

Clinical Researcher

November 2021

HOME STUDY TEST

Fine-Tuning Your Organization's Research Dynamics

Earn 2.0 Continuing Education Credits

Two articles from the November 2021 issue of *Clinical Researcher* have been selected as the basis for a Home Study test that contains 20 questions. For your convenience, the selected articles and test questions are combined and posted in the form of this printable PDF at <https://www.acrpnet.org/professional-development/training/home-study/>, where the test may be purchased. *The test will be active until November 30, 2022.* This activity is anticipated to take two hours. **Answers must be submitted using the electronic answer form online (members \$30; non-members \$50).** Those who answer 80% or more of the questions correctly will receive an electronic statement of credit by e-mail within 24 hours. Those who do not pass can retake the test for no additional fee.

The *Clinical Researcher* archive is at <https://www.acrpnet.org/resources/clinical-researcher/>.

CONTINUING EDUCATION INFORMATION

The Association of Clinical Research Professionals (ACRP) is an approved provider of clinical research continuing education credits.

Contact Hours

The Association of Clinical Research Professionals (ACRP) provides 2.0 contact hours for the completion of this educational activity. These contact hours can be used to meet the maintenance requirements for certification programs of the Academy of Clinical Research Professionals. (ACRP-2021-HMS-011)

ACRP DISCLOSURE STATEMENT

The Association of Clinical Research Professionals (ACRP) requires everyone who is in a position to control the planning of content of an education activity to disclose all relevant financial relationships with any commercial interest. Financial relationships in any amount, occurring within the past 12 months of the activity, including financial relationships of a spouse or life partner, that could create a conflict of interest are requested for disclosure. The intent of this policy is not to prevent individuals with relevant financial relationships from participating; it is intended that such relationships be identified openly so that the audience may form their own judgments about the presentation and the presence of commercial bias with full disclosure of the facts. It remains for the audience to determine whether an individual's outside interests may reflect a possible bias in either the exposition or the conclusions presented.

ACRP EDITORIAL ADVISORS

Suheila Abdul-Karrim, CCRA, CCRT, FACRP
Tara Bresnahan, RN, BSN
Victor Chen, MSc
Staci Horvath, CCRA
Stefanie La Manna, PhD, MPH, ARNP, FNP-C
Christina Nance, PhD, CPI
Paula Smailes, DNP, RN, MSN, CCRP
Jerry Stein, PhD, ACRP-CP, ACRP-MDP, FACRP
Shirley Trainor-Thomas, MHA:
Nothing to Disclose

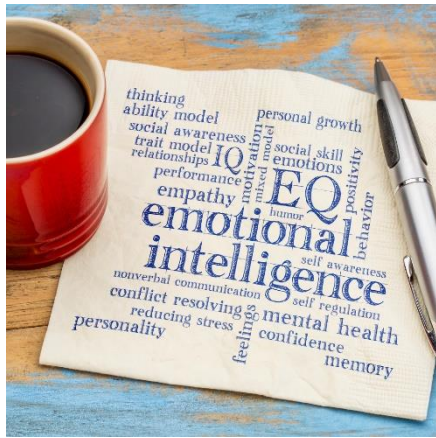
ACRP STAFF/VOLUNTEERS

James Michael Causey (*Editor-in-Chief*)
Gary W. Cramer (*Managing Editor*)
Jan Kiszko, MD, ACRP-CP
Barbara van der Schalie:
Nothing to Disclose

PEER REVIEWED

How the Pandemic Has Magnified the Importance of Soft Skills for Clinical Research Associates

Agnieszka Finlayson, MSc, MA



Before the COVID-19 pandemic, soft skills for use in clinical trial environments were already challenged, {1} with each clinical research associate (CRA) left to his or her own devices in forming and improving upon these skills. CRAs hardly, if ever, received formal training on what soft skills are needed to thrive in this demanding role; only with time and experience could they, like anyone else, strengthen their communication practices.

Without formal training, the most natural way for humans to communicate effectively is in person, which is what traveling CRAs relied upon. However, during lockdown, any sort of face-to-face communication was restricted. CRAs could communicate with busy sites only through digital means. Site staff still needed support and training, but CRAs no longer had the luxury of doing this while being present physically for utilizing both verbal and non-verbal cues to build rapport with site staff.

As with other industries, the clinical research enterprise turned to online tools to get important work done in pandemic conditions. Teleconferences became video calls, onsite visits became remote visits, and face-to-face conversation became e-mails. As these were not proper substitutes for the lack of physical interaction, the difficulty that CRAs already faced with training and motivating site staff was intensified.

While CRAs are intensively trained in hard skills such as source data verification or investigational medicinal product accountability, as well as the systems required to support their work on the study, soft skills are usually ignored. It was as if forgotten that a CRA's role is effectively dealing

with people—be they site staff, fellow CRAs, or vendors. The time for CRAs to start focusing on their soft skills has already passed us; however, the importance of not doing it has never been laid as bare as it is now.

The author of this article believes that post-pandemic online courses are a perfect medium to teach any required soft skills, as has been written about by others in *Clinical Researcher*.^{2} By being better at communicating and dealing with people, CRAs (as with everyone involved in clinical trials) can not only improve the quality and efficiency of their studies, but they can improve the quality and efficiency of their lives.

What are Soft Skills?

Soft skills are human skills,^{3} as Simon Sinek puts it. They are a combination of various capabilities and ways in which we interact with others. Empathy, communication, listening, and general “people skills” are all examples of soft skills. They are the qualities which distinguish us from each other and from any machine or a robot.

Through an optimal use of these skills, we can connect with other people. We can understand what is important to others and, through this, we can communicate in a way that motivates and inspires them. Soft skills can be improved with training, practice, and time.

The opposite of soft skills are hard skills—the things you need to know in order to do your job. These are normally industry- and job-specific skills and, as is the case with CRAs, are also attained through training, practice, and time.

How Do Soft Skills Apply to the CRA Role?

Empathy

CRAs work in a highly regulated yet dynamic environment. Functions around CRAs may be under various pressures while trying to meet conflicting deadlines. CRAs have to be empathetic to the people they work with to keep doing their work without being demotivated or taking things personally. If site staff are stressed and struggling and CRAs cannot empathize with them, it will be almost impossible for CRAs to build great collaborative relationships^{4} with sites.

Communication

CRAs are a liaison between the sponsor and the site staff. Study management may sometimes need to achieve aggressive deadlines and inadvertently may put pressure on CRAs. However, site staff need to stay focused and motivated. It is therefore necessary for CRAs to communicate urgency to, and help set priorities for, site staff, but at the same time not induce panic or stress because that would be counterproductive.

Each site is different in what support it needs from CRAs to do the best work. For instance, some site staff like phone call reminders to do something, others prefer e-mail reminders, while others get offended by either. Some people require e-mails that are quick to read and a list of tasks that are arranged by priority, while others require explicit and detailed instructions.

CRAs must tailor their approach to each individual. Consequently, CRAs have to be able to listen carefully to all the messages that site staff convey, both verbally and non-verbally. CRAs have to look for cues about their site's level of workload in order to have the site prepared for a deadline and be confident it can meet that target.

Motivation

CRAs are in a unique position of having to motivate their site staff and create effective collaboration without having any mandate over them. Without soft skills, this will simply not be possible. Site staff are usually allocated to multiple studies and CRAs need to stay on top of them—no matter how many other pots they are stirring—for the good of their particular sponsor's study. CRAs can help site staff be effective, efficient, and motivated to do a high-quality job. This is a key area where CRAs with strong soft skills will prevail over those with weaker soft skills.

Before the Pandemic

Normally, people exercise their soft skills face-to-face. When next to another human being, we use our social skills and emotional intelligence to “read” people and respond appropriately in order to build rapport and communicate effectively. Once a relationship with a study team or site staff is established in person, that usually increases collaboration.

When CRAs or site staff find themselves inevitably under pressure, they will be more forgiving due to the rapport that has already been established. Because site staff have met their CRA in person, they will trust them in the future and vice versa.

When CRAs join a new company, such as a contract research organization (CRO), they get a lot of training. However, a vast majority of this training is about hard skills and technical aspects of the job: the tenets of Good Clinical Practice, creating and following standard operating procedures and study-specific procedures, etc. As CRAs develop and gain more experience, they are assigned to more complex studies and receive more study-specific training. CRAs become well-trained and well-prepared for the complexity posed by the indications and protocols they are working on, but only on a technical level.

Unfortunately, at no time are CRAs provided with extensive soft skills training, if they are provided with any at all. Often, CRAs need to rely on their own wits and support and advice from other CRAs through informal networks in order to get their tasks completed. This state of affairs is tolerated because at the end of the day, CRAs meet their goals and it is physical interactions that help get them over the line.

During the Pandemic

The COVID-19 pandemic brings challenges at every level for everyone. Lockdowns, travel bans, and social distancing each bring their own set of difficulties that CRAs, like anyone else, must overcome. In-person interaction, with all its fragile elements that were previously done subconsciously and taken for granted, is severely restricted.

CRAs can no longer attend site visits. Everything moves online and is done remotely. In addition, CRAs have to train site staff in this new way of doing things. Soft skills that were already lagging behind hard skills become even more essential. Across the industry, new tools and new processes are quickly adopted, causing friction and hassle in what was already a fragile network of relationships. These new tools bring with them new challenges.

Zoom Etiquette

Video conferencing comes to the fore to replace face-to-face meetings. Even though this mode of communication is not exactly new, the extent to which we are currently using it is unprecedented. Tools like Zoom, Teams, and Skype, all video-conferencing interfaces, become part of our human interaction with anyone who does not live in our household. Out of all the available video conferencing tools, Zoom is probably the most famous for both the right and wrong reasons. Therefore, this article will focus on Zoom as an example of all similar tools.

Because communicating face to face is nothing like communicating on Zoom, we needed some guidelines to convey our message via this medium as accurately as possible. Collectively and informally, participants in Zoom calls created a set of rules to communicate online effectively called Zoom etiquette. While Zoom etiquette is difficult to define and out of scope of this article, one key example is through eye contact.

When participating in a video call, each participant has to make a choice between looking directly into the camera (to give the other participants the illusion of having a real physical conversation) or looking at the monitor (to get non-verbal cues via their video streams). This means that it is now impossible to have a conversation and hold eye contact at the same time.

Any video conversation will always lack the synchrony of a conversation as you may miss facial expressions when looking at the camera, or other participants may miss your gestures as they are looking at their camera while mimicking physical eye contact (instead of looking at their monitor).

Zoom etiquette rules come about to lower expectations and tell participants that even if others are not “looking” at us through their cameras, it is because they are paying attention to what we say, hence looking at their monitor. This is particularly true if people’s setups mean their cameras are out of position relative to their monitors.

Through these video calls, soft skills are “working overtime.” The disconnect between video and face to face communication needs to be compensated with soft skills in order to foster a positive human-to-human interaction. To top it all off, the psychological reward that we would normally receive from physical communication which would make us alert is not really there.^{5} This leads to Zoom fatigue.

Zoom Fatigue

Zoom fatigue is a term used to describe the tiredness, anxiety, or worry resulting from overusing virtual platforms. Video conferences are mentally exhausting.^{6} Sensory overload may also be playing a part. We are now using our eyes, ears, and facial expressions in disjointed ways which we are not used to.

Staring at a monitor all day is tiring. The lack of movement and the required high level of focus all come together to exhaust us. On the top of it, we are forced to “overuse” our soft skills, foster attentiveness while on camera, and we have to do all this without the natural energy boost from a physical conversation.

Zoom fatigue can be contagious. When you are speaking to somebody who appears tired, that tiredness can transfer to you. If it is your first call for the day and their sixth, you will know it and start feeling their fatigue, too. This, unfortunately, is the flip side of being an empathetic CRA.

Languishing

There is also an emotional, long-term effect of the pandemic. A feeling of stagnation and emptiness that a lot of us are feeling is known as languishing. It is claimed to be the most dominant emotion of 2021.^{7} Adam Grant explains languishing as an emotion that lies between depression and flourishing. Critically, we need soft skills to combat it—we need to feel connected to others, to be a part of a community.

CRAs are in a great position here because of the meaningful nature of the work they do. As an industry, we need to keep reminding ourselves of the good we are collectively doing and stay focused on achieving our goals. We need to make sure that we remember the bigger picture of getting the medicine to market and the patients who will benefit.

After the Pandemic

What will become of the skills and solutions that we used during the pandemic when the dust settles and we reach a “new normal”? It is hard to think that everything we learned during the

pandemic (e.g., communicating through video conferencing, remote working, and online training) will fade away as our state of practice reverts to how it was before.

A balance of the “old” and “new” must be the way forward. In this, the “old” will include tasks such as making traditional physical site visits when required or attending investigator meetings and seeing everyone involved in a study face to face. Meanwhile, the “new” may include further remote or flexible working, more remote monitoring visits than prior to the pandemic, and an appreciation of when to use video conferencing.

Ultimately, we will all organize our time differently and start prioritizing human connections above all. In-person interaction and time spent with family and friends will prevail over superficial interactions.

If these auxiliary interactions can be permanently shifted online, much like during lockdown, we can gain more valuable time for ourselves. Furthermore, if more “static” content can be consumed via online pre-recorded media, then we can further gain time and flexibility by eliminating commutes and pausing or playing back content as needed.

Time to Appreciate Soft Skills

No matter what the outcome is after the pandemic has subsided, what has been made clear is that our current lack of focus on soft skills in general, let alone their training and development, is not a sustainable position. We managed to stumble our way through awkward Zoom calls and e-mails without context or tone of voice. These lessons will not go away quickly, nor will the repercussions of not being prepared.

Soft skills training and development must go hand-in-hand with hard skills training and development. By ignoring effectively half of a CRA’s role, pharmaceutical companies and CROs are only harming themselves, their studies, and ultimately the investigational medicinal product.

The Right Tool for the Job

One of the instrumental methods that CRAs, and indeed anyone else in clinical research, should be utilizing going forward is the medium of online courses. We have collectively enjoyed not losing

time on commutes or long travel to training sessions at the office where in-person training can have negligible results.

Instead, taking our lessons learned from the pandemic, we can shift all of this online. Online courses allow CRAs to complete them at their leisure, working in-between their personal and professional needs. As new training is made available, it is simply posted online for CRAs to complete. Much like hard skills training, more advanced soft skills courses can be made available to CRAs as they progress in their careers.

While it took a global pandemic to shake the status quo, ultimately this disruption will be of benefit to the industry as a whole. CROs and pharmaceutical companies massively benefit by having CRAs trained in both hard and soft skills, as this will lead to having more efficient sites, reduced study costs (compared to before the pandemic), and higher quality studies with the potential of going to market sooner. Meanwhile, CRAs are more likely to be happier with their roles leading to lower churn and creating an upwards spiral of skill and experience. Ultimately, a healthy work-life balance for CRAs (and indeed all clinical research professionals) means better studies and better results.

References

1. <https://acrpnet.org/2017/06/20/soft-skills-hard-part/>
2. <https://acrpnet.org/2018/01/16/training-crcs-cctrn-using-online-learning-platform/>
3. <https://www.youtube.com/watch?v=o9uzJOLgvT0&t=201s>
4. <https://www.forbes.com/sites/amyblaschka/2019/02/19/the-soft-skill-gary-vaynerchuk-simon-sinek-and-oprah-winfrey-say-is-crucial-for-leaders/?sh=28ca76d84e9b>
5. <https://www.psychiatristimes.com/view/psychological-exploration-zoom-fatigue>
6. <https://www.psychologytoday.com/us/blog/the-desk-the-mental-health-lawyer/202005/virtual-platforms-are-helpful-tools-can-add-our-stress>
7. <https://www.nytimes.com/2021/04/19/well/mind/covid-mental-health-languishing.html>



Agnieszka Finlayson, MSc, MA, (aga@whitewisteriaacademy.com) is Founder and Director of the [White Wisteria Academy](#), which focuses on training for clinical research associates and is based in the United Kingdom.

Clinical Researcher—November 2021 (Volume 35, Issue 8)

PEER REVIEWED

Documenting Training Using REDCap

Carol Brooks, BHS, ACRP-CP; Robin Ryan, MPH, CCRP



The International Council for Harmonization (ICH) Guideline for Good Clinical Practice (GCP) states, “Each individual involved in conducting a [clinical] trial should be qualified by education, training, and experience to perform his or her respective task(s).”^{ 1 } It is of great importance that the trial can be reconstructed as it happened. An external observer should be able to confirm that the current protocol was

followed, the data and information collected were accurate, and the staff conducting the trial were properly qualified and trained to do so. Proper documentation will provide an audit trail that will validate the trial if, and when, required.

Protocol-specific training can delay the activation of a study as well as a potential subject’s enrollment. Systemizing and documenting staff training for multidisciplinary trials is challenging. For those cooperative group studies with multiple investigators and other study staff, it can especially be quite challenging. Schedules are full and often are geographically scattered. Accommodating time to schedule an in-person group training or finding time for individuals to complete self-training is difficult. For some individuals, completion of training can be overlooked since it is not necessarily a top priority for busy clinicians.

Children’s Mercy Hospital is a pediatric medical center located in Kansas City, Mo. that integrates holistic care, translational research, breakthrough innovation, and medical education to provide care for those 21 years old and below. The not-for-profit hospital has received national recognition from *U.S. News & World Report* in 10 pediatric specialties.^{2} Its mission is to “transform the health, well-being, and potential of children, with unwavering compassion for those most vulnerable.” The research program at the hospital includes nearly 100 physicians and scientists actively participating in research studies. Research is especially important in the oncology section, as most of the active trials are treatment options for patients to whom they could be beneficial.

Past Training Methods at Children’s Mercy

Prior to 2018, the Oncology Section at Children’s Mercy did not have a systematic method of training and documenting protocol-specific training compliance. Pediatric oncology research includes numerous treatment and non-treatment protocols for the various types of cancer. Children’s Oncology Group (COG) is the main consortium that sponsors research in the Oncology Section. Efforts to maintain current training and documentation among our COG team were difficult, as we have more than 30 active COG protocols and more than 60 COG site personnel to train. While in-person trainings and e-mail documentation were utilized, these were not consistent or easily validated. Additionally, e-mail created extra work for the coordinator—to keep track of the progress of each team member and forwarding reminders for those pending completion.

In 2017, the research team within the Division of Hematology/Oncology/BMT was restructured to create a separate regulatory coordinator role. Part of the rationale for this separation of regulatory work from patient-facing study coordination was to be more rigorous with training and documentation thereof. The oncology research team wanted to identify an efficient way to distribute and track completion of protocol-specific training for study team members.

An informal review of training options was undertaken by the institution’s research leadership. This involved looking at available technology for possibly accommodating the needs. In 2018, it was decided to determine if REDCap could effectively document training.

Elements of REDCap

REDCap ([Research Electronic Data Capture](#)) is a secure web application from Vanderbilt University that can be used to build and manage online surveys. There is no special software installation needed for utilization. If institutions have this application available, there are no fees charged to use it. This web application is versatile and is used widely among different fields. At Children’s Mercy, REDCap was already being used for databases, survey tools, research data collection, and e-consenting. If the team could utilize REDCap for training, it would provide an easily available option.

Rationales for choosing REDCap as a training platform included the fact that the survey tool is able to track the progress of completion. Using the survey feature, the regulatory coordinator can send protocol training to the identified study team. Survey recipients do not need special access to REDCap to get a link to review the training and attest to completion. For each personnel added to the participant list, REDCap will show if they have responded to the survey. REDCap will also show if there will be an upcoming invitation that is scheduled to be sent.

Further, REDCap can be set up to send automatic e-mail reminders. Keeping up with manually reminding delinquent personnel to complete training is time consuming. With REDCap, the frequency of the reminders, date, and time are all customizable.

REDCap also features an application that can generate a report of those who have submitted the surveys which can then be used as a training log. The reports are customizable, but can contain the date training was complete, timestamp, names, e-mail, and/or signatures (see Figure 1).

Figure 1: Example of a REDCap-Generated Training Log

Record ID record_id	Survey Identifier redcap_survey_identifier	Survey Timestamp redcap_training_template_timestamp	I have reviewed the [PROTOCOL #] training [MATERIALS]. reviewed	After reviewing the [MATERIALS] questions	Questions or comments comments	Name name	Please add your email address to attest to your completion. You will ... s form without this completed. email	Date date	Provide Signature: signature	Complete? redcap_training_template_complete
<u>1</u>		06-22-2020 12:10	Yes (1)	I have no questions or comments (1)		Test 1	test1@gmail.com	06-22-2020	<input type="button" value="Download"/>	Complete (2)
<u>2</u>		06-22-2020 12:11	Yes (1)	I have questions or comments (2)	Insert questions here.	Test2	test2@gmail.com	06-22-2020	<input type="button" value="Download"/>	Complete (2)

Development of a Training Template

There are a few important items that should be included in the survey for training. At our site, initial training includes a PowerPoint module reviewing the important aspects of the protocol. This PowerPoint is usually provided by the sponsor, but, if one is not available, it can be created by the site's principal investigator (PI). Attaching the written protocol and/or manuals for reference and as supplemental material is always a good idea.

For amendment training, the survey includes a summary of changes, an updated PowerPoint module, and the newly amended protocol. Within the survey, a section is included to attest that review of training materials has been completed, a block to include questions and/or concerns, a name stamp, an e-mail address stamp, and a date stamp (see Figure 2 for the training template).

Implementation of REDCap for the Oncology Team

Implementing this new format for the COG team was challenging due to the large number of team members. A simple workflow, however, was established and made to fit to accommodate the various COG protocols.

As new protocols are activated, the regulatory coordinator pushes out initial protocol training surveys to appropriate team members. The team member roster is determined at the time of protocol start-up. Required amendment training is determined based on content of the amendment.

Any amendment changing therapy, eligibility, or other major changes to the protocol will be forwarded as a REDCap survey training by the regulatory coordinator. All training surveys include a deadline date for completion.

As the training deadlines pass, the regulatory coordinator will communicate to the PI the list of delinquent team members. The PI alerts these individuals, and if failure to comply continues, repercussions will include the removal of the team member(s) from the study. Figure 3 is a representation of the workflow explained above.

Figure 2: REDCap Training Template

As a person involved in [DEPARTMENT] research, you are asked to review the training for [STUDY TITLE]

Thank you!

Because you participate or may participate in the conduct of [DEPARTMENT] trials at Children's Mercy, you are required to complete this training. Please review the [LIST MATERIALS SUCH AS PROTOCOL OR SLIDES] attached. At the end of this survey, you will be required to attest to having completed the review.

If you have any questions or comments, there is also a place to note that.

[PROTOCOL Number/Title] Required Training

Attach training slides

Attach protocol here

ATTESTATION

I have reviewed the [PROTOCOL #] training [MATERIALS]. Yes

No

*** must provide value**

Reset

After reviewing the [MATERIALS]

I have no questions or comments

*** must provide value**

I have questions or comments

Reset

SIGN AND SUBMIT

Please add your e-mail address to attest to your completion. You will not be able to submit this form without this completed.

* must provide value

Date  Today M-D-Y

Provide Signature:

Submit

Figure 3: Representation of Workflow for Protocol Training



When this training system was implemented, it was with the knowledge that there would be a learning curve and that turnaround for completion was going to be less than satisfactory. Numerous auto-generated reminders were necessary to get people “onboard.” As team members became more familiar with the process, compliance improved dramatically.

Organization for the regulatory coordinator with multiple studies and amendments also required a system. With multiple training surveys in process at once, and most deadlines for completion in a four- week range, a tracker of active surveys was developed. Another useful tool is a master study team list. As the studies the lead author is involved in can include as many as 65 people from multiple disciplinary teams at one time, a spreadsheet listing the personnel, their e-mails, and roles comes in handy. With this, all that is needed is to copy and paste e-mail addresses into the study participant list when a survey is created. The lead author also created a document listing e-mail templates for when she sends REDCap survey invitations or reminders, and has developed e-mail templates for initial training for new studies and applicable amendment training.

Dissemination Within the Institution and to Other Institutions

Once our process was established, it was shared at the Fall 2018 COG Poster Session. The lead author has met numerous people interested in learning more about using REDCap surveys for training. Upon follow-up a year later to each inquiry, three (from the University of Florida, CancerCare Manitoba, and Dana- Farber Cancer Institute) have expressed gratitude and intend on using REDCap as the main platform for training documentation.

Within Children’s Mercy, the REDCap training process is now being used within other sections of the hospital with resources on how to create the successful workflow shared with research teams that inquire. The institutional Research Quality team recommends the REDCap training system to other teams during monitoring visits and provides contact information to learn more.

Conclusion

Attributes for good documentation as described by the U.S. Food and Drug Administration are attributable, legible, contemporaneous, original, accurate, complete, consistent, enduring, and available.^{3} REDCap meets all these attributes and creates an audit trail of documentation reflecting compliance with GCP. REDCap has become the main tool used for providing and documenting training at the Children’s Mercy Hospital—Oncology Section, as this effort has been very effective and user-friendly.

References

1. See ICH GCP E6(R2) at <https://www.ich.org/page/efficacy-guidelines>.
2. <https://health.usnews.com/best-hospitals/area/mo/childrens-mercy-hospitals-and-clinics-6630340/pediatric-rankings/cancer>
3. <https://conductscience.com/portfolio/alcoa-c/>



Carol Brooks, BHS, ACRP-CP, (cmbrooks@cmh.edu) is a Clinical Trials Coordinator (Regulatory) for oncology/bone marrow transplant studies with Children's Mercy Hospital in Kansas City, Mo.



Robin Ryan, MPH, CCRP, is Research Program Director, Division of Hematology/Oncology/Stem Cell Transplant, Children's Mercy Hospital.

ACRP HOME STUDY

CLINICAL RESEARCHER—NOVEMBER 2021 (VOLUME 35, ISSUE 8)

Fine-Tuning Your Organization's Research Dynamics

Article #1: How the Pandemic Has Magnified the Importance of Soft Skills for Clinical Research Associates

LEARNING OBJECTIVES

After reading this article, the participant should be able to define soft skills, cite examples of their importance to the work of clinical research associates in current industry conditions, and outline steps for their continued development in individuals most in need of improvement in this regard.

DISCLOSURES

Agnieszka Finlayson, MSc, MA: *Nothing to disclose*

1. According to the author, how has training in soft skills for clinical research associates (CRAs) traditionally been approached?

- a. Sponsors/contract research organizations (CROs) have been federally mandated to supply such training to new CRA hires.
- b. Sites have taken advantage of a wealth of training programs to assist CRAs in developing their soft skills.
- c. CRAs have typically found no difference in the soft skills needed to be monitors versus those needed for their previous clinical research role(s).
- d. CRAs hardly, if ever, received formal training on what soft skills are needed to thrive in the role and had to develop them on their own.

2. What is the author's favored delivery method for teaching any required soft skills to CRAs in post-pandemic conditions?

- a. Classroom instruction
- b. Online courses
- c. Journal articles
- d. Mentorships

3. What is the difference between soft skill and hard skills?

- a. Soft skills are only considered important during hiring, while hard skills are generally neglected in interviews.
- b. Soft skills generally involve interactions with people, while hard skills concern job-specific knowledge.
- c. Soft skills can only be developed through rigorous coursework, while hard skills come to people naturally.
- d. Soft skills are only important in informal situations, while hard skills are useful in any social setting.

- 4. What is the main value of empathy to CRAs as they do their work?**
- Identifying significant results in study patients versus placebo responses.
 - Understanding that most principal investigators need more support.
 - Building collaborative relationships with the staff at study sites.
 - Adjusting monitoring reports to allow for missed study targets.
- 5. Which of the following characterizes the relationship between CRAs and study site staff members?**
- CRAs have to motivate site staff but have no real authority to do so.
 - CRAs have full authority to reward or penalize site staff as needed.
 - CRAs rely on site staff for job performance review feedback to sponsors.
 - CRAs can perform almost all their duties without involving site staff.
- 6. What does the author cite as a shortfall of CRA training as they gain more experience in the role?**
- Most sponsors/CROs only train new CRAs during the first year of their duties.
 - Much of the training is highly repetitive and not specific to expected study procedures.
 - Their training focuses only on the technical level of the studies they will monitor.
 - Not enough training deals with Good Clinical Practice and standard operating procedures.
- 7. Which of the following is cited by the author as something soft skills can compensate for?**
- Study participants feeling they are not being treated with the standard of care.
 - Unprepared clinical research coordinators making errors in data collection tasks.
 - Disagreements between site leaders and sponsors over study budgets and schedules.
 - The disconnect in human interaction between video and face-to-face communication.
- 8. What does the author say should help CRAs stave off a sense of “languishing” during the pandemic?**
- Remembering the meaningful nature of the work they do.
 - Expected overtime pay and year-end bonuses from their employers.
 - Personal contact with grateful study participants and their families.
 - Planning to transition into a new role as soon as possible.
- 9. What does the author say will be the “new normal” for CRA monitoring duties in post-pandemic conditions?**
- All tasks will be able to be completed remotely with sufficient sponsor/CRO support.
 - A hybrid approach of completing some tasks face-to-face and others remotely.
 - All tasks will revert to being completed in person as much as possible to please sites.
 - CRAs who are not willing to work remotely will be shifted to data management duties.
- 10. Which of the following is cited as an advantage of gaining soft skills training online?**
- Such training can be provided at no cost to sponsors/CROs.
 - In-person training has proven itself to be too complicated.
 - CRAs can complete online courses at their leisure as needed.
 - Online courses are known as the best motivator of employee retention.

Article #2: Documenting Training Using REDCap

LEARNING OBJECTIVES

After reading this article, the participant should be able to describe the challenges to, and importance of, proper documentation of training for specific clinical trials in a research-intensive environment, summarize the approach taken by Children's Mercy Hospital, and list several advantages of timely online training and tracking.

DISCLOSURE

Carol Brooks, BHS, ACRP-CP; Robin Ryan, MPH, CCRP: *Nothing to disclose*

11. Proper documentation of a trial is cited in the article as necessary for which of the following purposes?

- a. Completion of sponsor billing procedures and investigator compensation guarantees.
- b. Preparation of documents for sharing study results with participants and their families.
- c. Validation that the trial's protocol was followed, data are accurate, and staff were qualified.
- d. Federally mandated maintenance and storage of study results for at least 25 years.

12. What was the situation for documentation of Children's Oncology Group studies prior to the use of REDCap?

- a. So few studies were under way at any one time that documentation was not a challenge.
- b. Site personnel were largely capable of documenting their own protocol training and compliance.
- c. Documentation was handled by an outside vendor with widely mixed results in quality.
- d. So many studies were under way at once that consistent documentation was difficult.

13. What is cited as the original goal of the Division of Hematology/Oncology/BMT research team in terms of training and documentation?

- a. Gaining efficiency in distributing and tracking completion of protocol-specific training for study team members.
- b. Demonstrating increased productivity and capacity of individual coordinators for handling more studies simultaneously.
- c. Collecting data on study activities to justify requests for increased budgets and technology support from sponsors.
- d. Expanding the types and scales of studies to be undertaken based on the strengths of staff identified through tracking.

14. What is the status of REDCap's availability to research institutions?

- a. It is available for use based on contracted annual payment agreements.
- b. It is freely available for use with no special software necessary.
- c. It is a proprietary product solely used by Children's Mercy Hospital.
- d. Its use by others is strictly at the discretion of Vanderbilt University.

15. What is the purpose of automatic e-mail reminders sent through the REDCap system?

- a. To alert study team managers about protocol deviations and noncompliance.
- b. To alert sponsors when too many coordinators are assigned to any one study.
- c. To alert personnel who are delinquent to complete necessary training online.
- d. To alert institutional review boards when study documentation is complete.

16. Reports generated in REDCap about those who have submitted surveys can be used for which of the following purposes?

- a. Cost containment
- b. Training logs
- c. Legal indemnification
- d. Investigator's brochures

17. PowerPoint modules covering study protocols included in REDCap training surveys at Children's Mercy usually are provided by whom?

- a. Sponsors
- b. Institutional review boards
- c. Principal investigators
- d. Compliance officers

18. Who at Children's Mercy pushes out initial training surveys as new protocols are activated?

- a. Principal investigator
- b. Clinical research associate
- c. Regulatory coordinator
- d. Medical science liaison

19. Who at Children's Mercy alerts study team members when they are delinquent in meeting their training deadlines?

- a. Institutional review board
- b. Regulatory coordinator
- c. Clinical research associate
- d. Principal investigator

20. Which of the following are utilized by the regulatory coordinator at Children's Mercy to keep training and documentation processes organized?

- a. PowerPoint presentations and checklists from sponsors.
- b. A tracker of active surveys and master study team list.
- c. Flowcharts and automatic e-mail reminders from institutional review boards.
- d. Inspection Observations and Warning Letters from clinical research associates.