seeing and determine where you can make improvements," said Forney. "It also helps us ensure that the data is accurate."

The implementation of the CTMS was led by Steve Shapiro.

The newly integrated tool also aids MUSC researchers in choosing the appropriate trials and right-sizing them—setting a realistic enrollment goal—for the institution.

"CTMS/RINS is helping us take an even more informed approach to the trials that we're selecting, where we're placing them, where the greatest needs are and where the gaps are," said Signe Denmark, an associate director in the OCR. "We're becoming better overall at knowing what our clinical trial portfolio looks like and how we manage it."

With the enterprise's recent expansion into more South Carolina counties as part of MUSC Health's Regional Health Network (RHN), financial and patient accrual data available through CTMS/RINS can help clinical research leaders to select not just the right trials but the right location for those trials.

"We're exploring how we can offer more research opportunities to these rural communities," said Sampson. "People in Florence, Marion, Lancaster and Chester counties live hundreds of miles from the nearest academic medical center or cancer treatment center, where clinical trials are typically offered. The CTMS/RINS integration could help us to select the appropriate trials to bring to them. That's going to be the innovation."

The integration also standardizes data collection across study teams and primes them to continue updating their data.

"With a system like a clinical trials management system, when study teams start using this as a main source to track their study, they are responsible for keeping their information updated. So, it's more transparent, too," said Wenjun He, Ph.D., research assistant professor at BMIC.

MUSC can report these performance metrics to the trial sponsors, giving the institution's study teams a competitive edge.

Early adopters of CTMS/RINS were the OCR, which used it to launch and track COVID-19 clinical trials, and the Hollings Cancer Center (HCC) Clinical Trials Office.

"Hollings Cancer Center began using the new clinical trials management system in the Fall of 2020 to maintain all study- and patient-level data," said Tricia Bentz, administrative director for the Clinical Trials Office at

HCC. "The CTMS/RINS integration has improved the data quality of study details within institutional systems and generated new efficiencies and work tools for management and staff. The integrated data structure is a promising foundation for real-time reporting and support of data-driven strategic planning."

Since March, all new study teams have been required to enroll their studies into the new CTMS. This process will be ongoing and supported by OCR staff. Continuous improvements will be made to MUSC's CTMS/RINS integration. Plans are already underway to take it to the next level and create dashboards to provide transparent, easily accessible data to support study teams, explained Sampson.

The CTMS/RINS integration will not only benefit MUSC's clinical trials but could also provide a model for CTSAs nationwide, albeit one that would need to be tailored to each institution's particular data ecosystem.

"It's in the core of our mission to make the process from discovery to population impact faster and more efficient, with better outcomes," said Harvey. "This just rolls into the mission of the CTSA as an area we need to look at."

More information: Royce Sampson et al, An integrated approach to improve clinical trial efficiency: Linking a clinical trial management system into the Research Integrated Network of Systems, *Journal of Clinical and Translational Science* (2022). DOI: 10.1017/cts.2022.382