

# Clinical Researcher™

The Authority in Ethical, Responsible Clinical Research

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**The More Things Change...**

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## Clinical Researcher™

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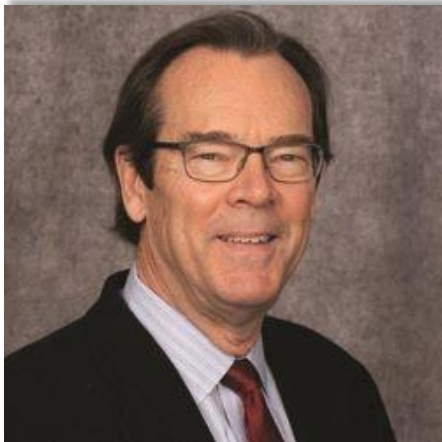


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EXECUTIVE DIRECTOR'S MESSAGE

**The More Things Change...**

Jim Kremidas



Many aspects of most people's home and work lives have fallen prey to unprecedented upheavals since *Clinical Researcher's* editorial calendar was first crafted for 2020, but it still makes a lot of sense that the original idea for this issue was to focus much of its contents on change management. Although world events of late have caused most contributors to want to write about other timely topics in the clinical research enterprise, including lessons being learned from how professionals in the field are adjusting to

the "new normal" and how efficient and ongoing training remains the bedrock of a sterling clinical trials workforce, in a way, we are still dealing with change as a motivator for improvement in these pages.

Whether you're working from home for the first time, or juggling childcare now that schools and summer camps are generally closed, times like these emphasize the inevitability of change and the importance of intelligent change management.

On the positive side, the clinical trial industry has risen to the challenge of the pandemic with inspired work and a new sense of collaboration. We've made great strides toward embracing decentralized trials, remote technologies, and pursuing other advancements that will hopefully make clinical trial even more patient-centric and effective in the years to come.

Yes, change is inevitable. However, we have a choice in *how* we respond to change. Do we resist? Do we try to ignore or minimize it? Or do we accept it and find ways to bring out the positive elements?

We on the ACRP staff have done some survey work of our own in recent weeks to try and determine what clinical trial professionals have learned during this unprecedented experience. We'll be sharing our findings very soon. Watch this space.

What I'd like to highlight right now is that, even as some clinical trials begin to resume onsite and, in pockets of the country at least, the pandemic appears to be subsiding, we have the opportunity to use some of this relative "down time" to become better at our jobs. That can mean pursuing additional training, participating in one of ACRP's virtual conferences, or writing for ACRP's *Clinical Researcher* and sharing your knowledge with others.

Those are just a few ideas, of course. There are many other ways for you to grow and further contribute to the clinical trial mission of advancing medicines, alleviating suffering, and prolonging life. As the old saying goes, "The more things change, the more they stay the same." As far-reaching as the changes we are living through now may turn out to be for the healthcare industry at large, the underlying calling for clinical researchers everywhere to excel individually and for the profession to improve universally remains the same.

Thank you again for all you do. Your work has never been more important—or appreciated.

**Jim Kremidas** ([jkremidas@acrpnnet.org](mailto:jkremidas@acrpnnet.org)) is Executive Director for ACRP.

CHAIR'S MESSAGE

## The Best of Both Worlds

Paul Evans, PhD



I recently had the opportunity [to appear on an episode](#) of ACRPtv's "Spotlight On..." series to discuss some of the challenges I see looming ahead of us as an industry as we move toward virtual or hybrid trials. I'm no Luddite, and I'm excited about many of the upsides well-designed virtual trials can bring us, beginning with the delivery of the benefits of clinical trials to wider swaths of the population.

It's no secret that many minorities and people living in rural areas of the country are vastly underrepresented in clinical trials today. Virtual trials have the potential to change that.

Obviously, we should all support anything that delivers the benefits of clinical trials and clinical research as a care option to more patients in a safe and effective manner.

However, I'm concerned we're letting our enthusiasm get ahead of reality. Transforming an onsite trial into a virtual trial isn't something that can be done by flipping a switch. Just ask teachers who've been told to make their in-class lessons virtual, as if the challenge could be solved with the creation of a few Excel forms and a Zoom meeting or two.

Before we get too far ahead of ourselves, we must address overly complex protocols. We've seen a classic case of "mission creep" over the past several years as trials have become more complex and the demands on clinical trial practitioners more stringent. We need to ask ourselves if we really need certain datapoints as we set up a trial, or are we asking a question merely for the sake of asking it?

I worry that, minus taking a close look at how we operate, we will revert to form in some ways as the COVID-19 crisis begins to recede from memory. Historically, our industry has not been quick to welcome new technologies and new ways of doing things. For example, the rollout of electronic data capture technology arguably took us the better part of two decades to truly adopt it and get to the point where it's now routine.

The kinds of protocols we need to adopt this new modality simply aren't there yet, and it's going to take some time to reach the point where they are available. Frankly, it's probably not this generation of protocols where we will meet the challenge. It's what we do with the next generation of protocols where we can seize the opportunity to truly modernize clinical trials from a technology and best practices standpoint.

COVID-19 has been a frightening and sometimes horrific experience, especially for clinical trial workers on the front lines who have watched people suffer and die. However, it has also presented us with a chance to improve. Let's work together to adapt the best of hybrid and virtual trials while holding onto the best of in-person monitoring.

We owe it to our industry, to our patients, and to ourselves to wrest anything positive we possibly can out of this experience.

**Paul Evans, PhD**, is President and CEO of Velocity Clinical Research, and Chair of the Association Board of Trustees for ACRP in 2020.

PEER REVIEWED

## **Impact of a Risk-Based, Study-Specific Training Program on Research Coordinator Competency**

Jessica Fritter, MACPR; Melissa Metheney, BSN, CCRC; Sally Jo Zuspan, RN, MSN



Clinical research coordinators (CRCs) are on the front lines of clinical research and play an integral role in human subjects' protection and protocol adherence. Despite this critical role, many CRCs report inadequate training for the roles to which they were assigned.{1}

The Pediatric Emergency Care Applied Research Network (PECARN) is the only federally funded pediatric emergency research network in the United States. The network was established by the Health Resources & Services Administration, Maternal Child Health Bureau, Emergency Medical Services for Children program in 2001. It is currently comprised of 18 clinical centers (Hospital Emergency Department Affiliates) and nine Emergency Medical Services Agencies.{2}

There are approximately 80 CRCs across PECARN sites that contribute to PECARN research studies. Our recent work concluded that many PECARN CRCs feel less than competent to perform their jobs adequately after their institutional onboarding process.{3} Despite local institutional onboarding programs that include shadowing, web training, simulation, and online courses, most CRCs did not report feeling confident to conduct clinical research.

From this prior work, we suggested that there is a need for CRC core competency training and education in clinical research. Recent regulatory changes in Good Clinical Practice (GCP) Guidance (ICH E6(R2) from the International Council for Harmonization) recommend that a risk assessment process should be used to identify key study activities that pose a risk to patient safety, data integrity, or regulatory compliance.{4} High- and moderate-risk study activities



should have a risk mitigation plan and a method for evaluation of these risks throughout the trial. We studied whether a targeted, competency-based training program focused on moderate to high risks would result in high levels of competency and performance in CRCs.

We conducted our study while PECARN implemented the Traumatic Injury Clinical Trial Evaluating Tranexamic Acid (TXA) in Children (TIC-TOC) study.<sup>{5}</sup> The TIC-TOC study is a multicenter, randomized, double-blinded, placebo-controlled trial collecting preliminary data on the safety of TXA in severely injured children and the feasibility of conducting a large definitive trial.

Our study-specific, competency-based training program combined both the Joint Task Force Competency Domains (JTFCDs) and the ICH E6(R2) risk assessment process into a training program for PECARN CRCs.<sup>{1,4}</sup> We evaluated perceived competency of CRCs in the PECARN based on the JTFCDs.

Our objective was to determine whether a targeted, competency-based training program focused on moderate- to high-risk aspects of a specific trial would result in both perception of competency among CRCs and actual performance competency on required study activities. We hypothesized that a CRC competency-based training program targeting high- and moderate-risk protocol activities would result in CRCs reporting that they felt competent to perform study activities as well as demonstrate their competency in performance of key study tasks.

## **Methods**

We designed a risk-based, study-specific competency training program, including a study training plan and simulation activity. The study team at the PECARN Data Coordinating Center (DCC) and the TIC-TOC study lead investigators completed a risk assessment of the trial protocol, based on the ICH E6(R2) guidelines, prior to study implementation.

The study team identified risks to subject safety and data integrity. Once these were defined, they then evaluated the risks for probability of occurrence, impact to the study data or subject safety, and likelihood of detection at the DCC. We identified several high-to-moderate risks in this trial. This includes administration of study drug in a chaotic Emergency Department environment,

limited time windows to complete study procedures, three study arms with mg/kg dosing, enrollment of children with or without parents present, and time-sensitive eligibility criteria.

We then developed a training plan (see Appendix A) that included a staff training checklist incorporating competency domains and the key study risks. Due to the complex nature of the TIC-TOC study procedures, we also devised a simulation activity in which CRCs could demonstrate competency of study skills inside their own Emergency Department.

A simulation activity is a common training exercise in medical settings where a patient scenario is created and participants must manage decision-making and treatment and assessment activities. Teams may use either a verbal outline of interventions (often known as a table top activity) or fully enacted role-play using patient mannequins and real medical interventions. The choice of table top or fully enacted simulation activity was selected by each site based on its standard approach to training simulations.

Simulations or mock trauma scenarios are a common training method in Emergency Departments, and all sites practiced trauma simulations routinely. Simulations can be a useful tool in training staff in research.<sup>{6}</sup> It took approximately four hours for CRCs to complete the study checklist and between 45 and 90 minutes to complete the simulation.

We also developed two surveys to evaluate the self-perceived competence of CRCs after site initiation training (competency survey) and after a study-specific simulation scenario. We piloted the competency survey among independent clinical research staff, including project managers and data analyst, for face validity. Under 45 CFR 46.101 of the *Code of Federal Regulations*, the Nationwide Children's Hospital Institutional Review Board found the study to be exempt from the need for further review.

The in-person CRC training session for the TIC-TOC trial covered the study protocol, enrollment activities, and basic research competencies such as regulatory, ethics, and human subject safety. We also included mock scenarios during the in-person training session that highlighted moderate- and high-risk key procedures that could pose a risk to subject safety or data integrity based on the risk assessment. The mock scenarios allowed CRCs to practice key procedures in a

low-stress training environment as a preparation for the simulations that would be held at their respective sites.

High- or moderate-risk trial procedures are ones that are judged to be complex, vary from standard of care, or must be administered within a strict timeline to avoid protocol deviation. For example, the TIC-TOC study protocol required drug administration within the specific time window from the time of injury. A miscalculation in this time window might not allow enough time for randomization and drug administration.

The study population was 20 emergency medicine CRCs from four hospitals in PECARN participating in the TIC-TOC trial. Respondents were recruited by e-mail and completed the competency survey using a REDCap survey tool after completing the study training. Once the survey tool was completed, CRCs were required to complete the study-specific simulation activity (described below) in their respective Emergency Departments.

After the simulation activity, participants completed a post-simulation survey to evaluate their perceived competence after the simulation exercise. The trainings, surveys, and simulations were administered prior to site enrollment, in April 2018. We did not use a “pre-post” survey design in this study for timing and logistical reasons. We designed this study to demonstrate perceived and actual competency, but were unable to evaluate these specific items prior to the training implementation.

### *Description of Survey Tools*

We administered the competency survey to the CRCs at the completion of the study training. The survey collected demographic information and perceived competence in areas relevant to the TIC-TOC trial. CRCs scored their perceived competency on a Likert scale from “not at all competent” to “very competent.” The competency survey delineated study procedures into each competency domain (see Table 1) in both a competency and survey pathway. Results were analyzed to measure CRCs’ level of perceived competence after completing the risk-based, study-specific competency training session.

**Table 1: Competency and Survey Pathway**

Scientific Concepts and Research Design	<ul style="list-style-type: none"><li>• Explaining Phase II trial</li><li>• Identifying key data required for outcome measures</li></ul>
Ethical Participant and Safety Design	<ul style="list-style-type: none"><li>• Informed consent</li><li>• Human subject protections</li></ul>
Investigational Products Development and Regulation	<ul style="list-style-type: none"><li>• Study drug dosage</li><li>• Identifying adverse events/serious adverse events (AEs/SAEs)</li></ul>
Clinical Study Operations (GCPs)	<ul style="list-style-type: none"><li>• Inclusion/exclusion criteria</li><li>• Collection procedures</li><li>• Randomization process</li><li>• ICH E6(R2) GCP guidelines</li></ul>
Study and Site Management	<ul style="list-style-type: none"><li>• Site-specific workflow</li></ul>
Data Management and Informatics	<ul style="list-style-type: none"><li>• Electronic data capture systems</li></ul>
Leadership and Professionalism	<ul style="list-style-type: none"><li>• Leadership and professionalism</li></ul>
Communications and Teamwork	<ul style="list-style-type: none"><li>• Communicating key information to site personnel (i.e., physicians, nurses, pharmacists, etc.)</li></ul>

*Description of Simulations*

After we surveyed the CRCs, each site held study-specific simulations conducted in the Emergency Department trauma resuscitation area or a table top simulation with trauma team members. A clinical research moderator led the simulation at each Emergency Department using a script and a list of specific tasks and procedures identified by the risk assessment and the JTFCD competencies (see Appendix B).

Participants were presented with patient-specific scenarios that might occur during an enrollment. Participants were evaluated on a pass/fail basis based on their performance of key study activities using a standardized tool that assessed competence in study-specific skills.

Each participant was required to successfully complete the simulation activity with a passing score. Passing was defined as completing all five sections of the simulation activity accurately according to the protocol. Participants were allowed three attempts to successfully pass the simulation activity. The study activities included screening and eligibility, informed consent,

study drug administration/randomization, baseline activities/sample collection, and follow-up and AE/SAE reporting.

The data analyzed included the results from two surveys evaluating perceived competence among participating CRCs in the TIC-TOC study after completion of the staff training checklist and the simulation, and the CRCs’ results (pass/fail) from the study-specific simulation.

**Results**

There were 20 survey participants with varying backgrounds (see Table 2).

**Table 2: Competency Survey Demographics**

	<b>n (%)</b>
<b>Job Title</b>	
Enroller	0 (0%)
Research Assistant	5 (25%)
Research Coordinator	13 (65%)
Research Associate	0 (0%)
Research Manager	2 (10%)
Other	0 (0%)
<b>Years of Experience in Clinical Research</b>	
<1 year	5 (25%)
1 to <2 years	5 (25%)
2 to <3 years	4 (20%)
3 years or more	6 (30%)
<b>Clinical Research Certifications Obtained</b>	
Certified Clinical Research Associate (CCRA)	3 (15%)
Certified Clinical Research Professional (CCRP)	1 (5%)
Certified Clinical Research Coordinator (CCRC)	3 (15%)
Other	13 (65%)
<b>Highest Level of Education</b>	
High School Diploma or GED	0 (0%)
Associate Degree	0 (0%)
Bachelor’s Degree	16 (80%)
Master’s Degree	4 (20%)
Doctoral Degree	0 (0%)

After the training, more than 80% of CRCs reported feeling “very competent” in informed consent, GCP, and leadership and professionalism. Most CRCs reported being “very competent” in the definition of the trial, the study outcome, study drug dosing, inclusion/exclusion criteria, workflow, electronic data capture, and communication. About half of the CRCs reported being “very competent” in sample processing, randomization, and defining the study outcome. The remainder indicated they felt “somewhat competent” in these areas (see Table 3). Few CRCs indicated they felt “slightly competent” or “not at all competent” in these areas. CRCs reported varying levels of competence in understanding and reporting safety and AE/SAE issues in the trial, with 50% feeling “very competent,” 30% feeling “somewhat competent,” and 20% “slightly confident.”

**Table 3: Competency Survey Results**

Scale: 1=Not at all competent; 2=Slightly competent; 3=Somewhat competent; 4=Very competent

<b>Scientific Concepts and Research Design</b>	<b>3.5 (0.46)</b>
After reading the protocol, how competent do you feel in explaining the definition of a Phase II randomized, double-blinded, placebo-controlled trial?	3.65 (0.49)
After reading the protocol, how competent do you feel in identifying the key data elements required for the primary outcome measure of the trial: the total amount of blood products transfused in the initial 48 hours?	3.35 (0.59)
<b>Ethical and Participant Safety Considerations</b>	<b>3.83 (0.28)</b>
Regarding the site-specific informed consent document, how competent do you feel in describing all eight required elements of informed consent to prospective participants in the trial?	3.75 (0.55)
Regarding your site’s specific informed consent document, how competent do you feel in selecting an appropriate location where you will discuss informed consent with the family?	3.75 (0.55)
Regarding Protection of Human Subjects, how competent do you feel in understanding protection of human subject's guidelines from required training? (This may include CITI training or other site-specific systems.)	4 (0)
<b>Investigational Products Development and Regulation</b>	<b>3.45 (0.67)</b>
How competent do you feel in determining the appropriate dose of study drug to give to the participant?	3.6 (0.68)
How competent do you feel in understanding how to identify and report AE/SAEs and other participant safety issues?	3.3 (0.8)
<b>Clinical Study Operations (GCPs)</b>	<b>3.61 (0.43)</b>
How competent do you feel in applying the inclusion and exclusion criteria to evaluate subject eligibility?	3.7 (0.47)
How competent do you feel about collection procedures including sample processing, sample storage, tube priority, storage, and shipping of study samples?	3.55 (0.6)

How competent do you feel in understanding the randomization process and what to do if the Use Next Box is not available?	3.35 (0.93)
Regarding Good Clinical Practice (GCP), how competent do you feel in understanding the ICH E6(R2) GCP guidelines around conducting clinical trials?	3.85 (0.37)
<b>Study and Site Management</b>	<b>3.65 (0.59)</b>
How competent do you feel with your site-specific work flow and carrying it out to complete enrollment of participants in compliance with the protocol?	3.65 (0.59)
<b>Data Management and Informatics</b>	<b>3.68 (0.54)</b>
Regarding electronic data capture (EDC) systems, how competent do you feel in utilizing OpenClinica and REDCap?	3.75 (0.44)
In regards to EDC, how competent do you feel in utilizing Query Manager?	3.6 (0.82)
<b>Leadership and Professionalism</b>	<b>3.95 (0.22)</b>
How competent do you feel in your leadership and professionalism skills?	3.95 (0.22)
<b>Communications and Teamwork</b>	<b>3.75 (0.44)</b>
In regards to Communication, how competent do you feel in communicating key information to all site personnel involved in the study (i.e., Emergency Department clinicians, nurses, pharmacists)?	3.75 (0.44)

Fourteen out of the 20 CRCs successfully completed the simulation activity and all participants were able to pass in fewer than three attempts. In the simulation survey, 64% of CRCs reported feeling “very competent” in screening and eligibility for eligible patients, 86% “very competent” in informed consent, 64% “very competent” in study drug administration/randomization, 50% “very competent” in baseline activities/sample collection, and 57% “very competent” in follow-up and AE/SAE tracking. This is further shown in Table 4.

**Table 4: Simulation Survey Results**

	<b>Not at All Competent</b>	<b>Slightly Competent</b>	<b>Somewhat Competent</b>	<b>Very Competent</b>
How competent did you feel you could screen for eligible patients?	0% (0)	0% (0)	36% (5)	64% (9)
How competent did you feel going through the informed consent process?	0% (0)	0% (0)	14% (2)	86% (12)
How competent did you feel with study drug administration and randomization?	0% (0)	0% (0)	36% (5)	64% (9)
How competent did you feel with sample collection?	0% (0)	0% (0)	50% (7)	50% (7)
How competent did you feel with AE/SAE tracking?	0% (0)	14% (2)	29% (4)	57% (8)

## Discussion

We devised a risk-based, competency-focused training program combining the JTFCDs and the ICH E6(R2) risk assessment process into a study-specific program for PECARN CRCs. We combined these two approaches to address our previous finding that institutional onboarding processes did not adequately prepare PECARN CRCs to perform their jobs effectively. The risk assessment process helped identify moderate- to high-risk study procedures that could potentially impact study data or patient safety in a PECARN clinical trial. The staff training checklist helped direct the CRCs to the key risk areas *prior* to the training, and required them to identify potential problems in integrating the key study procedures at their own site.

We designed the training session to emphasize the moderate- and high-risk procedures both by using didactic lectures and mock scenarios. We felt “hands-on” scenarios combined with the lectures would help to instill confidence in the CRCs. Eligibility determination, obtaining parental permission, study drug administration, and sample collection were all determined to have higher than standard risk and elevated complexity, and were therefore integrated into the Staff Training Checklist and the study training session.

Finally, we implemented a study-specific simulation activity at each site that required CRCs to demonstrate competency in performing the moderate- to high-risk procedures as well as the activities in the JTFCDs. Importantly, the simulation activity required CRCs to demonstrate competence by successfully performing both standard skills representing the JTFCDs as well as the key procedures identified in the risk assessment.

Our results suggest that this focused approach helped CRCs feel competent in the high- to moderate-risk areas of the trial as well as in the standard areas of research. The risk-based approach combined with the JTFCDs resulted in a highly focused training session designed to increase CRC perceived competence as well as demonstrate competence in a study simulation activity. We suggest that this sort of measure is a critical piece of determining competence in



perceived and actual performance, and recommend that other programs integrate similar programs.

While many CRCs felt “very competent” on most of the skills, there were CRCs who indicated they felt only “somewhat competent” on key study activities. It is difficult to distinguish whether those who felt “somewhat competent” were more modest in their self-evaluation, or whether that categorization reflects a perceived shortfall in knowledge.

CRCs’ perceived competency varied across the different areas of the survey. For example, 70% or more of CRCs perceived they were competent in informed consent, the ICH E6(R2) GCP guidelines, and the study drug administration in the competency survey, but fewer CRCs selected “very competent” for AE/SAE reporting and sample collection. This disparity could have been related to the amount of training time devoted to each topic, the topic’s complexity, or the baseline knowledge of each CRC.

We acknowledge that there are areas in which our training may have fallen short, and we will address the areas with lower perceived competence in our next training. We also noticed differences in perceived competency between the two surveys. Seventy percent of CRCs indicated they were “very competent” in determining the “appropriate study dose” in the competency survey, but only 64% indicated they were very competent in “study drug administration and randomization” in the simulation survey.

While we cannot make any statistical comparison nor conclusion between these two groups, we suggest the difference may be because an individual’s perception of competence does not always match their performance of a specific task. The variation in the wording of the questions could have contributed to this difference, or the time period in which the survey was administered may have impacted these responses.

Despite these differences, we are encouraged by the fact that most participants ranked their competence in the upper two categories (“very competent” and “somewhat competent”). Each CRC successfully passed the simulation activity by demonstrating competency in key study activities. This suggests that perception of competence is not an adequate predictor of

performance, or that despite *demonstrating* competency in performing the task, CRCs may have lingering doubt about their own individual perceived competency, and thus the scores may never match the performance.

## **Limitations**

Competence evaluations rely on self-report of the participants and are subjective. We did not know what the levels of perceived competency were before the CRCs completed the study training. The study simulation activities were conducted as was customary in each institution's Emergency Department and were not standardized. While we provided a study script and a standardized competency check-off form, the actual simulation activity may have varied among sites, and this could have affected results.

Another limitation is a difference between the number of participants in the competency survey (20) and the simulation survey (14)—because they are not identical, it is difficult to draw conclusions of relevant competency within both groups. We also realize that the options on the competency survey and the simulation survey (“not at all,” “slightly,” “somewhat,” and “very” competent) were not defined, and this could have resulted in different interpretations by the participants.

## **Conclusion**

CRCs successfully demonstrated key study skills and reported feeling competent in key study activities after completing a risk-based, competency focused training program for a randomized clinical trial of severely injured children. A risk-based training program that incorporates JTFCDs may lead to better performance of study procedures in a clinical trial. It will be beneficial to follow up with the participants to see if, after having enrolled study patients, they feel as though the training helped sustain their confidence.

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PEER REVIEWED

## **Navigating a Career as a Clinical Research Professional: Where to Begin?**

Bridget Kesling, MACPR;Carolynn Jones, DNP, MSPH, RN, FAAN; Jessica Fritter, MACPR; Marjorie V. Neidecker, PhD, MEng, RN, CCRP



Those seeking an initial career in clinical research often ask how they can “get a start” in the field. Some clinical research professionals may not have heard about clinical research careers until they landed that first job.

Individuals sometimes report that they have entered the field “accidentally” and were not previously prepared.

Those trying to enter the clinical research field lament that it is hard to “get your foot in the door,” even for entry-level jobs and even if you have clinical research

education. An understanding of how individuals enter the field can be beneficial to newcomers who are targeting clinical research as a future career path, including those novices who are in an academic program for clinical research professionals.

We designed a survey to solicit information from students and alumni of an online academic clinical research graduate program offered by a large public university. The purpose of the survey was to gain information about how individuals have entered the field of clinical research; to identify facilitators and barriers of entering the field, including advice from seasoned practitioners; and to share the collected data with individuals who wanted to better understand employment prospects in clinical research.

### **Background**

Core competencies established and adopted for clinical research professionals in recent years have informed their training and education curricula and serve as a basis for evaluating and

progressing in the major roles associated with the clinical research enterprise.{1,2} Further, entire academic programs have emerged to provide degree options for clinical research,{3,4} and academic research sites are focusing on standardized job descriptions.

For instance, Duke University re-structured its multiple clinical research job descriptions to streamline job titles and progression pathways using a competency-based, tiered approach. This led to advancement pathways and impacted institutional turnover rates in relevant research-related positions.{5,6} Other large clinical research sites or contract research organizations (CROs) have structured their onboarding and training according to clinical research core competencies. Indeed, major professional organizations and U.S. National Institutes of Health initiatives have adopted the Joint Task Force for Clinical Trial Competency as the gold standard approach to organizing training and certification.{7,8}

Recent research has revealed that academic medical centers, which employ a large number of clinical research professionals, are suffering from high staff turnover rates in this arena, with issues such as uncertainty of the job, dissatisfaction with training, and unclear professional development and role progression pathways being reported as culprits in this turnover.{9} Further, CROs report a significant shortage of clinical research associate (CRA) personnel.{10} Therefore, addressing factors that would help novices gain initial jobs would address an important workforce gap.

## **Methods**

This mixed-methods survey study was initiated by a student of a clinical research graduate program at a large Midwest university who wanted to know how to find her first job in clinical research. Current students and alumni of the graduate program were invited to participate in an internet-based survey in the fall semester of 2018 via e-mails sent through the program listservs of current and graduated students from the program's lead faculty. After the initial e-mail, two reminders were sent to prospective participants.

The survey specifically targeted students or alumni who had worked in clinical research. We purposefully avoided those students with no previous clinical research work experience, since

they would not be able to discuss their pathway into the field. We collected basic demographic information, student's enrollment status, information about their first clinical research position (including how it was attained), and narrative information to describe their professional progression in clinical research. Additional information was solicited about professional organization membership and certification, and about the impact of graduate education on the acquisition of clinical research jobs and/or role progression.

The survey was designed so that all data gathered (from both objective responses and open-ended responses) were anonymous. The survey was designed using the internet survey instrument Research Electronic Data Capture (REDCap), which is a secure, web-based application designed to support data capture for research studies. REDCap provides an intuitive interface for validated data entry; audit trails for tracking data manipulation and export procedures; automated export procedures for seamless data downloads to common statistical packages; and procedures for importing data from external sources. { 11 }

Data were exported to Excel files and summary data were used to describe results. Three questions solicited open-ended responses about how individuals learned about clinical research career options, how they obtained their first job, and their advice to novices seeking their first job in clinical research. Qualitative methods were used to identify themes from text responses. The project was submitted to the university's institutional review board and was classified as exempt from requiring board oversight.

## **Results**

A total of 215 survey invitations were sent out to 90 current students and 125 graduates. Five surveys were returned as undeliverable. A total of 48 surveys (22.9%) were completed. Because the survey was designed to collect information from those who were working or have worked in clinical research, those individuals (n=5) who reported (in the first question) that they had never worked in clinical research were eliminated. After those adjustments, the total number completed surveys was 43 (a 20.5% completion rate).

The median age of the participants was 27 (range 22 to 59). The majority of respondents (89%) reported being currently employed as clinical research professionals and 80% were working in clinical research at the time of graduate program entry. The remaining respondents had worked in clinical research in the past. Collectively, participants' clinical research experience ranged from less than one to 27 years.

Research assistant (20.9%) and clinical research coordinator (16.3%) were the most common first clinical research roles reported. However, a wide range of job titles were also reported. When comparing entry-level job titles of participants to their current job title, 28 (74%) respondents reported a higher level job title currently, compared to 10 (26%) who still had the same job title.

Twenty-four (65%) respondents were currently working at an academic medical center, with the remaining working with community medical centers or private practices (n=3); site management organizations or CROs (n=2); pharmaceutical or device companies (n=4); or the federal government (n=1).

Three respondents (8%) indicated that their employer used individualized development plans to aid in planning for professional advancement. We also asked if their current employer provided opportunities for professional growth and advancement. Among academic medical center respondents, 16 (67%) indicated in the affirmative. Respondents also affirmed growth opportunities in other employment settings, with the exception of one respondent working in government and one respondent working in a community medical center.

Twenty-five respondents indicated membership to a professional association, and of those, 60% reported being certified by either the Association of Clinical Research Professionals (ACRP) or the Society of Clinical Research Associates (SoCRA).

### **Open-Ended Responses**

We asked three open-ended questions to gain personal perspectives of respondents about how they chose clinical research as a career, how they entered the field, and their advice for novices entering the profession. Participants typed narrative responses.

***“Why did you decide to pursue a career in clinical research?”***

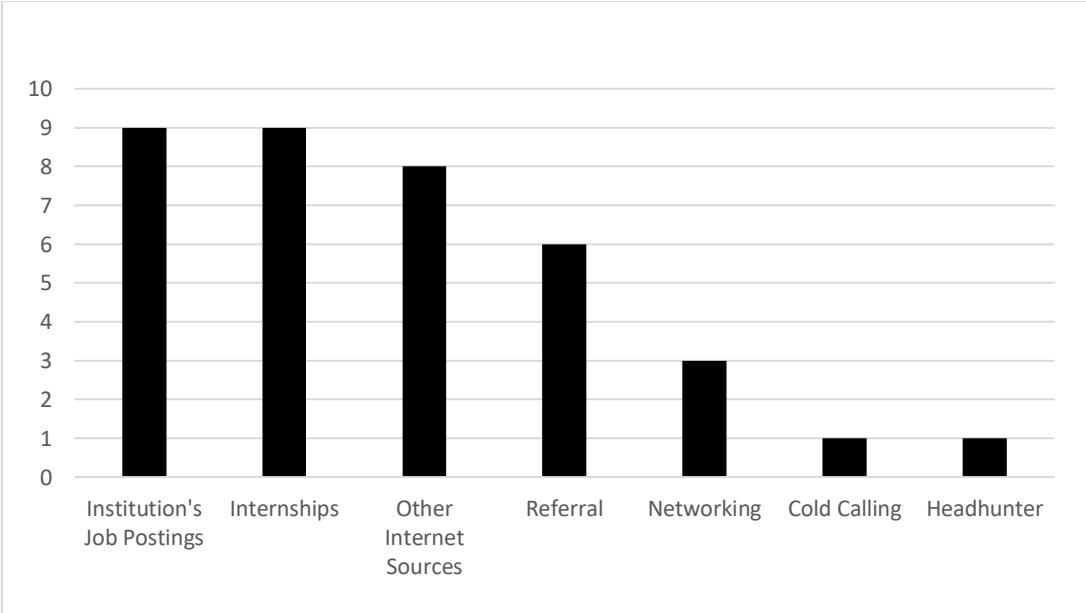
This question was asked to find out how individuals made the decision to initially consider clinical research as a career. Only one person in the survey had exposure to clinical research as a career option in high school, and three learned about such career options as college undergraduates. One participant worked in clinical research as a transition to medical school, two as a transition to a doctoral degree program, and two with the desire to move from a bench (basic science) career to a clinical research career.

After college, individuals either happened across clinical research as a career “by accident” or through people they met. Some participants expressed that they found clinical research careers interesting (n=6) and provided an opportunity to contribute to patients or improvements in healthcare (n=7).

***“How did you find out about your first job in clinical research?”***

Qualitative responses were solicited to obtain information on how participants found their first jobs in clinical research. The major themes that were revealed are sorted in Figure 1.

**Figure 1: How First Jobs in Clinical Research Were Found**





Some reported finding their initial job through an institution's job posting.

*"I worked in the hospital in the clinical lab. I heard of the opening after I earned my bachelor's and applied."*

Others reported finding about their clinical research position through the internet. Several did not know about clinical research roles before exploring a job posting.

*"In reviewing jobs online, I noticed my BS degree fit the criteria to apply for a job in clinical research. I knew nothing about the field."*

*"My friend recommended I look into jobs with a CRO because I wanted to transition out of a production laboratory."*

*"I responded to an ad. I didn't really know that research could be a profession though. I didn't know anything about the field, principles, or daily activities."*

Some of the respondents reported moving into a permanent position after a role as an intern.

*"My first clinical job came from an internship I did in my undergrad in basic sleep research. I thought I wanted to get into patient therapies, so I was able to transfer to addiction clinical trials from a basic science lab. And the clinical data management I did as an undergrad turned into a job after a few months."*

*"I obtained a job directly from my graduate school practicum."*

*"My research assistant internship [as an] undergrad provided some patient enrollment and consenting experience and led to a CRO position."*

Networking and referrals were other themes that respondents indicated had a direct impact on them finding initial employment in clinical research.

*"I received a job opportunity (notice of an opening) through my e-mail from the graduate program."*

*“I was a medical secretary for a physician who did research and he needed a full-time coordinator for a new study.”*

*“I was recommended by my manager at the time.”*

*“A friend had a similar position at the time. I was interested in learning more about the clinical research coordinator position.”*

***“What advice do you have for students and new graduates trying to enter their first role in clinical research?”***

We found respondents (n=30) sorted into four distinct categories: 1) a general attitude/approach to job searching, 2) acquisition of knowledge/experience, 3) actions taken to get a position, and 4) personal attributes as a clinical research professional in their first job.

Respondents stressed the importance of flexibility and persistence (general attitude/approach) when seeking jobs. Moreover, 16 respondents stressed the importance of learning as much as they could about clinical research and gaining as much experience as they could in their jobs, encouraging them to ask a lot of questions. They also stressed a broader understanding of the clinical research enterprise, the impact that clinical research professional roles have on study participants and future patients, and the global nature of the enterprise.

*“Apply for all research positions that sound interesting to you. Even if you don't meet all the requirements, still apply.”*

*“Be persistent and flexible. Be willing to learn new skills and take on new responsibilities. This will help develop your own niche within a group/organization while creating opportunities for advancement.”*

*“Be flexible with salary requirements earlier in your career and push yourself to learn more [about the industry's] standards [on] a global scale.”*

*“Be ever ready to adapt and change along with your projects, science, and policy. Never forget the journey the patients are on and that we are here to advance and support it.”*

*“Learning the big picture, how everything intertwines and works together, will really help you progress in the field.”*

In addition to learning as much as one can about roles, skills, and the enterprise as a whole, advice was given to shadow or intern whenever possible—formally or through networking—and to be willing to start with a smaller company or with a lower position. The respondents stressed that novices entering the field will advance in their careers as they continue to gain knowledge and experience, and as they broaden their network of colleagues.

*“Take the best opportunity available to you and work your way up, regardless [if it is] at clinical trial site or in industry.”*

*“Getting as much experience as possible is important; and learning about different career paths is important (i.e., not everyone wants or needs to be a coordinator, not everyone goes to graduate school to get a PhD, etc.).”*

*“(A graduate) program is beneficial as it provides an opportunity to learn the basics that would otherwise accompany a few years of entry-level work experience.”*

*“Never let an opportunity pass you up. Reach out directly to decision-makers via e-mail or telephone—don't just rely on a job application website. Be willing to start at the bottom. Absolutely, and I cannot stress this enough, [you should] get experience at the site level, even if it's just an internship or [as a] volunteer. I honestly feel that you need the site perspective to have success at the CRO or pharma level.”*

Several personal behaviors were also stressed by respondents, such as knowing how to set boundaries, understanding how to demonstrate what they know, and ability to advocate for their progression. Themes such as doing a good job, communicating well, being a good team player, and sharing your passion also emerged.

*“Be a team player, ask questions, and have a good attitude.”*

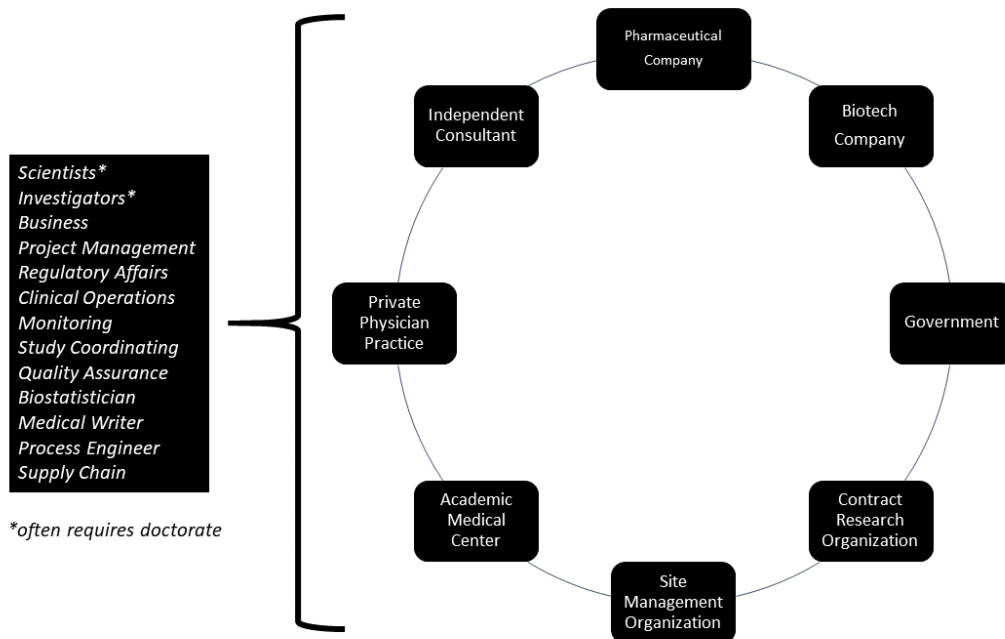
*“Be eager to share your passion and drive. Although you may lack clinical research experience, your knowledge and ambition can impress potential employers.”*

*“[A] HUGE thing is learning to sell yourself. Many people I work with at my current CRO have such excellent experience, and they are in low-level positions because they didn't know how to negotiate/advocate for themselves as an employee.”*

## Discussion

This mixed-methods study used purposeful sampling of students in an academic clinical research program to gain an understanding of how novices to the field find their initial jobs in the clinical research enterprise; how to transition to a clinical research career; and how to find opportunities for career advancement. There are multiple clinical research careers and employers (see Figure 2) available to individuals working in the clinical research enterprise.

**Figure 2: Employers and Sample Careers**



Despite the need for employees in the broad field of clinical research, finding a pathway to enter the field can be difficult for novices. The lack of knowledge about clinical research as a career option at the high school and college level points to an opportunity for broader inclusion of these careers in high school and undergraduate curricula, or as an option for guidance counselors to be aware of and share with students.

Because most clinical research jobs appear to require previous experience in order to gain entry, novices are often put into a “Catch-22” situation. However, once hired, upward mobility does exist, and was demonstrated in this survey. Mobility in clinical research careers (moving up and general turnover) may occur for a variety of reasons—usually to achieve a higher salary, to benefit from an improved work environment, or to thwart a perceived lack of progression opportunity.{9}

During COVID-19, there may be hiring freezes or furloughs of clinical research staff, but those personnel issues are predicted to be temporary. Burnout has also been reported as an issue among study coordinators, due to research study complexity and workload issues.{ 12} Moreover, the lack of individualized development planning revealed by our sample may indicate a unique workforce development need across roles of clinical research professionals.

This survey study is limited in that it is a small sample taken specifically from a narrow cohort of individuals who had obtained or were seeking a graduate degree in clinical research at a single institution. The study only surveyed those currently working in or who have a work history in clinical research. Moreover, the majority of respondents were employed at an academic medical center, which may not fully reflect the general population of clinical research professionals.

It was heartening to see the positive advancement in job titles for those individuals who had been employed in clinical research at program entry, compared to when they responded to the survey. However, the sample was too small to draw reliable correlations about job seeking or progression.

## Conclusion

Although finding one's first job in clinical research can be a lengthy and discouraging process, it is important to know that the opportunities are endless. Search in employment sites such as Indeed.com, but also search within job postings for targeted companies or research sites such as biopharmguy.com (see Table 1). Created a LinkedIn account and join groups and make connections. Participants in this study offered sound advice and tips for success in landing a job (see Figure 3).

**Table 1: Sample Details from an Indeed.Com Job Search**

<b>Position</b>	<b>Company</b>	<b>Minimum Qualifications</b>
Clinical Research Patient Recruiter	PPD	Bachelor's degree and related experience
Clinical Research Assistant	Duke University	Associate degree
Clinical Trials Assistant	Guardian Research Network	Bachelor's degree and knowledge of clinical trials
Clinical Trials Coordinator	Advarra Health Analytics	Bachelor's degree
Clinical Research Specialist	Castle Branch	Bachelor's degree and six months in a similar role
Clinical Research Technician	Rose Research Center, LLC	Knowledge of Good Clinical Practice and experience working with patients
Clinical Research Lab Coordinator	Coastal Carolina Research Center	One year of phlebotomy experience
Project Specialist	WCG	Bachelor's degree and six months of related experience
Data Coder	WCG	Bachelor's degree or currently enrolled in an undergraduate program

Note: WCG = WIRB Copernicus Group

## Figure 3: Twelve Tips for Finding Your First Job

- Seek out internships and volunteer opportunities
- Network, network, network
- Be flexible and persistent
- Learn as much as possible about clinical research
- Consider a degree in clinical research
- Ask a lot of questions of professionals working in the field

- Apply for all research positions that interest you, even if you think you are not qualified
- Be willing to learn new skills and take on new responsibilities
- Take the best opportunity available to you and work your way up
- Learn to sell yourself
- Sharpen communication (written and oral) and other soft skills
- Create an ePortfolio or LinkedIn account

Being willing to start at the ground level and working upwards was described as a positive approach because moving up does happen, and sometimes quickly. Also, learning soft skills in communication and networking were other suggested strategies. Gaining education in clinical research is one way to begin to acquire knowledge and applied skills and opportunities to network with experienced classmates who are currently working in the field.

Most individuals entering an academic program have found success in obtaining an initial job in clinical research, often before graduation. In fact, the student initiating the survey found a position in a CRO before graduation.

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SPECIAL FEATURE

## **Using a Master Protocol and Mobile Technology to Accelerate COVID-19 Research**

Ingrid Oakley-Girvan, PhD, MPH



The COVID-19 pandemic continues to have an unprecedented impact on individual lives, families, communities, healthcare systems, and economies around the world. For the public health and scientific community, there is an immediate need to accelerate COVID-19 research for diagnostic testing, immunity monitoring, and drug and vaccine development. At the same time, there is a critical need to ensure progress on existing clinical research for keeping active trials in flight while ensuring the safety of trial participants and healthcare workers.

As the COVID-19 pandemic has reinforced, traditional clinical trial processes and timelines are insufficient to meet the world's need for safe, timely, and effective treatments. We believe the industry can and must move into a more decentralized approach to trials, including remote data collection via digital and mobile technologies, process innovations, and collaborative research approaches that span multiple stakeholders within the trial and research ecosystems.

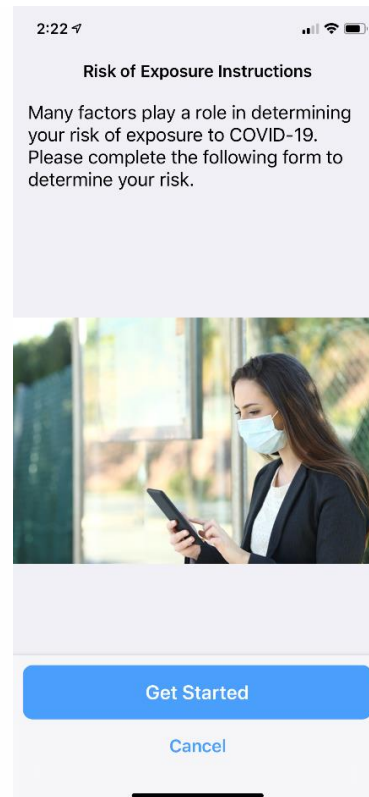
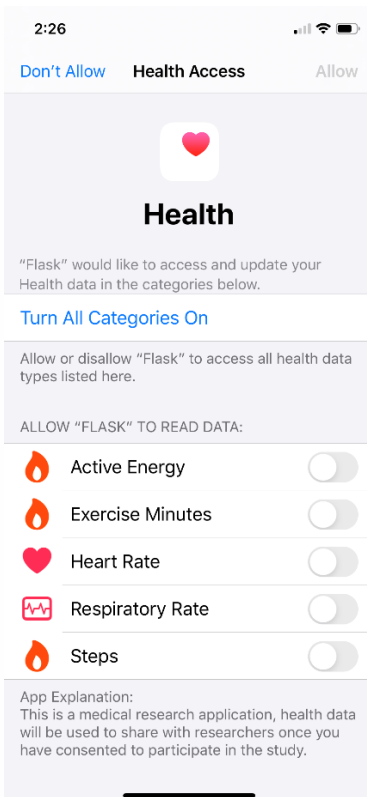
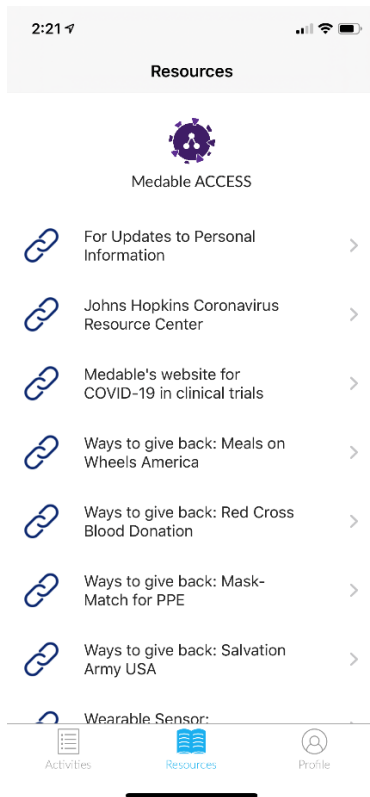
This is possible because the technology is here, and has been for quite some time. However, until recently, virtual or decentralized trials were considered a progressive, “nice to have” option when designing a trial or research study. Traditional processes and mindsets dominated, despite the well-known issues of significant trial costs, slow timelines, poor enrollment, retention challenges, lack of participant diversity, and other challenges.

The tide is turning, though, and COVID-19 is a catalyst. Remote visits and mobile devices are absolutely vital now as people are expected to stay at home and keep their distance. Of the 55,000 trials in flight, some are good candidates for a fully decentralized model—while many others can be managed in a hybrid model. Patients can be recruited and consented remotely. Physician “visits” can often be conducted remotely via telemedicine. Data can easily be captured remotely (and frequently) via medical devices and mobile technology.

### **The ACCESS Initiative**

While decentralized trials provide both a short- and long-term solution to ensuring clinical research progress, we also believe the industry needs to adopt more creative and collaborative approaches to research. To that end, Medable recently partnered with several like-minded companies to launch the ACCESS initiative—short for American COVID-19 Collaborative Enabling Seamless Science. ACCESS is a master observational protocol that uses digital and mobile technologies to enable groundbreaking research. Our goal is to accelerate disease and immunity testing and clinical drug and vaccine development for COVID-19.

Powered by a mobile consumer application (see screenshot examples on next page), ACCESS is always available to hundreds of thousands of individuals in the U.S. whether they are home or not. It provides a digital onramp to diagnostics, monitoring, and clinical trials with an intensity of purpose around scientific discovery that can help people get back to work safely.



ACCESS makes it easy for individuals to contribute specific information about their COVID-19 experience, and then (with their permission) combine health records and wearable device data to enable rapid and significant discoveries. Participants can also opt in to learn more about current and future studies for diagnostics, treatments, and vaccines. The aggregated data provide researchers with a foundational framework for dynamic implementation of projects critical to help beat this disease.

The multi-company ACCESS initiative is led by Medable, together with technology, healthcare, and life sciences companies including [BioIntelliSense](#), [Datavant](#), [Parexel](#), [PWNHealth](#) and the [American Heart Association’s Center for Health Technology and Innovation](#). The infrastructure combines opt-in medical-grade wearable sensors, patient-reported data and outcomes, opt-in historical health data, and health record aggregation. Participants maintain control over their personal health data—and decide how they want to engage in potential studies.

As a master observational protocol, ACCESS accelerates research and clinical trials in the following important ways:

- Provides a ready-to-go, mobile primary protocol framework that can digitally harmonize essential clinical data across a diverse population of participants;
- Creates a foundational dataset for qualified researchers comprised of robust and validated medical data across a large participant population;
- Enables a pool of prequalified participants by using algorithmic matching to exclusion and inclusion criteria for sub-study clinical trials to reduce recruitment and enrollment timelines;
- Supports a flexible framework to accelerate participant digital consent and onboarding to sub-studies and clinical trials; and
- Removes barriers to participation and evidence generation through a decentralized clinical trial infrastructure that facilitates at-home research participation.

## **Treatment and Vaccine Development**

One of the goals for ACCESS is to accelerate treatment and vaccine development by removing time-consuming barriers throughout the clinical drug development lifecycle (see Table 1). The strategy is to leverage the master protocol to collect critical baseline clinical trial data. These data are then rapidly used to derive research insights and establish a pool of prequalified or “trial-ready” participants for sub-study clinical trial recruitment. This participant-powered process is tied into best practices for informed consent and study transparency. If a participant is interested in a matched sub-study, the framework enables seamless consent, enrollment, and participation.

**Table 1: Methods for Removing Time-Consuming Barriers to Drug Development**

Clinical Research Requirement	Accelerator
<b>Baseline Data</b>	<ul style="list-style-type: none"> <li>● Primary protocol collects robust baseline data to inform case and control datasets and provide natural history disease knowledge</li> </ul>
<b>Protocol Deployment</b>	<ul style="list-style-type: none"> <li>● Streamlined framework for rapid sub-study protocol deployment that can be easily configured from within the master protocol to accommodate sub-study requirements</li> </ul>
<b>Recruitment</b>	<ul style="list-style-type: none"> <li>● Prequalified population of individuals interested and actively participating in research</li> </ul>
<b>Enrollment</b>	<ul style="list-style-type: none"> <li>● Data-driven prequalification enables activation of interested and eligible participant within 24 hours</li> </ul>
<b>Evidence Generation</b>	<ul style="list-style-type: none"> <li>● Synthetic control data from master protocol data</li> <li>● Potentially improved retention with decentralized/at-home trial format</li> <li>● Data tokenization enables long-term follow-up and outcome data capture across medical record databases</li> </ul>

**Real-World Data Collection and Vital Sign Monitoring**

One challenging barrier to drug and vaccine development is the collection of real-world evidence for long-term outcome tracking. ACCESS reduces the barrier by enabling self-reported and biosensor data along with robust and validated real-world data capture across typically hard-to-consolidate data sources, including but not limited to prescription, medical record, lab, claims, and mortality data. Data may be collected for a 10-year duration to enable hard-to-measure long-term outcomes. Tokenization utilizes unique participant data elements to retrieve data from data repositories. Importantly, these data are only included from participants who actively consent for real-world data collection.

In our evaluation of research studies and clinical trials for diagnostic testing, treatment, and vaccine development with healthy participants or participants with mild to moderate COVID-19, the need to collect physiological data was common and important for active infection monitoring. Therefore, ACCESS enables real-time physiologic data collection across core vital signs using common consumer devices, including the Apple Watch. For research studies requiring continuous vital sign monitoring or U.S. Food and Drug Administration–cleared data collection, ACCESS currently provides the BioIntellisense BioSticker as a provisioned and integrated device and other devices, including AliveCor’s KardiaPro 6L for ECG monitoring and other biometrics.

Remote monitoring is also important to identify adverse reactions to therapies and vaccines. ACCESS provides an analytics framework to monitor data as well as remote nursing capabilities to monitor and manage participants. These aspects are critical to enabling at-home research, as few clinical trial teams can quickly provide at home in-person services when needed—and data volumes can often exhaust standard site and data management resources.

### **Contribution and Impact**

ACCESS is a novel digital research framework that enables participants to power critical research from the comfort of their homes. The immediate purpose is to accelerate critical COVID-19 knowledge, research, and clinical drug and vaccine development. As a master observational protocol, it will allow partners to capture and combine information via pre-integrated digital technology—and rapidly launch sub-studies to accelerate research when time is of the essence.

We believe there is no going back to the “old” clinical trial structure. The new normal will be an improved, technology-enabled approach that is more efficient, decentralized, and patient-centric. Together, we can harness the power of the people to contribute to finding cures for disease, regardless of where they live.



**Ingrid Oakley-Girvan, PhD, MPH**, is Senior Vice President of Research and Strategy at Medable, a member of the Stanford Cancer Institute and the Canary Center at Stanford for Cancer Early Detection, and Director of the Data and Technology Proving Ground at the Public Health Institute.

GOOD MANAGEMENT PRACTICE

## How to Master the Clinical Trials Data Explosion

Lars Behrend, PhD; Michael Sigmund, DVM



According to an annual survey of the American software company Veeva, 81% of all professionals use spreadsheets during the start-up phase of clinical trials.<sup>{1}</sup> Therefore, it is hardly surprising that all of the survey respondents (100%) considered improvements in the processes between study sites, sponsors, and contract research organizations (CROs) to be necessary.

In clinical trials in particular, it is challenging to coordinate a number of teams and different disciplines in a time-critical working environment and with highest commitment to patient safety. Increasingly tough regulatory requirements and the advance of digitalization are producing more and more data that have to be documented, reviewed, and evaluated for trial leaders to make the best decisions. A clinical trial management system (CTMS) based on a low-code platform could be the solution, especially for medium-sized pharmaceutical, biotech, and medical device companies.

In multidisciplinary projects, the use of information technology (IT) systems based on separate applications inevitably produces data silos that are not practicable and that limit manageability. Moreover, in clinical trials, sponsors and CROs risk losing data and breaching data security requirements or Good Clinical Practice (GCP) standards by using spreadsheets and local data storage. High IT standards including central storage, regular backup, and user access management practices that are mandatory in a research field that involves handling patient data and has implications for people's health.



## **Critical Decisions Require Consolidated Information**

A project manager in charge of clinical trials has to handle a flood of information. Especially in an environment that is heavily dependent on outsourcing through many subcontractors, content is delivered in different formats, with variable degrees of complexity, and with different topicality. If information is not consolidated properly, drawing the right conclusions will be challenging. Unwanted developments could pass unnoticed and delay timelines as a consequence. Further, compliance and patient security may be at risk if lack of oversight results in wrong decisions or missing interventions.

A CTMS can assist project managers and teams in a clinical study alike by providing all relevant information in one location. These systems create a central workspace for all stakeholders and make information available to members of the project team. The functionalities usually comprise:

- Project management
- Budget planning
- Patient management and recruitment
- Document management
- Reporting system
- Risk management
- Project status
- Drug safety
- Regulatory submissions and requirements
- Investigational medicinal product (IMP) management

## Ways of Implementing a CTMS

Once the decision has been made to implement a CTMS, different routes can be taken. In order to choose the right approach, parameters such as the size of the company, budget, internal IT competency, and existing IT structure—as well as the demand for functionality, reports, and flexibility—should be taken into account. In principle, there are three possible ways to implement a CTMS:

1. Using a **commercial, off-the-shelf system**, which is usually based on software as a service (SaaS). A growing number of CTMSs have been launched by software companies in recent years.
2. Developing a **proprietary system** on the basis of a low-code platform where pre-existing building blocks are used for programming customized features.
3. Building a completely **new software system** by having staff or vendors write the new source code according to your preferences.

Let's take a closer look at each of these options.

### The Commercial, Off-the-Shelf System (COTS)

A COTS has a host of functionalities central to clinical trial management (e.g., assisting with keeping track, creating reports, and identifying time-critical paths). Key features include a customizable web page, sophisticated access control mechanisms, accessibility for new programmers, and the possibility to connect to other systems.

Most COTSs are based on SaaS, and are therefore easy to use and highly convenient. On the other hand, a COTS offers only limited flexibility when applications require customization in response to specific customer needs.

Clinical projects often differ in terms of geographic location, distribution of tasks between different stakeholders, or object of study (i.e., medical device or IMP). Limited adaptability could therefore be a disadvantage for the user. In addition, COTSs are cost-intensive and CROs may face problems transferring the costs to the sponsor of a study.

## **Programming on a Low-Code Platform**

Programming a customized CTMS is usually not a feasible option for small to medium-sized companies. Indeed, developing a new system from scratch requires a dedicated team of programmers, substantial financial resources, and large outlays of time. Here, the development of a customized CTMS solution based on a low-code platform could provide an alternative.

Low-code platforms significantly reduce the development time needed, since even staff with relatively low levels of technical skills can access and use them, as the biggest proportion of programming is done automatically. The standardized toolkit used in these systems facilitates consistent quality and usability for programmers and users alike. Drag-and-drop elements can be applied into spaces on webpages and configured to satisfy all needs of the company and the customer.

Configuration on a low-code platform includes aspects such as appearance, visibility, and function. Data for these systems are usually stored securely in the background using modern, on-premise technologies or cloud solutions. Commonly used products for the background data model are Microsoft SQL Server, Oracle, or MySQL. These software products all handle data in a relational model optimized for a low-code approach. This provides the company with the best ratio between complexity, adaptability, and performance.

## **Development of New Software**

If the decision has been made to build a CTMS based on a completely new software system, all functionalities (including the creation of a new user interface) have to be developed from scratch. Such a path is only economically meaningful if the company already has a strong IT background with a team of programmers and commercializes its CTMS products afterward.

The advantage of a CTMS based on a newly developed system is complete freedom of design and 100% flexibility in adapting the system to individual needs.

## **How a Low-Code Based CTMS Can Help to Increase Flexibility**

The clinical research enterprise is characterized by highly diverse project settings. A CTMS has to meet a whole range of unique requirements that depend on the specific services being covered by a CRO company during a project, on country-specific technological and regulatory differences in multinational trials, and on technological and managerial differences between the interacting teams and their IT systems. In such settings, a self-programmed solution which is quickly adaptable has outstanding advantages.

Two examples from the experience of the authors with low-code platforms show the flexibility of such solutions:

- 1) In only 10 days, a voting system for a trial steering committee was programmed, tested and implemented, allowing the committee members to vote on the eligibility of patients. A presentation with diagnostic images of each new patient is created by a diagnostic lab and loaded into the CTMS. This triggers an e-mail with a link to all committee members. The link guides them to the presentation, and each member can vote for or against the patient's eligibility. If the decisions of two members are in line, the system closes, allowing no further votes.
- 2) In only three weeks, a management system for an IMP was implemented and went live prior to the start of a multinational trial. The system allows trial managers to track available stock at sites and automatically triggers an order before sites run out of the IMP. Furthermore, IMP delivery, destruction, and potential temperature deviations are tracked by the system.

## **Conclusion**

A CTMS based on a low-code platform allows trial leaders to create a very flexible IT workspace for managing the conduct of the trial. Such systems can be implemented with reasonable effort, thereby providing an interesting alternative to COTS solutions for mid-sized companies.

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## SITE STRATEGIES

### **Is Your Site’s CRC Training Methodical or “Trial by Fire”?**

Elizabeth Weeks-Rowe, LVN, CCRA



Learning to become a clinical research coordinator (CRC) can be an exhilarating and overwhelming process. Whether you are employed at a small research site or a large academic institution, the expectations are the same: to gain a foundational understanding of clinical research and new position responsibilities. Allowing sufficient time for this assimilation process to run its course is critical if performance gains are to follow.

The probationary employment period for a new CRC is a test of diligence, endurance, and resourcefulness. It is an emotional roller coaster of anxiety/accomplishment. A day filled with understanding confirms this life-changing career choice; a day fraught with misunderstanding renders uncertainty over it. The probationary learning period is critical for developing the behaviors to successfully conduct this position: critical thinking, comfort, and confidence. Organizational investment in an appropriate employee onboarding/developmental process promotes a confident, sustainable workforce.

## **Different, But Not Equal, Paths to Follow**

There are several training methods for the CRC role, and your institutional model, policies, and resources generally determine the method used. Most sites/institutions employ a methodical process of blended learning or lesson/practice—new CRCs initially attend training workshops (either sponsored by the institution or outsourced to a training vendor) to learn the elemental functions of their role. They also complete online Good Clinical Practice (GCP) training, Human Subject Protection (HSP) training, clinical research history, regulations and guidelines training, and site-specific research ethics/institutional review board policy training.

During, or soon after the theoretical portion, comes the execution of the learning process. This includes observation/sign-off on the fundamental responsibilities of the position. The new CRC would observe an experienced colleague conducting tasks such as consenting patients, completing study visits/procedures, data review/extrapolation, regulatory submissions, etc., and then the CRC is likewise observed completing the task until confirmation of independent conduct.

The experienced colleague serves as a mentor to supplement/support the learning process. The onboarding process can take from six weeks to three months, and generally includes a mixture of theoretical and executional elements noted above, with the exact contents being dependent on the individual learning process and the environment in which the training is conducted.

An alternative and less optimal learning process is the “trial by fire” learning process. This process does not allow a controlled learning environment where all candidates can flourish. It forces the new hire to complete his or her own haphazard, inconsistent onboarding since a formal training/mentoring process does not exist. This puts a large burden on study monitors, with trial progress contingent upon the CRC’s performance of duties, by forcing them to spend more time training and less attention to their workload. This impacts productivity and unnecessarily strains the CRC-monitor relationship.

Trial by fire training widens the disparity between angst and confidence, whereas a structured training helps transform anxiety to accomplishment with each lesson learned. It introduces error

into the learning process with the lack of direction, and it increases attrition/turnover of less resilient (but no less competent) employees who are unable to flourish in an ineffective training environment.

The approach of treating “error as a learning opportunity” is valid, but only at the end of a study or process, to ensure the next endeavor does not suffer the same mistakes. When new hires are given this—and only this—approach as the organization’s training method, it can impact fledgling confidence, not to mention create preventable quality/data issues.

### **Benefits from Following the Best Path**

There is no standardized blueprint for new CRC onboarding/development. Each site should include institutional best practices, available resources, and strong employees to facilitate the process.

Monitors observe and CRCs experience the results of organizational investment in employee training during monitoring visits in terms of the quality of data collected/reported, GCP-compliant safety levels achieved, recruitment and consenting processes successfully handled, and quality trials efficiently conducted. Indeed, during a recent site evaluation visit teleconference with a new CRC, I observed firsthand the confidence, transparency, and resourcefulness that is possible in an employee whose organization has made an investment in their proper training and support.

The process for such teleconference evaluation visits is identical to the onsite evaluation visit process, and includes protocol and recruitment discussions with the investigator and key staff; confirmation of regulatory activities, site training, research processes, staff experience, and workload; and assessment of the suitability of site staff, equipment, and facilities for study conduct. The confirmation letter for the visit includes an agenda of discussion points, timeframes, and key staff required for the discussions. It is best practice to include all relevant details required for preparation, as it must address a variety of experience levels.

The primary CRC with whom I was in touch for the confirmed evaluation teleconference worked for a large academic health center. She informed me that she would have an experienced



colleague attend the teleconference with her, as she was new and wanted to make sure I had the correct information. Her supervisor worked in the same office space and would be available by instant message to answer additional questions I had. She has also arranged for the research pharmacist to call in and provide information on study drug shipment/storage and preparation.

During the teleconference, she informed me that her training process included online GCP and CRC training, as well as an observation and sign-off process. She added that since this was her first independent visit, she and her supervisor had worked to ensure critical staff and information were available to facilitate the teleconference. She was organized, transparent, and earnest in her efficiency and presentation. Her confidence level for the study at hand was the welcome result of a structured training process that benefitted the employee, institution, and sponsor.



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([elizabethwrowe@gmail.com](mailto:elizabethwrowe@gmail.com)) is a former CRC who now works in site selection and education in the contract research organization industry. She last wrote for *Clinical Researcher in December 2019's* "[An Overview of Oversight.](#)"

PI CORNER

## 4 Tips on Implementing Change in Clinical Research

Christine Senn, PhD, FACRP



*Everyone realizes how brilliant or necessary the new plan is. It's a no-brainer. You'll tell people what to do, and they'll do it. That's their job, after all. ...*

I don't know about you, but there are probably 30 activities that are good for me that I don't do. Cold plunges. Hot saunas. Green, leafy vegetables. Fatty fish. Meditation. High-intensity interval training. Wim Hoff breathing. (It's a thing.) The list goes on.

The moment you remember that absolutely no one—yourself included—changes a behavior because they “should” change it, the better place you'll be in to actually help people change.

In psychology, we do this through “motivational interviewing”—a method for talking to someone to determine every way in which he or she has ambivalence about making a change. By “interviewing” them about both practical and emotional obstacles they have to an idea, the therapist can help the person find ways to overcome those obstacles or think about the change in a new way.

I know bells are going off right now as you realize that everyone has ambivalence about change—even change that sounds positive. Name any singular thing that you, your best friend, your kid, or your partner is not doing that they “should” be doing, and you can probably guess at least one obstacle or objection standing in the way of them making that change. The goal I see in business is to predict the most likely obstacles and objections to a new behavior and preemptively remove or diminish them.

## **Taking the Angst Out of Change**

If you haven't read James Clear's book *Atomic Habits*, do yourself a favor, because it's superb. He describes four ways of fostering behavioral change: make the new behavior obvious; make it attractive; make it easy; make it satisfying.

Let's take the example of decreasing consenting errors. A site research director has updated the procedure for documenting consent.

### *Make it Obvious*

Rather than simply sending out the new procedure to staff, the director could also post a one-page version of the step-by-step procedure on the wall of every research staff member, or laminate the sheet and ensure every clipboard used to hold paper consent forms has the laminated procedure clipped to it.

### *Make it Attractive*

Since quality assurance (especially in consenting) is so important to the U.S. Food and Drug Administration (FDA) and other regulators, and for patient safety, it may be worth rewarding staff for consenting well. For example, each perfect consent form completed could be worth an entry into a monthly drawing for a nice lunch. The director could also track the number of consent forms with no errors and, at 50 consecutive error-free forms, the staff member receives a monetary reward.

### *Make it Easy*

After sending out the procedure, the director could conduct a short training on the new process. Consistent with motivational interviewing, it is this hands-on training that allows the director (if her or she actively solicits this feedback) to hear any obstacles or objections to the new plan.

Let's say the new process requires the director to review the consent form before the patient begins the screening process. A very likely obstacle to this process is that the director is often

unavailable due to meetings, and so could choose to train several people to do the review in his or her absence, thus making the process easier to follow.

In contrast, there could be an objection that a coordinator or investigator doesn't believe they need anyone to check behind them. Objections are usually best handled by discussing the "why." In this case, the director could reassure her staff that she thinks everyone is highly capable but that the FDA regulations and inspections by its Biologics Monitoring Program (BIMO) are highly focused on proper consenting, so this plan is entirely about keeping the research site, the investigators, and of course the patients, safe.

### *Make it Satisfying*

A key to a new behavior being satisfying is having the reward follow the behavior as quickly as possible. Think of smoking: The dopamine jolt immediate follows the first inhale, so quitting smoking is difficult partly because finding a substitute behavior that is as immediately rewarding is difficult. In this way, waiting a month to receive an incentive does not meet this criterion. Instead, the director could plan immediate rewards for the first three months of the program, such as daily or weekly drawings for a smaller prize, or frequent public recognition of quality consent forms.

### **But Wait, There's More...**

Bonus time! This one example highlights tactics in behavioral change but skipped my absolute favorite tip: habit stacking. You want this one in your toolbox, so stick with me a little longer.

BJ Fogg introduced habit stacking in his book *Tiny Habits*. It simply involves adding a new behavior to an existing behavior.

Let's say you want to start doing 10 pushups or 10 minutes of meditation each day. You're also a coffee drinker and brew a fresh pot every morning. Starting tomorrow, as soon as you press the brew button on the coffee maker, you then do your new behavior (pushups or meditating). As soon as the coffee finishes brewing, you have completed the new behavior, and it will soon

become a habit because you have made it easy and removed obstacles. It will soon become satisfying, as well, as you start feeling physically or emotionally stronger.

Habit stacking in clinical research is just as easy. Perhaps the site director wants to have patients complete a satisfaction survey after the randomization visit. He or she can follow all four ideas above: make it obvious by having surveys pre-printed and on display in every exam room; make it attractive by letting staff know that positive feedback could be posted on the site's webpage; and make it satisfying by helping staff view this as a way to see how they make an impact on others.

As a tactic, habit stacking is usually seen in the “make it easy” step. In this example, how will the staff remember to give the survey to a patient at this very specific and very busy visit? I'd recommend either adding the survey into the source document checklist for every randomization visit or adding the survey into the checkout process for the randomization visit. It is the site's software and existing processes that will determine where to stack this new behavior, but paper source documents, electronic source documents, and clinical trial management software can all be mechanisms for stacking a new behavior (task) into an existing process.

## **Conclusion**

What I always remember when implementing a new task, new software, or new process is this: Everyone wants to do well. Particularly in our field, people actively want to do the right thing. Our industry and processes are so complex that it can become overwhelming for anyone. The behavioral tactics described here are intended to help you help your people be the successes you want them to be—and that they themselves want to be.



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SCIENCE & SOCIETY

## Learning from System Readiness During a Pandemic: Africa's Response to COVID-19

Al O. Pacino; Yonnie Otieno



*During these times of international efforts to reduce COVID-19 cases, noticeable systems put in place and plans enacted throughout Africa have successfully preempted the virus from uncontrollably spreading. Scientific and healthcare organizations, governments, as well as biotechnology companies have established a cooperative presence on the continent that has led to increased stability in the region.*

Africa's preparedness in containing the spread of COVID-19 is currently determined by several factors. So far, the focus has been on the continent's weak health infrastructure and systems. However, the region's strength is in the growing digital technology transformation and in cross-sectoral collaboration within health and research. These strategic developments are what informs the kinds of health training practices, patient care, and policy matters that are often largely ignored by many.

There has been a worldwide focus on the development of diagnostics, vaccines, and drugs for SARS-CoV-2 (the virus which causes the COVID-19 disease). In this context, it is important to emphasize that African scientists are connected with institutions of excellence in leading, groundbreaking technological advancements already under way in Africa—through both a collaborative network and through ties with many individual institutions and stakeholders.

Several research institutions are doubling their digital application use in several emerging health technologies and cloud applications services to share and exchange information on SARS-CoV-2. More than six years ago, during the Ebola epidemic in 2014, the flow of scientific information and data varied due to inconsistent and inaccurate reports using technology that was under-serviced in West African countries.

Recent developments that have impacted technological implementation include the Personal Data Protection Guidelines for Africa announced in 2018.<sup>{1}</sup> The guidelines were reflected in the European Union's enactment of the General Data Protection Regulation (GDPR), which outlines the ownership of an individual's right to their personal information.<sup>{2}</sup> The guiding principle for the guidelines convey the importance of data management for every subject's protection of member countries to safely use GDPR-compliant applications and protection systems.

Such regulations are becoming key to modernizing health and research institutions for digital advancements. The aim is to make sure that Africa countries can effectively benefit from the application of safety protections and use of digital technology systems. The importance of this is increasing as many countries are becoming equipped for groundbreaking research using data systems, software applications, mobile health apps, cloud-based infrastructure, telemedicine, and artificial intelligence.

### **Sharing Important Breakthroughs**

Less than a week after the first confirmed case of COVID-19 in Africa, local scientists reported details on open source databases for SARS-CoV-2 from Africa. The data were immediately available for use by the global scientific community and the World Health Organization (WHO). By March 1, 2020, cases of COVID-19 were being reported in record turnaround time, almost instantaneously, with accuracy in analysis consistent with the travel history of the infected person who entered Africa either from Europe or the United States.

The application of collaborative efforts by several institutions, non-governmental organizations, biopharma stakeholders, governments, and public benefit organizations is what led to this

successful outcome, unlike what happened during the 2014 Ebola epidemic, when obtaining such information in real-time via electronic tools in Africa was a monumental challenge.

The establishment of many national public health institutions connected to national electronic data capture systems created centralized health data for most local governments. The plan and support put in motion by the WHO was known as the District Health Information Software 2 (DHIS2), which is currently used in 47 countries.<sup>{3}</sup> The initiative incentivized regional activity and implementation of digital revolutions which shared disease information at a global scale never witnessed before.

These advances mark a significant change over the past seven years. For instance, in the early stages of the Ebola outbreak in Liberia and Sierra Leone, these countries did not have national electronic reporting systems. The sharing of health information and tracking of the exact number of cases affected by Ebola was made extremely difficult. The limited availability of up-to-date information meant the countries could only estimate the number of those who died or survived during the epidemic.

## **Conclusion**

A major lesson to be learned from the in-depth planning that has taken place throughout Africa as a result of the COVID-19 crisis is that institutional and international market cooperation is needed. By developing detailed pathways for national and international infrastructure to equip sites and other industry stakeholders with broad connectivity, we can increase the confidence of a nation's public health system.

Taking steps to ensure countries are updated on recent privacy and compliance laws and providing the proper connective tools are necessary to improve accountability and safety. By embracing an interconnected future, we will empower research professionals to quickly share their findings while respecting the modern-day standards of privacy and security.



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## Research with a (Re)Purpose (or, Everything Old is New Again)

Gary W. Cramer



We've tackled the topic [before in the ACRP Blog](#) of how the repurposing of existing drugs (whether available on the market or long unused in some pharmaceutical company's vault) may offer hope for treatments for conditions other than those for which they were originally studied and/or commercialized. Suddenly this concept is in vogue again to a degree perhaps never before seen, as the COVID-19 pandemic has researchers scrambling to bring effective treatments

for combatting the SARS-CoV-2 virus and relieving any of the range of serious symptoms it has proven to bring with it in different populations.

Presented here are excerpts from a variety of press announcements regarding expert perspectives on repurposing, and some of the drug research efforts currently under way in the midst of this global health crisis:

### Repurposing Existing Drugs for COVID-19 a More Rapid Alternative to a Vaccine

Repurposing existing medicines focused on known drug targets is likely to offer a more rapid hope of tackling COVID-19 than developing and manufacturing a vaccine, [argue an international team of scientists](#) in a review in the *British Journal of Pharmacology*.

Researchers representing the International Union of Basic and Clinical Pharmacology say there will be no “magic bullet” to treat the disease, and argue that a multipronged approach is needed

to find new drugs. They caution that an effective and scalable vaccine is likely to take over a year before it can be used to tackle the global pandemic.

“Any drug to treat COVID-19 will need to focus on the three key stages of infection: preventing the virus entering our cells in the first place, stopping it replicating if it gets inside the cells, and reducing the damage that occurs to our tissues, in this case, the lungs and heart,” said Professor Anthony Davenport from the University of Cambridge, one of the authors of the review. “[We know that two specific] proteins play a role in this coronavirus infection, [so] we can focus on repurposing drugs that already have regulatory approval or are in the late stages of clinical trials. These treatments will have already been shown to be safe and so, if they can now be shown to be effective in COVID-19, they could be brought to clinical use relatively quickly.”

One promising candidate is remdesivir, a drug originally developed for Ebola. Although clinical trials found it to be insufficiently effective at treating Ebola, studies in the U.S. have suggested the drug may be beneficial for treating patients hospitalized with COVID-19, and the U.S. Food and Drug Administration (FDA) has approved it for emergency use.

The review authors say that we need to move quickly to identify existing drugs that are effective in clinical trials so that we can begin treating patients as rapidly as possible, but also because cases are likely to fall during the summer—meaning there will be fewer people who can be recruited to clinical trials ahead of an anticipated second wave of the disease in autumn. They estimate there are currently more than 300 clinical trials taking place worldwide, though many of these investigational drugs are unlikely to be effective for widespread use, because either it is not clear which part of the disease pathway they are targeting or they cause unpleasant side effects.

Source: *Newswise*

### **Scientists Discover 59 Repurposing Drug Candidates for Sepsis in COVID-19 Cases**

Scientists from UK-headquartered artificial intelligence precision medicine group PrecisionLife [have identified 59 repurposing drug candidates](#) that could be used to develop new therapeutic strategies to boost survival rates for patients who develop sepsis while suffering from severe COVID-19. Sepsis is observed in 60% of severe COVID-19 patients and has a mortality rate of

approximately 20%. The team identified mutations in 70 sepsis risk genes, 61% of which were also present specifically in severe COVID-19 patients, and 13 of which are known to be druggable. The study has also identified 59 compounds and drugs known to be active against these 13 targets.

Source: *PharmaTimes*

### **New Database Focuses on Repurposing Drugs for COVID-19**

Excelera, a data and analytics company, has released a [COVID-19 Drug Repurposing Database](#), which presents a compilation of previously approved small molecules and biologics with known preclinical, pharmacokinetic, pharmacodynamic, and toxicity profiles that can rapidly enter either Phase II or II clinical trials on a fast-track basis for COVID-19. In addition, the database includes [information on promising drug candidates](#) that are in various clinical, preclinical, and experimental stages of drug discovery and development for COVID-19.

Source: *BioSpace.com*

### **Repurposing Drugs Might Help Fight Coronavirus Pandemic**

In just a few weeks, Nevan Krogan, a molecular biologist at the University of California, San Francisco, and his collaborators managed to do what typically takes years: they purified 26 of the coronavirus's 29 proteins, identified the human proteins that they latched onto, and suggested existing drugs that made good candidates for treating the disease—69 of which were already FDA-approved or in clinical trials. They reasoned that [repurposing existing medications might be faster](#) than developing a new drug.

Krogan's team is not alone. The World Health Organization (WHO) is beginning its own global trial, called Solidarity, to investigate which older drugs can treat this new disease. Potential therapies include those currently used to treat HIV, malaria, Ebola, and inflammation.

Source: *Technology Review*

## **Researchers Call for Rapid Drug Repurposing to Fight COVID-19**

Filling the therapeutic gap for coronavirus treatments with existing drugs approved for other uses could greatly benefit patients around the world. Researchers from the University of Kentucky [urged the scientific community to quickly identify drugs](#) that may be repurposed in the fight against COVID-19 in an opinion piece published May 8 in [Science](#).

The authors called on researchers, ethics boards, and regulators to coordinate rapid hypothesis-generating studies now, during the first peak, which will justify a smaller number of larger trials in later peaks.

The authors cited two existing treatments with the potential to reduce viral entry of SARS-CoV-2. The first is recombinant human angiotensin-converting enzyme 2 (rhACE2, or APN01), originally under development for acute lung injury and pulmonary arterial hypertension, but currently being investigated for viral blockage in COVID-19 patients. The second is a transmembrane protease serine 2 (TMPRSS2) inhibitor, camostat, which is approved in Japan for the treatment of chronic pancreatitis and postoperative gastric reflux. The drug can block viral entry by inhibiting proteolytic processing of the spike protein. Clinical trials of camostat and the related agent nafamostat for COVID-19 have already started in the Netherlands and Germany.

Source: *The Science Advisory Board*

## **Company to Develop Potential COVID-19 Treatment in Collaboration with NCATS**

Acer Therapeutics Inc. [announced it has entered into a research collaboration agreement](#) with the National Center for Advancing Translational Sciences (NCATS), one of the National Institutes of Health, to develop emetine hydrochloride as a potential treatment for patients with COVID-19. Acer is working toward an Investigational New Drug submission in mid-2020 and targeting clinical trial initiation in the third quarter of 2020, subject to additional capital.

Emetine is a drug used as both an anti-protozoal and to induce vomiting. The company has proposed an adaptive design Phase II/III randomized, blinded, placebo-controlled, multicenter

trial to evaluate the safety and antiviral activity of emetine in high-risk, symptomatic adult patients with confirmed COVID-19 infection not requiring hospitalization. The trial objectives as planned are to determine the safety and efficacy of emetine via clinical status at a specific timepoint in addition to disease resolution.

Source: *Acer Therapeutics*

### **Arthritis Drug May Improve Respiratory Function in Severe COVID-19 Cases**

A [small study in Greece](#) has found that the clinically approved anti-inflammatory drug anakinra, used to treat rheumatoid arthritis, improved respiratory function in patients with severe COVID-19. The eight patients also had a condition called secondary hemophagocytic lymphohistiocytosis (sHLH), which is characterized by overactivation of the immune system and organ failure. One patient, who did not require mechanical ventilation, improved rapidly after starting treatment with the drug and was discharged from the hospital nine days later. However, the therapy did not prevent three out of seven patients on ventilators from dying, and it's not yet clear whether it improves mortality rates. The report appeared in the journal *Cell Host & Microbe* from authors with the Medical School of the National and Kapodistrian University of Athens.

Source: *Newswise*

### **UCLA Launches Clinical Trial to Help Reduce Severity of COVID-19 Illness in Men**

UCLA researchers [have launched a new clinical trial](#) that uses a hormone suppresser commonly used to treat men with prostate cancer to help improve clinical outcomes for men infected with COVID-19. The Phase II trial will assess if temporarily suppressing male hormones will reduce the severity of COVID-19 illness by helping patients get out of the hospital faster, decrease the need for intubation, and improve mortality. The study is being conducted at the Veterans Affairs Greater Los Angeles Healthcare System and other VA sites across the country.

“It’s becoming pretty clear that men are more likely than women to die from COVID-19, and we think there is a connection between prostate cancer research and our understanding of COVID-

19 research,” said principal investigator Matthew Rettig, MD, professor of medicine and urology at the David Geffen School of Medicine at UCLA and member of the UCLA Jonsson Comprehensive Cancer Center.

In the trial, researchers will suppress male hormones using the FDA-approved medication known as degarelix to temporarily shut down the production of TMRSS2 and block the virus from entering lung tissue.

Source: *Newswise*



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