ACRP

WHITE PAPER

The Impact of Increased Technology Use on the Clinical Research Workforce

RISE OF TECHNOLOGY USE IN CLINICAL TRIALS

Technology now impacts most aspects of our daily lives, and clinical research is no exception. At the press of a button we can have next-day delivery of goods, on-demand streaming of favorite entertainment, on-demand transportation, and a video conversation with someone in another country. As clinical research evolves with an increased focus on a positive patient experience, there is a desire to leverage technology to make participation less of a burden on patients and more accessible to all who want to participate.

Use of technology in clinical research is increasing. According to the Tufts Center for the Study of Drug Development, "sponsors and CROs (contract research organizations) use approximately six applications to support each clinical study," which is double what was used 10 years ago. Key applications of technology within clinical trials include systems for electronic informed consent (eConsent), electronic source documentations (eSource), electronic patient-reported outcomes (ePRO), electronic clinical outcome assessment (eCOA), patient portals, and site portals, as well as the introduction of wearables, sensors, connected devices, and telemedicine platforms. While some of these technologies were created to support remote work with the patient, there may be continued use even when the patient is onsite.

Use of technology (and associated process modifications) is even more substantial in decentralized clinical trials (DCTs). Choosing when to implement a decentralized study will be determined by a number of factors, including therapeutic area, investigational drug profile (e.g., how it is administered, possible adverse reactions), what procedures are necessary, and current regulations for that country or region. Decentralized trials have many advantages:

- Increased convenience and flexibility for patients
- Increased participation, particularly for those not located close to a research site since extensive travel is no longer required
- Increased patient diversity from removing the geographic barrier
- Improved patient recruitment and retention because of added patient convenience
- Better/faster reporting of adverse events/serious adverse events (AEs/SAEs) due to more frequent communication and real-time access to data
- Increased data quality through direct collection versus data transcription

While there are benefits from bringing more technology to clinical research, it can also put additional burden on the study sites. We have often seen that the drug development industry has not fully considered the impact to the sites when implementing more technology. We encourage more collaboration between all stakeholders as new technology is introduced to help ease this burden. In addition, some sites are now assessing, selecting, and implementing their own technology to become more efficient across all studies.

Due to the COVID-19 pandemic, many sponsors/CROs and sites now have experience with various aspects of decentralization, and it is probable that many future trials will include one or more of these parameters. Some sponsors are mandating that DCTs be considered for every protocol. Other sponsors are adding contingency options into their protocol templates to allow the use of technology (e.g., telemedicine) as an option to facilitate trial procedures. This increasing use of technology, for all trials, means that clinical research roles will need to evolve and operate differently to accommodate this new environment.

Several professional organizations are now investigating the impact of DCTs on the industry, including detailing the regulatory needs as well as determining which trials are most appropriate for this new method. The Association of Clinical Research Professionals (ACRP) is interested in how the increased use of technology affects the clinical research workforce in terms of roles, as well as competencies, needed to be successful.

ACRP Working Group

ACRP is focused on improving the quality of clinical research by directly impacting the individuals who conduct clinical trials. The group offers the gold standard in professional certification and is leading innovation in workforce development. Since 2013, ACRP has been a key contributor to the Joint Task Force (JTF) for Clinical Trial Competency, which was convened by MRCT (Multi-Regional Clinical Trial Center of Brigham and Women's Hospital and Harvard). The JTF competency framework provides overarching expectations for clinical research professionals at different experience levels, but doesn't provide detailed expectations for various roles. ACRP has been translating the general competencies into role-specific guidelines, which it makes available to the industry at no cost:

- Clinical study monitoring competency guidelines (2017)
- Clinical research coordinator (CRC) competency guidelines (2018)
- Competency-based hiring guidelines for entry-level CRCs (2018)
- Principal investigator (PI) competency guidelines (2019)

- Competency development and assessment roadmap for entry-level CRCs (2020)

In January 2020, ACRP convened a Working Group of sponsors, CROs, technology companies, and site representatives to provide a recommendation regarding both roles and competencies needed for trials that require extensive use of technology. Soon after, the COVID-19 pandemic impacted the world, forcing the use of more technology in clinical research than ever before. We took the opportunity to gain information from this situation to further inform the Working Group's recommendations. An ACRP initiative led by Workforce Innovation Officer Beth Harper surveyed clinical research professionals that were directly impacted by the pandemic and asked how roles had changed and what competencies were needed to work in this new environment. This white paper outlines both these results as well as the Working Group recommendations.

The following companies supported this work by allowing these individuals to participate in developing recommendations:

Name	Type	Company	Role
Candace Saldarini, MD	Sponsor	Otsuka	Senior Director, Applied Innovation & Process Improvement
Christine Gilmour	Sponsor	Roche	Patient Recruitment & Retention Lead
Karen Noonan	CRO	Association of Clinical Research Organizations	Senior Vice President, Global Regulatory Policy
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Blake Adams	Technology	Florence Healthcare	Vice President of Marketing
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Jim Kremidas		ACRP	Executive Director
Kimberly Ray		ACRP	Working Group Leader (consultant)

Definition of Decentralized Trials

There are many different definitions of DCTs throughout the industry. As a working group, we differentiated between a fully decentralized trial (one that utilizes all technology aspects to their fullest extent) and a hybrid trial (one that combines some aspects of a DCT with those of a traditional clinical trial). There is significant variation when designing hybrid studies, and these range from having all sites perform both traditional and decentralized processes to having one country work in a decentralized fashion while another country works in a traditional model.

For further clarity, the Working Group put together the following graphic to map how we defined each type of study.

	PROTOCOL	START-UP	ENROLLMENT	FINAL REPORT
TRADITIONAL	• Design Study • Approve Protocal • Country Feasibility • Drug Supply Chain	• Site Identification • Site Selection • Regulatory & Contracts • IRB Approval • Site Initiation • Build Database • Patient Identification • Additional Technology Optional	• Advertise/Recruit Patients • Consent/Enroll Patients • Patient Visits at Site • Dispense Study Drug • Other Assessments (e.g., Xray) • Collect Patient Data at Site • Motivate Patient • Medical Monitoring • On-site Monitoring (remote is optional) • Motivate Site	• Query Sites • Close Database • Statistical Analysis • Write Report
DECENTRALIZED	• Design Study for DCT with enhanced patient safety plan • Approve Protocol • Country Feasibility (including applications use/internet access) • Drug Supply Chain Modifications	• Minimal* Site Identification • Minimal* Site Selection • Regulatory & Contracts • IRB Approval • Minimal* Site Initiation • Build Database for Multiple Data Sources • Patient Identification Optional • Additional Technology Required	• Advertise/Recruit Patients with Technology • eConsent/Enroll Patients • Visit Location is Patient-Centric • Study Drug Shipment is Patient-Centric • Other Assessments (Convenient Location) • Patient Data Collected Through Tech (wearables, digital surveys) • Motivate Patient Through Tech • Medical Monitoring Through Tech • Remote Monitoring Virtually Through Tech • Motivate PI Virtually Through TECH	• Query Patient Contact Person • Close Database • Statistical Analysis • Write Report
HYBRID DCT	• Design Study with Some Remote Visits/Procedures • Approve Protocol • Country Feasibility (Including Applications Use/Internet Access) • Drug Supply Chain	• Site Identification • Site Selection • Regulatory & Contracts • IRB Approval (Including Hybrid DCT Language & Patient Documents) • Site Initiation • Build Databases for Multiple Data Sources • Patient Identification • Additional Technology Required	• Advertise/Recruit Patients (Tech Optional) • Consent/Enroll Patients (Tech Optional) • Patient Visits (Remote via Tech Optional) • Dispense Study Drug (Accountability Via Tech) • Other Assessments (At Site or Remote Via Tech) • Collect Patient Data at Site (Tech Optional) • Motivate Patient (Tech Optional) • Medical Monitoring (Tech Optional) • On-site Monitoring (Remote Optional With Tech) • Motivate Site (Tech Optional)	• Query Sites • Close Database • Statistical Analysis • Write Report

*Could be as few as one site in trial

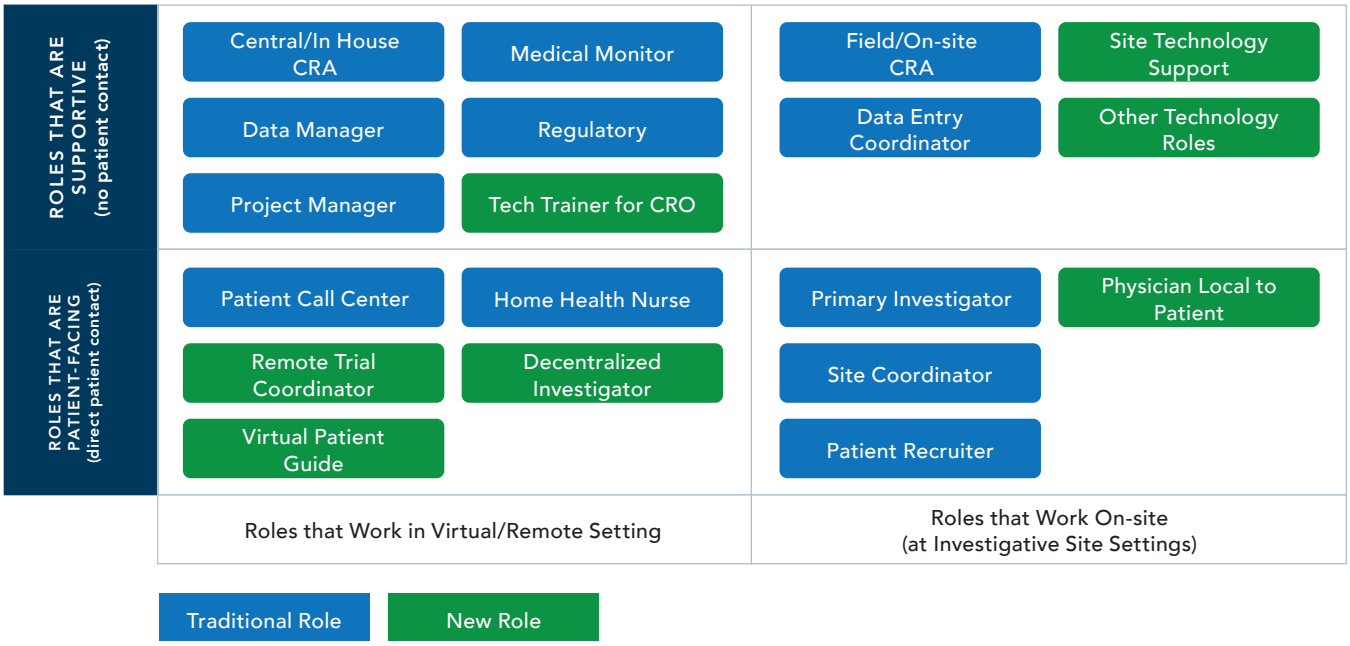
The Working Group believes that the majority of trials that implement decentralization, at least in the near term, will be hybrid trials. However, in the long term, fully decentralized trials could become more common as technology permeates more of our daily lives. With the recent pandemic, the Working Group expects that aspects of decentralization (e.g., virtual visits) will be leveraged more often and will have more overall acceptance by the industry.

As DCTs/hybrid/extensive technology trials are implemented, it will be important for sponsors/CROs to have open and transparent communication with research sites. It should be shared why the model is being used for a specific trial, what technologies are being used and why, and how these processes will affect the patient and the site. Collaboration between sites and sponsors/CROs when designing workflows will also be beneficial allowing sites to prepare/modify standard operating procedures (SOPs) as well as train their teams. Sponsors/CROs should also consider how the need for additional training and resources for the sites (e.g., technology support) could affect their budgets and timelines. Patience and understanding will be important as sites navigate this new concept. It should also be recognized that a site's receptiveness to adapt its workflows to include DCTs/hybrid trials, as well as its access and ability to conduct them, may vary by site and by region.

TECHNOLOGY'S IMPACT ON CLINICAL TRIAL WORKFORCE ROLES

The increased use of technology in clinical research will impact nearly every role involved to some extent. However, rather than being a threat to job roles, the Working Group believes DCTs/extensive technology trials will actually generate the need for new roles as well as bring unprecedented flexibility to some existing roles. For example, in a hybrid trial, coordinators could work from home one or more days a week when their patient interaction is virtual.

The following graphic presents information on roles that the Working Group believes will change as well as potential new roles that may be created.



For clarity, we grouped the roles based on whether they have patient contact and whether they work at a physical site versus a central/virtual setting. However, we do believe that all roles will continue to evolve and that many of the on-site roles will have a virtual component. The positions in blue are traditional roles that will be modified to work in this environment, and the positions in green are potential new roles that may be needed in the future based on the volume of these types of studies.

Traditional Roles

For DCTs and/or extensive technology trials, technology training must be standard practice and written into each site manual and delegation log.

- **Principal Investigator (PI):** While all of the traditional responsibilities of the investigator will remain, we see three ways this role will be impacted.
  - **Will need to be able to diagnose, evaluate, and engage with patients through technology via telemedicine.** We believe that telemedicine will grow to be more and more prevalent in clinical research. As it is used more routinely for general healthcare, most physicians will become comfortable using it. Not only will physicians need to be able to diagnose and evaluate patients (including uncovering AEs) through a telemedicine visit, they will need to be able to engage and retain patients through this medium. Telemedicine etiquette should also be part of the overall technology training. For some trials, patient compliance may be challenging, so diligence and vigilance of the investigator when leveraging technology will be critical. It will also be important that investigators stay current regarding licensure requirements for their region.
  - **Will need to learn technology to be able to monitor the patient's progress throughout study.** Much of the data that the investigator will use to monitor the patient's progress will be delivered through technology systems (e.g., wearable, micro-sampling, patient e-diaries). In the past, some investigators delegated all of the technology use to their coordinators, but this practice may no longer be feasible. Investigators will need to be trained on how to access the data from multiple systems so that they can analyze it for patient care. They will also need to understand the contingency plan if a technology fails and how to advise the patient. Even if the telemedicine visits are delegated to a sub-investigator, it is important that the PI is trained and can use the technology for these studies. Increased technology use may also increase the length of investigator meetings to ensure that there is sufficient time for training. Accordingly, sites will need to be compensated for this extra time away from patients.
  - **Will need to provide oversight of protocol procedures that do not occur at the site (e.g., patient's home).** PIs are still responsible for the full oversight of their patients. That includes remote services that may be performed at a study participant's home/other location. At the beginning of a DCT/hybrid study, sponsors will need to clearly designate where the accountability lies for all aspects of the trial (e.g., in case of inspection). Responsibility for training of non-site personnel to ensure protocol compliance will also need to be determined. An important task for the investigator will be to lead the change management needed with the staff, institutional review board (IRB), and local administration when conducting these types of

trials. Note that having others conduct some of the assessments (e.g., home health nurse) could impact investigator fees, as they may be less involved in these visits.

- **Clinical Research Coordinator (CRC):** In a fully decentralized trial, there may be no need for a traditional CRC at a site; however, there will be a need for someone to support the patient through the study (see new roles below). The complexity of the trial and the needs of the study will determine the qualifications required for this individual. Additionally, we expect very few fully decentralized trials in the near term and many more hybrid trials, which will require support from site coordinators. We believe that there will be three primary impacts to this role:
  - **Will need to be able to communicate, recruit, and retain patients through technology via telemedicine.** Similar to the investigator, the coordinator will need to learn how to conduct remote patient visits as well as nurture relationships remotely. Both recruitment and retention will need to be managed virtually and, in some trials, engagement may be supported through apps. During visits, it will be important to conduct assessments (including potential AEs) of patients through video. The coordinator will likely still be the primary contact for the patient and will liaise between the patient, investigator, and other team members (e.g., home health nurse). Additionally, training patients in technologies being used for the trial (e.g., wearables, e-diary) will likely fall to the coordinator. This will be particularly important for patient compliance and safety—especially for patient populations that are not comfortable with technology. Finally, coordinators will need to stay up-to-date on their local privacy laws before beginning the study.
  - **Will need to be trained on new technology as well as modify site processes so technology can be included.** In a hybrid trial, many "normal" processes will be impacted by the introduction of technology (e.g., informed consent, use of eSource, wearables). Coordinators will need to be flexible and modify how certain processes are done to incorporate this technology (e.g., medication compliance by counting pills on-screen during telemedicine visit). The activities of the coordinator will likely be focused less on events (i.e., lab draw) and more on ensuring that activities happen within window and/or in the correct sequence. Coordinators will need to be able to work with remote information to help assess patient compliance and engagement (e.g., working with patients to manage data queries). Because data will be arriving closer to "real-time," it will be important for CRCs to have a workflow that allows them to stay current with the data as well as understand how the technologies work and interface together. They will also need to be able to troubleshoot basic technology issues (e.g., speakers for telemedicine) and have contingency plans for when technology does not work (e.g., helpdesk). If there is no technology support at the site, it will fall on the CRC to understand the lead time needed for setting

up systems in their facility. At the beginning of a DCT/hybrid study, sponsors will need to make clear where the accountability lies for all aspects of the trial (e.g., technology certifications in regulatory binder, responsibility during an inspection). Finally, the coordinator will need to determine how these changes will impact their workload so that study budgets can be modified.

  - **Will need to coordinate with more external groups.** In DCTs/hybrid trials, there will be many more areas needing coordination, including lab results from external sources, home health staff performing patient visits (e.g., guided physical exam), and investigational product shipments directly to patients. There will be cases when a patient's home environment is not appropriate for remote/home nurse visits and back-up alternatives will need to be located. All patient-facing screens and technology details will need to be included in the IRB submission. Coordinators should also work with their IRBs to understand any new requirements when using these technologies as their use becomes more routine.

- **Patient Call Center/Patient Recruiter:** This role typically is involved in patient recruitment and scheduling. In the future, these activities will remain important and this role could expand to take on additional responsibility for DCTs. If the trial is not complex, this individual could take on the virtual patient support role (see below) but would need more training to ensure that they could carry out these additional responsibilities. In addition, DCTs (and some hybrid trials) typically involve patients from a larger geographic area, so the triage of patients may be more complex. Further, lack of a geographic barrier will likely increase the screening/recruitment volume, so the call center must be staffed appropriately. Finally, this group will likely remain separate from any technology helpdesk call center where work will continue to support trials as needed.
- **Field/On-site Clinical Research Associate (CRA):** There could be a situation in a fully decentralized trial where on-site visits are never needed; however, the Working Group believes that this would be a rare occurrence. As more trial activities become decentralized and more data come from technology, there will be less need for CRAs to travel to sites and the role will become more virtual. To support this, there are now technology solutions available that allow a CRA to visually inspect a site virtually. As more sites install their own technology, CRAs may be asked to review/download information through site technologies (e.g., regulatory documents). Additionally, a key aspect of this role will be understanding that these changes are very new to the site; therefore, CRAs should provide ample support as roles change and technology affects both visits and data collection.
  - **Will need to be fully trained in all data collection technologies used in the trial.** The CRA will need full understanding of each technology, its use in the trial, its audit log, its validation, any associated regulations, and contingency plans if the technology fails (e.g., lost, broken, stolen). This position should

be comfortable using technology. This role will need training on how to evaluate analytics (e.g., data feeds and visualizations), how to report the findings, how to verify source captured through technology (e.g., validate telemedicine visits by monitoring audit trail, use drug administration platform to reconcile investigational product), and how to virtually monitor any site documents on paper. Data review may require "work-arounds" if there are limitations in technology and/or lack of integration with other systems.

- **Will need to advise and motivate site virtually.** On-site visits will decrease substantially and CRAs will need to learn how to use technology to not only monitor site data, but also to keep the site engaged. The CRA should share best practices with sites, especially those that have never conducted a DCT/hybrid trial. The CRA will also typically be responsible for training sites in technology both initially (which may lengthen initiation visits) and when new personnel are added at the site. Additionally, they will need to modify traditional monitoring activities to accommodate new parameters (e.g., investigational drug accountability when it is shipped directly to the patients). The CRAs can advise sites on IRB approvals and maintenance of approvals for these types of trials.
- **Will need to be a change agent and be experienced in clinical research.** CRAs for these types of trials ideally should be very experienced in traditional trials, so that they are a better support for the sites that are switching to new methodologies and technologies. Personnel in this role must be flexible, change adept, highly skilled, and willing to maintain ongoing learning. Therapeutic expertise remains very valuable, as DCTs may operate differently based on therapeutic needs and the level of invasiveness required. Finally, these CRAs should also be able to use data and analysis to support operational improvement at the sites (e.g., eConsent allows for operational learnings to improve process and raise patient engagement).

- **Central/In-house CRA:** This role is already very adept at using technology to collect data and analytics to review it. These skills will continue to be important, but the scope of the role will increase depending on whether there is any support from field CRAs for the study.
  - **Will need to support site beyond only data review.** This role will be fully responsible for all aspects of site performance if there is no (or limited) field CRA support. These CRAs will need to shift their mindset to evaluate processes and issue corrective actions. They will need to understand all risks associated with the therapeutic indication and the technologies used, as well as how to mitigate them (e.g., technology failure). The central CRA will need to be able to advise and support the site (both investigator and coordinator) on all trial aspects, including recruitment, patient retention, technology training, DCT training, IRB submissions, and AEs.

  - **Will need to manage data from multiple sources.** The central CRA will need to understand what technologies are being used and why. The role will continue reviewing critical data and will need to be fully trained on how to read, interpret, and communicate data from more sources than a traditional trial. The data analysis will need to be both timely and effective, so that they can quickly and appropriately take action in any area of risk—especially with multiple team members (home health) and multiple data sources (wearables)—and know when to deploy a field CRA (if this option is available). Also, they should be proficient in using data and analytics to support ongoing operational improvement at the site level.
  - **Will need to be a change agent and excellent communicator.** Since the site will be depending much more on this role for overall study support, the in-house CRA will need to be an excellent communicator to advise and troubleshoot as well as build relationships and motivate virtually. It will also be up to this position to instruct (and retrain for new headcount) in the protocol and associated technologies.
- **Data Manager:** Data managers in clinical research currently deal with multiple sources of data, so the role will not change significantly. With these trials, there likely will be even more data sources and more that come directly from the patient themselves. The data manager will need to synchronize/integrate data as well as ensure technology platforms complement each other to gather data efficiently and effectively. The data management plan will need to reflect the revised process flow (e.g., investigational drug shipped directly to patient), new timelines, integration strategies, reporting frequency, and how to potentially work with non-coordinator staff to resolve queries. Because more data will be available in "real-time," ongoing cleaning of the data will be important.
- **Medical Monitor:** The responsibilities for this role will remain the same. However, accommodating the volume of data and the access to it in near real-time will most likely require the medical monitor to modify their workflow. They must be proficient with the technology analytics to be able to assess patient safety in an efficient way. Additionally, with mobile technology capabilities (i.e., alerts, push notifications), CRAs and sites may bring queries directly to the medical monitor for immediate response. The information flow to/from the medical monitor may require the project communication plan to be modified to ensure all information is appropriately disseminated to the project team.
- **Project Manager (PM):** The skill set for a PM is not different from a traditional study; however, the knowledge base will need to be expanded. For example, the PM needs to know the questions to ask regarding data collection and integration with other systems. While this is important for any trial, a DCT/hybrid trial will likely have more sources of data and more complexity overall. These trials are best served by an experienced PM who can help the team and the sites adapt to the changes needed for a DCT/hybrid study.

- **Home Health Nurse:** This role will remain essentially the same, except that it may take on additional responsibilities based on the protocol. In some cases, this role will need to work under the video supervision of the investigator. They will continue to communicate closely with their primary contact on the study team to ensure patient safety and protocol compliance. They may also need to have specific Good Clinical Practice training based on their activities with the patient.
- **Regulatory:** This role will remain the primary expert on regulations for the trial. However, because the regulations regarding DCTs are new and project teams are not familiar with them, this role will likely need to allocate more time to support each trial.
- **Site Data Entry Coordinator:** For the near term, many trials will still require transcribed data entry into electronic data capture (EDC) systems. In the future, as more and more data are brought in as direct source, there will be less need for transcribed data entry. As data entry volume decreases, people in this position may elect to cross-train for other roles at the site, particularly new technology roles.

Potential New Roles

- **Virtual Patient Guide:** This is a new role that will be needed for fully decentralized studies, particularly if there is no research coordinator support. The position will interact with the patient throughout the course of a trial to help them navigate the procedures and technology. This role will help ensure that the patient always has someone available to them and that they get a "white glove" clinical trial experience. This role has many names, including patient navigator, research ambassador, patient concierge, and virtual patient guide. In addition, they may be responsible for supporting query resolution related to patient-generated data. The background and expertise needed for this role will be dictated by the complexity and needs of the protocol. For study coordinators who would like to work from home, this could be a new, more flexible, career opportunity.
- **Site Technology Support:** With the increased use of technology in all trials (especially in DCTs), sites are in need of an information technology (IT) support role that serves as a super-user for all of the technologies as well as a troubleshooter for any connectivity issues. The variety of technology and platforms needed for each trial is increasing, and for sites running multiple studies, the technology needs can be substantial. It is not realistic nor efficient to ask coordinators to stay proficient in numerous software systems; nor do coordinators have time to spend with multiple helpdesks throughout the day to sort a variety of issues from the site and the patient. Therefore, as sponsors/CROs ask sites to use more technology, sites will need to obtain their own technology resource and sponsors

may be asked to reimburse the sites for this additional overhead. Additionally, sites will need to provide clear justification language when asking for additional funds to support any sponsor regulatory documentation explaining their site payment amounts (e.g., US Sunshine Act). For sites that don't have the trial volume to justify their own technology support role, it may be that sponsors/CROs will consider offering this as a regional service to help support the sites. It is also an opportunity for a third-party vendor to provide these services to sites through a consulting agreement. In this situation, the vendor would need to have access to all the site's systems, which likely will require updated policies around vendor access and SOPs.

- **Decentralized Investigator:** As DCTs/hybrid trials increase, there could be sufficient volume to allow investigators to work exclusively from a remote location. The Working Group believes that the most likely scenario for this situation would be a remote sub-investigator supporting the PI for telemedicine visits. Serving as a sub-investigator has always been a good way for physicians to determine how much they want to pursue clinical research; the option of telemedicine virtual visits may allow more physicians to experience clinical research.
- **Physician Local to Patient:** With the decentralization of trials, it would be useful if the patient's personal physician, who is familiar and local to the patient, could be involved in the trial in some capacity. This position could perform some "hands on" procedures under the direction of the PI, perhaps while on a telemedicine call. It will also need to be determined what training in clinical research this local physician must have to be able to participate in a limited way, as well as what compensation would be appropriate.
- **Remote Trial Coordinator:** As the volume of trials with remote patient interactions increase, it is conceivable that there could be enough volume at large sites that a remote trial coordinator is needed. However, as this role is considered, it will also be important that the fewest number of people possible are contacting the patient, that the reporting to them is uniform, and that the overall communication to them about the trial is consistent.
- **Sponsor/CRO Investigational Product (IP) Manager:** If the investigational drug is handled in a non-traditional way (e.g., shipped to patient's home, shipped to home health nurse), the trial would likely benefit from someone directly overseeing this activity. This role will be even more critical if the IP is managed differently by each participating country.
- **Sponsor/CRO Technology Trainer:** As more technology is used in clinical research, it may be most efficient to have a technology trainer at the sponsor/CRO. This position would be available to train CRAs and new project teams on technology that the sponsor uses routinely. In addition, this position could train sites at the investigator meeting and support the sites virtually throughout the trial taking this responsibility from the CRAs. Finally, this position could act as a liaison between sponsors/CROs and the technology companies.

- **Other Site Technology Roles:** While many sites do not currently budget for their own technology applications (they depend on the sponsors to provide all technology needed), others are taking the initiative to choose and purchase applications that are best for their organization. Rather than continually trying to accommodate the various technologies provided by each sponsor/CRO for each trial, these sites are independently selecting their own technology to use across studies so that their staff can be more proficient and effective in their roles. For this situation, sponsors/CROs and sites will need to align on which technology applications can be used for each trial. Further, as sites become more sophisticated with their technology use, there will be a need for additional support roles. For example, the "site technology support" role (presented above) could further develop into multiple and more specialized roles. Listed below are roles that some large institutional sites are starting to create:
    - Application Specialists: This role is responsible for all user training for each of the site-based technologies. They answer all questions, develop support materials, and lead all training activities.
    - Business Intelligence Analyst: This role assesses the technological needs of the site, both near term and long term, and puts together a strategic plan to address these needs. This role evaluates, selects, and manages vendors to support the plan.
    - Clinical Trial Management System (CTMS) Manager: As more sites invest in CTMS, they will need someone who manages the system and sets up all new studies. This position would "digitize" the protocol into the system as well as provide reports to the site staff.
    - Technology Consultant: This person could be brought in to ensure that all of the site's technology is connected and the data flows as intended between applications.

Moving Forward: Certification of Roles

Because DCTs are highly variable, the Working Group does not believe a formal certification is needed at the site level at this time. It is recommended that site SOPs be amended to include the options of remote work/technology use in their studies.

However, ACRP does believe there is an opportunity to enhance certification for certain roles with the skills needed for DCTs/extensive technology trials. To work with these new methodologies, site personnel will need to have basic knowledge of what decentralized means, as well as the typical technologies that will be employed (e.g., web-based enrollment, telemedicine visits, wearable technology, electronic patient-reported data). Site personnel will need to be flexible and embrace

change as well as be technologically savvy enough to quickly learn new software on different platforms. They must also be able to interact and communicate with patients effectively over the phone/video. The recommendations highlighted in this paper will be used to update ACRP's current training and role certification program. Further, ACRP will continue to evaluate whether certifications in additional sub-specialties (e.g., technology roles) would be useful.

TECHNOLOGY'S IMPACT ON CLINICAL TRIAL WORKFORCE COMPETENCIES

A competency is defined as the combination of job knowledge, job skills/abilities, and job attitude. This combination is reflected in job behavior that is observed, measured, and evaluated.

Source: Competency based HR Management. Retrieved from: https://www.slideshare.net/ZainiIthnin1/competency-based-hr-management-18080989

In thinking about the new competencies that will need to be in place for DCTs and/or extensive technology trials, we looked at these three areas: knowledge, skills, and attitude (or soft skills). In addition to the recommendations of our Working Group, ACRP joined with Continuum Clinical to conduct a survey of clinical research professionals in May 2020. This survey asked about the skills needed to cope with the ongoing COVID-19 pandemic, since many of the same skills would be needed for DCTs/hybrid trials. There were 342 respondents to the survey, with 42% coming from site staff and 58% coming from others (including sponsors/CROs/technology companies/IRBs).

SITE STAFF

There were 145 responses to the survey from site staff. These data were provided by Coordinators (63%), Investigators (3%), Site Directors (22%), and other site staff (12%). The table below presents the top results for each category in descending order.

Knowledge	Skills	Attitude/Soft Skills
Best practices for telemedicine	How to operate selected technology for trial/team software for the site	Flexibility
Best practices to update SOPs for new workflows	Effective communication skills when remote (including instruction)	Adaptability
Any institutional/regulatory prohibitions of working remotely	How to train/support/ troubleshoot technology and new procedures with patient	Patience
What aspects of the trial will be conducted remotely	Strong planning/time management/organization to accommodate remote work	Embrace Change/Resilience
Best practices for demonstrating PI oversite for activities that occur off-site	How to create presentations	Creative Problem Solver/Proactive
Budget needed for additional work required (e.g., scanning/uploading)	How to review data from non-traditional sources for patient care	Quick Learner

For DCTs/hybrid/extensive technology trials, some of the activities performed at the site are the same as for a traditional study, except the work is done via technology versus face-to-face. However, if a professional is weak in one or more of these skills, this deficit is likely to be accentuated when working remotely.

The survey asked what three skills you would recommend a colleague develop to adapt to this new environment.

Soft Skills

The number one response from site staff was an increase in soft skills. This highlights how important attitude is when working in an area that is changing so rapidly. The skill mentioned the most was flexibility, with adaptability as a close second. As clinical research evolves, the successful professional will embrace change, be open to learning new technology and new processes, be flexible when there are obstacles, and be patient with others.

Modify Procedures

It is recommended that sites be proactive in updating their internal SOPs to reflect the option of working remotely. That could include information like how to obtain vital signs remotely, identify an impartial witness remotely, confirm patient identity for eConsent, ensure protected health information (PHI) security when working remotely, document remote visits, teach patients to take pictures or scan their diary for the site, access lab specimen results that were collected remotely, securely

transmit diary and other patient information while protecting PHI, redact patient information according to institution policy, update any forms needed for electronic audits, develop a checklist of questions for a telemedicine visit (e.g., to help detect potential AEs), ensure PI oversight when activities are occurring off-site (e.g., delegation log), and resolve issues in case of technology failure. Sites will also need to be sure that they are set up to do this type of trial effectively (e.g., storage, connectivity, appropriate resources, appropriate location for telemedicine). As the site becomes more comfortable working in this manner, they can look for workflow efficiencies to improve resource workload and economics.

Communication Skills

These skills also remain essential, and it may be worthwhile to practice communicating via technology to ensure that each team member is successful. It will be important to effectively engage patients, verify their understanding of the information (especially the informed consent and any study risks), continue to listen to the patient, be observant while assessing the patient (using video), manage any interruptions/distractions, interrogate the patient to determine if there are any AEs, answer patient questions, and instruct the patient employing technology. Using props (like pill bottles) and/or links to other videos can help improve patient understanding. Also, limit the number of people who contact the patient to ensure consistency and efficiency of messaging. It will further remain important to concisely communicate and collaborate with the sponsor and its representatives (e.g., articulate study challenges to monitors, succinctly justify need for additional funding, provide feedback to technology vendors, describe additional assets that would be useful to help ensure patient success with technology).

Computer/Technology Skills

Learning new software and technology will likely be an even bigger component of clinical trials going forward. It will fall to the site staff to both instruct patients (e.g., taking vitals, study procedures) as well as troubleshoot technology issues (e.g., connectivity problems). Successful technology companies will create products that are easy and intuitive to use, as well as develop strong relationships with all stakeholders for their product (i.e., sponsors, CROs, sites, patients). Patients will become more and more adept at telemedicine visits as they become more mainstream in routine healthcare. Sponsors will also need to ensure that the technology selected is available and usable by the targeted patient population (e.g., many elderly patients don't have smart phones nor know how to use them). If the technology is new to the target population, sponsors should consider how they can support and increase patient confidence when using these technologies.

Time Management Skills

As procedures and use of technology changes, it will be important to relook at daily schedules. Many processes will be slower initially, until all parties are comfortable with the technology, but should be more efficient later. Additionally, as some of these trials provide the flexibility to work from home, professionals will need to learn to manage their time effectively in a different environment. It is recommended that managers of remote employees set goals/metrics so that everyone is clear on expectations for the work carried out remotely. With that said, a number of survey respondents also cautioned professionals to consider work-life balance, as it becomes very easy to put in many extra hours when working from home.

Non-Site Staff

The survey asked what three skills you would recommend a colleague develop to adapt to this new environment. There were 197 survey responses from non-site staff, with 31% from CRAs/CRA managers, 17% from project managers, 16% from clinical management and 35% from other groups. Groups represented in the "other" category included quality, regulatory, and data professionals.

Technology Skills

The number one recommendation was strong technology skills. Technology that was specifically mentioned included video meetings (and etiquette), document sharing, presentation development, data analysis, and specific trial technology (e.g., eConsent, eSource, ePRO). This also includes resolving connectivity issues when working from home. It often falls to the CRAs to support and troubleshoot trial-specific technology with the sites requiring a strong skill set in this area.

Decentralized Trials

It is important to understand and know how to implement components of DCTs. While many respondents believe that fully decentralized trials will only be used rarely in the near term, they believe that hybrid trials will rapidly become more common—especially due to the impact of the COVID-19 pandemic. Use of specific components will grow, including eConsent, telemedicine visits, eSource, and real-time data collection (e.g., wearables). Leveraging these technologies also includes ensuring secure systems are in place to protect patient privacy as well as understanding institutional policy regarding the transmission of patient data.

Risk Management/Time Management

Mentioned almost as often as technology and DCT components was risk management/time management skills. Many respondents mentioned putting plans in place to mitigate risk, being creative in overcoming obstacles, and managing expectations regarding delayed timelines and increased budgets. Complementary to this was working remotely and being able to prioritize and organize activities to work effectively while at the same time respecting work/life balance. Some roles are experienced in working from home, but this is a new experience for others, and it was recommended that strong time management skills be utilized to succeed in this new work environment. Recommendations included the importance of setting boundaries, establishing an ergonomic workspace and ensuring uninterrupted time. Finally, large volumes of data will be coming in to review on a near real-time basis (e.g., from wearables, patient generated data), so resource allocation must be managed to stay current with the data and maintain patient safety.

Soft Skills

Flexibility was the number one soft skill mentioned among the survey respondents. Many of the same skills were cited as were mentioned by the site staff, including adaptability, patience, collaboration, trust, confidence, and professionalism. Working in this new capacity is a big change for sites, but non-site staff need to also embrace change and remain flexible as they navigate this evolving environment. Several respondents mentioned that relationship building and team collaboration are more difficult remotely but, while different, can be done successfully.

Communication Skills

Equally important to the soft skills are strong communication skills when working remotely. This includes effective communication through video, whether internally among the project team or externally with the sites/technology vendors. Transparency was also mentioned as being important when things are changing so significantly, as this will promote better collaboration among the key stakeholders. CRAs will need to be excellent presenters, communicators, and trainers in their work with sites.

Leading Remotely

Many professionals at sponsors and CROs are already leading remote teams, but for those who are accustomed to working directly with staff at an office, this is a big change. After the pandemic, it is likely that more and more people will be working from home, so learning how to lead, motivate, coach, and get results from remote teams will be an important skillset moving forward.

We asked CRAs for more specific information on knowledge, hard skills, and soft skills needed to work in this environment. Note that several respondents did not believe that any new skills were needed when working in this environment, as all of these should be utilized whether working remotely or face-to-face. The table below presents the results in descending order.

Knowledge	Skills	Attitude/Soft Skills
Best practices for a remote monitoring visit	How to operate selected technology both for trial and team collaboration	Flexibility
Best practices for telemedicine visit	Effective communication skills when remote (including instruction)	Adaptability
Best practices for site communication/engagement when remote (frequency, types)	Risk mitigation/leading under pressure/change agent	Patience, Calm, Cooperation
How to access systems remotely; policies for data transmission; how to manage queries with patients	Data analysis, interpretation, and reporting via technology	Creative Problem Solver/Highly Organized

POTENTIAL IMPACT GOING FORWARD

The hallmarks of clinical research are protecting patient safety, obtaining quality data, and ensuring a positive patient experience. To help further achieve these objectives, sponsors will continue to leverage technology as well as new methodologies like DCTs.

Trial Efficiency Will Increase Study Volume

The goal of technology use is to help sites, CROs, and sponsors be more efficient overall. As clinical research personnel get more familiar with the use of specific technologies, efficiency will be gained. As trials become more efficient, study volume will increase and the cost to conduct trials will be reduced. However, we must add that industry-wide agreement on technology standards (e.g., single sign-on, eSignature standardization), especially those that promote easier connectivity between systems (e.g., application programming interfaces), would vastly accelerate efficiency and remove site burden.

Impact on Personnel Roles

When new methodologies and technologies are introduced, typically there are concerns that some traditional roles will be eliminated. In this case, what we have found is to the contrary, these techniques introduce new flexbility for traditional roles (e.g., remote work) as well as create new roles (e.g., patient guide, technology support, in-house CRA). In addition to the technology provided by the sponsor for a clinical study, we believe that more sites will independently acquire their own suites of technology. Thus, managing technology and data at the site level will necessitate new support roles and result in new career paths moving forward. Further, the increased access to many types of data and expanded use of technology will create new roles at sponsors and CROs (e.g., specialized DCT project teams, patient navigators).

Impact on Competencies

In convening this working group and analyzing the survey results, the primary competencies and knowledge that are fundamental to clinical research do not change. Most of the same processes are performed but are modified so that technology can be leveraged. Traditional skills will need to be adapted and a proficiency with technology will need to be developed to be effective in this new environment. In addition, an attitude that embraces change will be important for success.

Modifying methodologies and increasing the use of technology will ultimately improve clinical research. Increasing convenience for patients should improve recruitment and retention. Introducing direct information streams will improve data quality. Overall, these changes will lead to shorter times to market for important medicines. However, it will require patience and understanding to navigate our way through this transformational change. All of the key stakeholders—sponsors, CROs, and sites—will need to collaborate closely to achieve these important goals.

[i] Impact Report, Tufts Center for the Study of Drug Development, Volume 20, Number 1, Jan/Feb 2018.