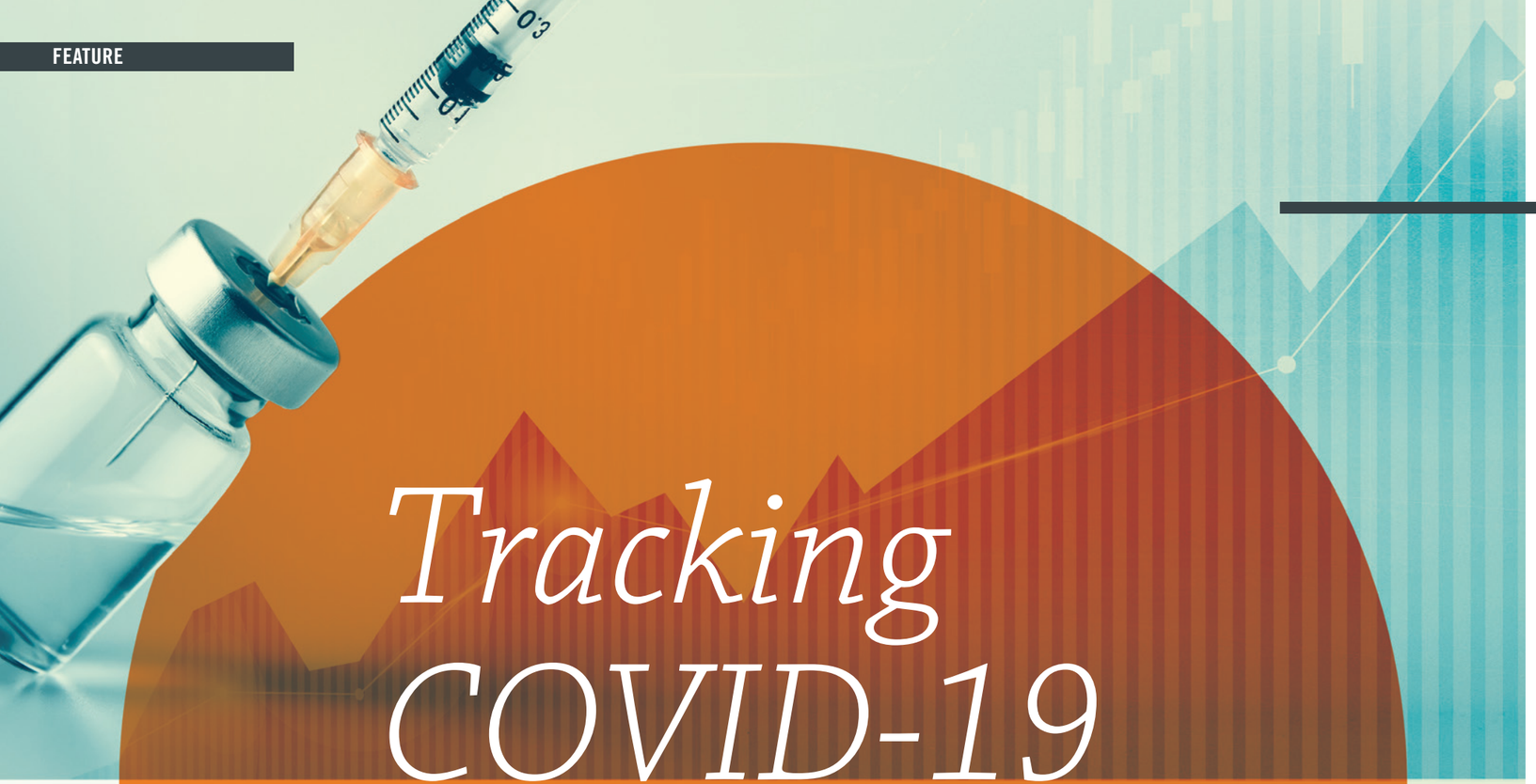

# Tracking COVID-19 Clinical Trials

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*Estimates of how long it takes clinical research findings to work their way into clinical practice range as high as 17 years. But that was before coronavirus. "We are definitely in an unprecedented time in terms of how research into COVID therapies and clinical practice are being integrated," says Alison Montpetit, PhD, RN, Director of Nursing Research and Innovation at VCU Health in Richmond, VA.*

New therapies are being prescribed for some COVID patients via compassionate use or expanded access pathways. Others may be receiving that same drug as part of an investigational trial.

"Research and clinical practice typically run alongside each other," Dr. Montpetit says. "But they're now tied together in a way we haven't seen before. As our infectious disease colleagues like to say—we're building the car as we drive it." Patients enrolled in one trial may, as they proceed through different phases of the disease, have that trial drug stopped and be considered for another investigational drug.

Given that pace, Dr. Montpetit and her colleagues had to figure out how to keep track of patients transitioning on and off different trials. They also wanted to ensure that patients and families were not being approached by a half-dozen different principal investigators.

To solve those issues, Dr. Montpetit and her colleagues ended up turning to a tool already well-established in the medical center: its patient flow software. It turns out that software designed to maximize bed management can also successfully track patients across multiple trials.

## Research Transformation

According to Dr. Montpetit, coronavirus has transformed just about every aspect of the research enterprise in her center. Many of the siloes that used to exist, slowing studies down, have dissolved with cooperation toward a common cause.

"What matters is the patients, and that concern is pushing translational science." It helps that the red tape that once slowed studies down seems to have been swept away. "What used to take months" in getting studies off the ground "now takes only days to weeks, without compromising their integrity."

In addition to its own investigations, VCU Medical Center is working on trials sponsored by pharmaceutical, device, testing and lab companies. With the center being approached for and participating in multiple trials, VCU created a committee—the COVID-19 research oversight committee—to keep track of them all and to determine which should be given priority."We are initiating studies in-house," says Dr. Montpetit, who sits on that committee, "but we are giving priority to those that offer the greatest benefit to patients and to larger, multi-site trials. There's a power in numbers, and larger studies that enroll more patients will lead to quicker answers."

As Dr. Montpetit explains, COVID-19 has several different phases, and "different trials are targeting those different phases." It's been very interesting, she adds, to see a clinical team recommend a trial because the patient's condition has changed. "I've never seen the intersection between research activity and the clinical team executed so beautifully."

## An Available Tool

But research, Dr. Montpetit points out, has many moving parts. Each trial has principal and secondary investigators and coordinators, as well as "physicians and other providers screening patients for safety and eligibility." There are also logistical and operational sides, as well as the investigational pharmacy compounding medications, and nurses navigating infusions with isolation precautions. "Each study team is like its own little business."

So how to keep all those moving parts straight and communicate among them all? The medical center has relied for many years on TeleTracking to track patient movements throughout the hospital. The software knows in real time who's being admitted and transferred where, when patients are being discharged, which stage of cleaning each empty bed is in, and where available beds are.

To figure out how to track COVID research, "we mapped out the entire process to identify communication gaps," says Dr. Montpetit. If a patient isn't eligible for one trial, for instance, how can another study team be alerted without multiple phone calls, texts or e-mails? And how can different research teams communicate about where individual patients are in terms of being screened and enrolled?

Engaging nurse leaders, research directors, and the performance improvement department, Dr. Montpetit and her colleagues hit on the idea of creating a digital whiteboard in TeleTracking dedicated exclusively to COVID patients. "In my mind," she says, "the movement of patients from bed to bed was very similar to being moved from trial to trial. TeleTracking supports team-to-team communication."

## Populating the Board

It took the in-house TeleTracking team about two weeks to create a board that includes only COVID patients; that original version then went through several piloted iterations before landing on the current one, which went live in May.

The board pulls some information—patient's name, status, and location, as well as demographics—from the center's EHR. But several columns use icons, notations and color codes to communicate about various steps within the research trials.

A column with a microscope icon, for instance, identifies with large capital letters any drug trial a patient is in: a capital R for remedesivir, an S for sarilumab or a C for canikinum-ab (two of several monoclonal antibodies being tested). A capital A is for a compound being trialed that's produced by the biotech Angion.

A magnifying glass icon indicates whether patients are active on a clinical trial. A hanging bag icon denotes convalescent plasma, with different colors indicating if a patient is being considered, has consented or has already been transfused. A blood drop icon indicates if patients have been approached for a blood sample for a registry or investigational studies and if they have consented or donated.

Checkmarks denote various stages: blue for screening, green for on-study, red for completed and yellow for a screen fail. Other columns show if patients have received trial doses on specific days, as well as trial comments, while other columns list the name of patients' attending physicians and bedside nurses. Study team coordinators update the information in real time.

"I hope this becomes the new norm of communication between research and clinical practice," says Dr. Montpetit. "With COVID, it's clear that the two are inextricably linked."

*Alison Montpetit, PhD, RN, Director of Nursing Research and Innovation at VCU Health in Richmond, Va. is helping breakdown silos and drive COVID-19 research.*

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