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Center for clinical and translational research COVID-19 clinical trial committee: The development of a review and prioritization matrix during a pandemic

Leslie Bobb[1], Lisa Richman Ballance[2], Antonio Abbate[1,3], Jesse C. Bain[4], Patricia J. Sime[3], F. Gerard Moeller[1,3], Margaret K. Lessard[5], Alison J. Montpetit[6], Mary P. Harmon[7], Michael P. Stevens[3] and Deborah DiazGranados[1,3]

[1]Wright Center for Clinical and Translational Research, Virginia Commonwealth University, Richmond, VA, USA; [2]Clinical Research and Compliance, Virginia Commonwealth University, Richmond, VA, USA; [3]School of Medicine, Virginia Commonwealth University, Richmond, VA, USA; [4]Pediatrics, Children's Hospital of Richmond at Virginia Commonwealth University, Richmond, VA, USA; [5]Children's Hospital of Richmond at Virginia Commonwealth University, Richmond, VA, USA; [6]Nursing Research & Innovation, Virginia Commonwealth University Health System, Richmond, VA, USA and [7]Clinical Research, Virginia Commonwealth University Health System, Richmond, VA, USA

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Address for correspondence:
D. DiazGranados, PhD, Associate Professor, School of Medicine, Virginia Commonwealth University, Theater Row, 730 East Broad St. Suite 4200, Office 4214. Box 980466, Richmond, VA 23298, USA. Email: diazgranados@vcu.edu

Abstract

The rate at which the coronavirus disease (COVID-19) spread required a rapid response across many, if not all, industries. Academic medical centers had to rapidly evaluate, prioritize, and coordinate the multiple requests for clinical trial participation. This involved redirecting resources and developing a collaborative system for assessment, decision making, and implementation. Our institution formed a team with diverse representation from multiple stakeholders to review and prioritize all research protocols related to COVID-19. To accomplish this, a prioritization matrix was developed to help determine the order in which the protocols should be placed for consideration by the treating clinician. The purpose of the team was to review the COVID-19 clinical trials in the pipeline, prioritize those trials that best met the needs of our patients, oversee training and resource needs, and lead the formulation of procedures for integration with clinical care. Resources from the Clinical Research Unit were then allocated to support the swift execution of such studies. This manuscript describes that process, the challenges encountered, and the lessons learned on how to make all clinical trials more successful in a complex and dynamic environment.

Introduction

The coronavirus disease (COVID-19) pandemic required health care systems around the world to rapidly adjust their operations and reprioritize clinical research studies to include an urgent response to a new disease. Being a novel entity, there was no known prevention or reliable screening method, no established treatment or cure, and delays in test confirmations. According to the Declaration of Helsinki [1], where no proven treatments exist, ethically conducted clinical research becomes a high priority in clinical care [1]. COVID-19 was declared a pandemic by the World Health Organization on March 11, 2020 [2]. The United States saw the first outbreaks in February of 2020, and by mid-March, most states had implemented lockdowns and other infection control measures [3]. Virginia Commonwealth University (VCU) instituted measures beginning March 23 requiring all research studies to be designated into clinical research tiers, to allow only the most necessary personnel on campus. By April 1, only approved clinical research activity, including COVID-19 related clinical trials, continued. Factors taken into consideration included the direct benefit to the research participants, adequate social distancing capability, protection of frontline providers, and supply limitations for personal protection equipment (PPE) and disinfectant materials. As the institution navigated these emerging processes, clinicians and researchers worked diligently to find adequate, evidence-based treatment options for patients. This resulted in a cascade of protocol submissions, all aiming to recruit from an overlapping participant pool. As of this report, there are 716 clinical trials in the United States currently recruiting or enrolling on COVID-19, and/or severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [4]. In total, between May and November 2020, there were 4510 trials with any status (i.e., not yet recruiting, recruiting, completed, etc.) worldwide, with 1086 in the USA. Since March 2020, the activation pipeline initiated at VCU has been approached for approximately 93 clinical trials and lab studies related to COVID-19.

With the activation pipeline flooded with COVID-19 research protocols, it became imperative to develop a method to streamline, assess, and initiate research activities. Studies needed to be evaluated in relation to potential therapeutic benefit to patients, demand on limited resources, appropriateness for VCU Health's specific patient population, and other studies currently recruiting. The complexity in some patients, the fact that the mortality rate from acute respiratory distress syndrome (ARDS) is high (reported to be between 34% and 64% in some series), often due to multiple organ failure (MOF) [5], and the increased demand in the clinical environment necessitated the input of a multidisciplinary team to place our patients and clinicians at the forefront of decision making. VCU, VCU Health System, and the Wright Center for Clinical and Translational Research (VCU's Clinical Translational Science Award (CTSA)-funded center) share an overarching goal to consider health disparities and access to care in all endeavors. As an urban safety net hospital, the concern about COVID-19 disproportionately affecting our most vulnerable patient populations further illustrated the need for a multidisciplinary team to address comorbid conditions.

A team was created with the purpose of reviewing the influx of COVID-19 clinical trials, prioritizing those trials that best met the clinical care needs of our patients, overseeing training and resource needs, and leading the formulation of procedures for integration with clinical care. The process for creating the team and the workflow processes are described in this article. We conclude with a discussion of the hurdles experienced during the process and ultimately what has been learned about how to leverage a CTSA to make clinical trials more successful in a complex and dynamic environment.

The Prioritization Process

Committee Formation

Within the staffing and resource limitations (e.g., PPE), we established a COVID-19 Clinical Trials Prioritization Committee as a vital part of the combined efforts of VCU/VCUHS to address the COVID-19 pandemic. The purpose of prioritizing clinical trials is to maximize therapeutic benefit, avoid competition for participants, which results in an unacceptable burden on the patients and their families, and to promote efficient use of resources while supporting study activation, enrollment of participants, and ultimately, success of the clinical trial.

With the university leadership's support, the Director of the Wright Center for Clinical and Translational Research (Wright Center), and VCU's CTSA principal investigator (PI), was appointed to assemble and chair the committee, which included a selection of medical and nursing professionals and specialties, all with significant research experience. The committee, representing a diverse set of disciplines, included experienced clinicians and researchers from infectious diseases, cardiology, pulmonary/critical care medicine, pediatrics, pharmacology, hepatology, pathology, nursing and other fields with relevant expertise in cytokines, inflammation, and clinical research. In addition, the committee included a representative from the investigational pharmacy, the interim COVID-19 Clinical Research Coordinator and the directors for Clinical Research from both VCU and VCU Health as members. The comprehensive assembly of the committee ensured that every step of the activation and implementation process was represented and there was appropriate expertise to examine clinically relevant biological mechanisms within the context of current evidence related to the treatment of COVID-19. Each member of the committee reviewed potential protocols through the lens of their specialty, adding to productive discussions regarding anticipated benefits, difficulties, or conflicts with incorporating each study into the flow. The participation of the Director of Clinical Research for VCU Health and the Executive Director for Clinical Research and Compliance for VCU allowed for an alignment of goals and an efficient passage through the Institutional Review Board (IRB) leading to the activation of those protocols that proceeded. The involvement of the Wright Center allowed us to assemble this network of experienced researchers, many of whom had collaborative relationships with the Wright Center, and had prior experience working with one another. Moreover, the fact that those who were involved in the committee had multiple institutional responsibilities (e.g., some members served roles on the executive committee of the Wright Center and the IRB, or the CRU, etc.) also facilitated the communication and the swift decision making made by the committee. As the process progressed, we were able to add a representative from our patient community to the committee. This allowed us to incorporate the Wright Center's high value on community-engaged research into the COVID-19 clinical trials oversight. The charter was quickly developed, and a rubric was designed to support scoring, with a goal of one week from introduction to the pipeline to implementation.

The Activation Process

Once the committee had a clear charter, a process was created which would address how to centralize, prioritize, and expedite activation of proposals. The goal was to ensure that the trials with the highest priority approaches were activated first, with a clear sequence for approaching patients based upon their individual clinical needs respective to their stage of disease, which was facilitated by the inclusion of experienced clinical trialists who were also providing direct care to COVID-19 patients. The scientific approaches were scrutinized, including ethical considerations regarding inclusion/exclusion criteria, and resources required to implement the protocols were debated.

Upon referral to the committee, potential studies enter a pipeline system with built-in feedback loops designed to identify clinical trials in various stages and monitor the activation pathway (see Figure 1). Investigators are invited to present the information the committee needs for quick decision making virtually using a standardized template, highlighting rationale, inclusion and exclusion criteria, how participation in the trial would impact the patient if their severity were to worsen, and resources that would be needed to support the trial. During the call, PIs deliver a brief presentation using the provided template (see Appendix 1) and then answer any questions the committee may pose. After the PI disconnects from the call, the committee discusses placement of the trial and steps needed to integrate with the patient care pathway (e.g., ways to ensure nursing coverage, training needs, and ways to minimize additional access and exposure for the clinical team).

A simple scoring system was created by the Wright Centers Bioinformatics team, using REDCap that allowed the committee members to vote individually and confidentially on each protocol (see Appendix 2). The goal was to route presentations, anonymize scoring, and calculate and report results. The scoring survey also includes a question to capture any conflicts of interest the voting member may have with the study sponsor. If such a conflict were to occur, the member would be excused from voting on that study. Committee members also recuse themselves from voting on studies they are proposing as PIs. The studies are scored on two metrics,

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Table 1. *Impact score description*

High impact	Should be strongly supported and made immediately available to patients. This would result in allocation of resources possible.
Moderate impact	Should be supported, and it should be made available to patients as a back-up option. This would result in allocation of some resources, but also include some restrictions.
Minor impact	Can be supported; it can be made available to patients, but only if certain criteria are met. This would result in limited resources being allocated as available.
No impact	Should not be supported; it should not be made available to our patients unless no other options exist. No institutional support allocated.

Note: Resources indicate items such as coordinator/person time, essential study supplies, and personal protection equipment.

Table 2. *Complexity score description*

Low complexity	Can be supported as required resources are readily available and commonly used.
Medium complexity	Multiple resources and specialized expertise may be required, but both are relatively common and/or readily available.
High complexity	Requires resources from multiple sources, specialized resources, acquisition of new resources, and/or requires specialized expertise.

Note: Resources indicate items such as coordinator/person time, essential study supplies, and personal protection equipment.

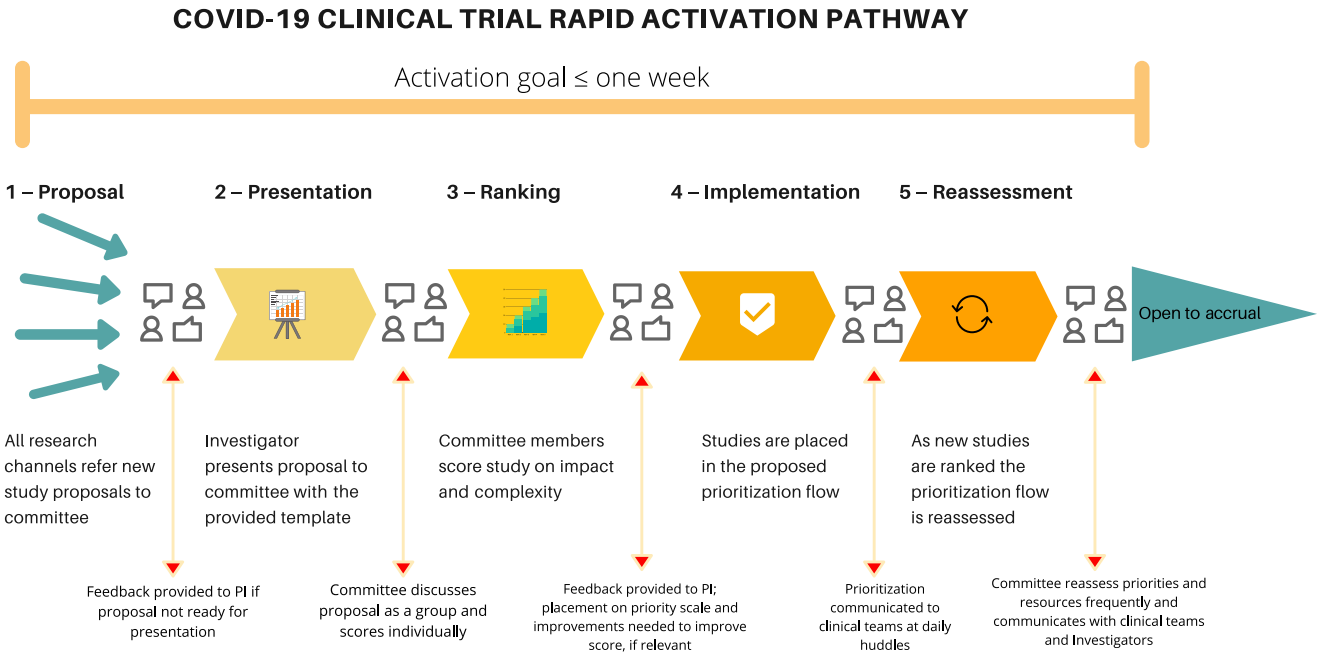

Fig. 1. Activation pathway.

"Complexity" and "Impact." In addition, a weighted composite score is calculated and provided to the committee. Lower scores in both areas are ideal, with the highest impact and lowest complexity yielding scores of *1* in each metric. Descriptions of Impact Score and Complexity Score are shown in Tables 1 and 2, respectively.

The rubric summarizes a variety of factors that are generally important to consider when evaluating new research projects, but are particularly salient in this situation. These factors may include, but are not limited to, the following.

Scientific Merit and Potential for Therapeutic Impact

The protocol must include a strong rationale and biological plausibility specific to COVID-19 (e.g., targeting the viral mechanism or the inflammatory- or coagulation-mediated injury to lungs or other organs). Studies that lacked a strong biological mechanism specific to COVID-19 or a poorly examined rationale were ranked lower on the impact score.

Therapeutic Benefit

Studies must offer a novel treatment option with direct therapeutic aims to the patient that would not be accessible to them outside of the study. Ideally, high-impact clinical trials are designed with a 1:1 or greater treatment-to-placebo ratio, maximizing the potential therapeutic benefit. Historical, observational, and other noninterventional studies were not discussed.

Feasibility of Study Design and Potential Barriers

Well-designed multisite trials that are coordinated or sponsored by clinical research organizations are prioritized over single-site trials

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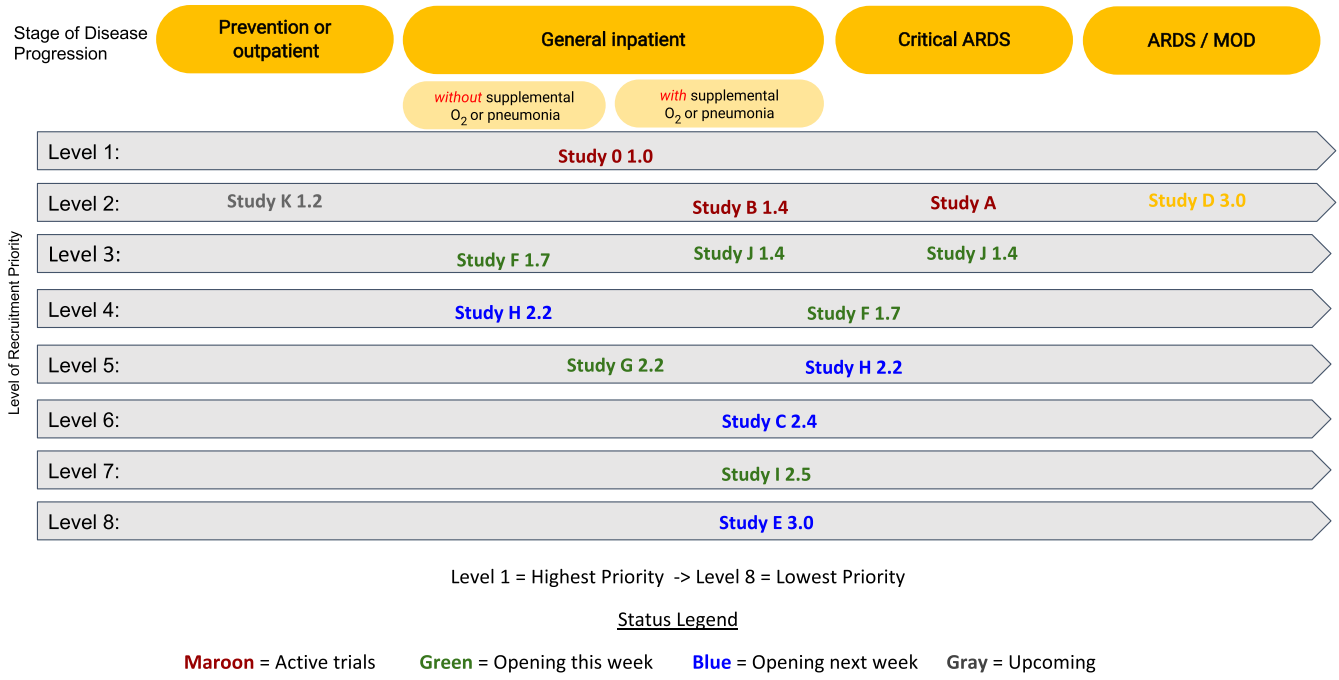

Fig. 2. Proposed recruitement flowchart.

exploring a small number of patients. Studies that have established research teams are scored as lower complexity than those needing research coordinators. The amount of time in direct patient care required to complete study procedures and PPE resource utilization are key feasibility criteria. Experienced investigators and well-established teams are considered more suitable than new investigators or newly formed research teams. Also taken into consideration are estimated access to adequate volume of patients and competition with other trials that address the same stage of disease or patient cohort.

Likelihood of Obtaining Timely Definite Results

Trials that were positioned to provide rapid benefit to the scientific community were prioritized over trials that would not result in any effective improvement to treatment standard for a long period of time. Again, multisite trials are more likely to meet recruitment requirements in a timely manner than single-site trials. Phase III trials and phase II/III trials are likely to provide more immediate benefit than phase I or phase II trials and were placed higher in the priority flow. Trials using drugs that already have the Food and Drugs Administration's (FDA) approval and known safety/risk profiles are prioritized over new drugs with unknown risks to patients.

Scoring results are reviewed in the following meeting and the committee discusses the study again, as needed, to determine the placement to a level in the proposed recruitment flow (see Figure 2). Level 1 represents the highest priority, and the levels descend in priority to level 8. Figure 2 shows the de-identified trials, with their composite scores noted, placed along a matrix indicating the stage of disease (*x*-axis) and level of priority (*y*-axis). A committee representative then advises the study PI on the placement in the clinical flow, recruitment expectations, and coordination of research activities given the sequence of prioritization for enrollment. In some cases, studies with low priority scores were never activated, mainly because global enrollment closed beforehand. In some other cases, the study was activated even if the score was lower. The activation of studies with lower scores was, indeed, never discouraged, as the enrollment for any specific study was expected to fluctuate based on the flow on the studies with higher priority score, so that in some cases a study with a rather low priority score would be expected to possibly be the only study available for a specific patient or group of patients.

Two-Way Communication

A primary focus for the activation pathway was to integrate feedback and two-way communication with the PI and clinical teams. As such, between each step of the pathway a deliberate contact point was placed, so that the committee was to engage in conversations with the PI or clinical teams. Once the presentation to the committee was completed, a nominal group approach was taken in that ratings were done individually and then discussed. When the score was finalized, the PI was informed and additional feedback was provided if there were opportunities to improve their priority scale rating. Moreover, we encouraged early review of the studies and it was not unusual that the same study would be presented multiple times to the committee after undergoing significant changes either because of changes while undergoing review by the FDA or by the IRB, or simply for the adaptive design of the study transition from an earlier phase I/II to a phase III over time.

As studies were placed into the prioritization flow, the clinical teams were updated at daily huddles. The clinical team representatives updated the committee at the biweekly meetings of any issues in clinical flow. Finally, a feedback loop was needed as new studies were added to the pool that needed prioritization. With a formalized activation pathway and deliberate points of two-way communication, the committee built a process that was inclusive, developmental, and patient centered.

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Translation into Patient Care

The final step in the prioritization pathway was the successful integration of trials with changing clinical processes to ensure high-quality care and patient and provider safety, while facilitating rapid enrollment. The CTSA-supported clinical research unit (CRU) was integral to the execution of these studies and their translation to clinical care. The nurse-manager and research nurses of the CRU provided support to the research teams serving as liaisons with the clinical units and providing just-in-time education for drug infusion and laboratory studies. On several occasions, the CRU team prepared training materials by way of online forms and videos that were available for immediate access to the nurse providing care for the COVID-19 patient in the room. The CRU nurses also assisted the clinical and research teams with the documentation of research tasks in the electronic health records and storage of research study material. This support was particularly critical between March and June when research staff was encouraged to limit the access to the hospital and work remotely. The medical director of the CRU assisted the research team by serving as the co-investigator or consultant for many of the studies, providing advice and being available onsite for strategies related to screening, recruitment and enrollment, and prompt management and reporting of adverse events.

In order to facilitate cross-communication of study team activities, the committee designated a single point of contact for trial logistics and supported the development of an electronic communication platform. The interim COVID-19 clinical research navigator has served to support study recruitment logistics, identify training needs, and answer any questions about study procedures for in-hospital active trials. This coordinator led daily huddles each morning to ensure that trial priorities were fully integrated with participant clinical needs and trial access was understood based upon availability of drug and other resources. The priority of the daily huddles was to ensure a patient-centered approach to study recruitment based on the priority schema. Integral to success of the huddles was the development of an electronic platform with live COVID-19 patient census information to facilitate transparent communication of study team activities in real time. The process of development and implementation of this platform is beyond the scope of this publication and the focus of a future manuscript.

Daily COVID-19 study huddles also provided a place for the study teams to review existing patient needs and the challenges with recruitment and completion of study procedures. Daily communication within the clinical team was vital as new information and guidelines were being developed on a frequent basis. The COVID-19 navigator participated in both the daily study team huddles and the bi-weekly committee meetings, providing a constant flow of up-to-date information and feedback between study teams. That communication has been essential in resolving complications, pivoting priorities, and shifting the focus of the rubric as needed based on the inpatient census of COVID-19 patients.

Discussion

This has been an unprecedented time and has required "all hands on deck." We have been highly successful in adapting trial assessment and delivery to this dynamic and uncertain environment. These efforts were catalyzed by the pandemic emergency and the redistribution of effort; however, they were maintained after the reopening of the standard operation in June, largely due to the fact that the structure was in place and there was ample support from the Wright Center. Cross-disciplinary clinical teams were highly motivated to be involved in helping care for COVID-19 patients, and we had more volunteers for supporting research than we anticipated, due in part to the freezing of nontherapeutic research operations. Yet, ultimately, we received more protocol choices than could reasonably be implemented. Not all studies could be determined to be the highest priority, if nothing else, due to limited human and other resources. Several issues arose throughout the course of this committee, and adaptation was needed to address them. However, there were several lessons learned that could provide valuable insights into the future of interdisciplinary clinical trial management across the profession. Both the issues and the lessons are discussed here.

Issues Encountered

The number of protocols submitted that focused on the same inclusion criteria and stage of disease created a competition for participants among investigators that had the potential to create confusion in the clinical teams and undue burden on the patient. This was one of the main reasons for the creation of the committee. Streamlining all protocols through the committee and ranking them with a standardized scoring metric served to adequately prioritize those trials with only the highest likelihood of providing benefit to the patient and the profession. Communication between the committee and the clinical teams ensured clarity in recruitment prioritization and reduced study burden on the patients. This unified and consistent method reduced any potential conflict between investigators as well. It is worth noting that the Wright Center as the facilitating center of the committee was likely a component in the ease with which this process was accepted by investigators and clinical teams. The Wright Center has a charge of promoting and supporting clinical research throughout the VCU community. Through the Wright Center-supported efforts and programs, the Wright Center has established itself as a nonbiased resource for researchers. Having this committee centered in the Wright Center allowed it to operate under that established reputation, with a level of trust that the recommendations would have the best interests of advancing science and providing exceptional clinical care as the only priorities. In addition, the Wright Center was able to supply the committee with resources, such as the bioinformatics and information technology teams that built the scoring system in REDCap.

A number of registry/biorepository/investigator-initiated protocols were presented, and it was evident they could not be processed with the same metrics as clinical trials. As the committee evolved, it became a logical decision to create a distinction between clinical trials and biorepository/registry protocols. A second committee was created with a similar interdisciplinary approach, including experienced researchers with expertise in biorepositories, specimen collection and storage, and registry management.

As mentioned, limitation of resources was another main reason for the creation of the committee. Many protocols were presented without funding or adequate personnel and other resources. This factor was taken into consideration when scoring the complexity of the study. For studies that scored high in impact, attempts were made to identify resources that could be shared or allocated to that study. In some instances, protocols were submitted by inexperienced investigators or teams. In these cases, often a more senior investigator was paired with the team to provide a higher level of experience and mentorship throughout the study. In three cases so far, faculty members who had not served as PI before were paired with experienced senior

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investigators and served as PI of an industry study, an NIH-multicenter study, and of an investigator-initiated study.

The size of the committee and meeting cadence worked well to address all other issues that arose. The committee consisted of 12 voting members, all contributing a different clinical specialty to the broad spectrum of expertise needed and including a former COVID-19 patient as a representative of the community. In addition, there were five nonvoting members who added unique perspective and expert advice in their particular fields. These nonvoting members included the Director of Clinical Research for VCU Health, the Executive Director for Clinical Research and Compliance for VCU, a representative from the investigational pharmacy, a representative from the pathology labs, and the interim COVID-19 clinical research navigator. There were enough committee members to ensure a quorum for every meeting without being too large a group to be productive. The frequency of meetings allowed for issues to be addressed in a timely manner. The length of the meetings (one hour) was enough to receive presentations and have brief discussions while respecting the incredible demands on the members' schedules.

Finally, to ensure integrity in research at all times, potential conflicts of interest needed to be addressed. As described earlier, any committee member with ties to industry or other conflicts of interest were asked to self-report. Members recused themselves from voting on protocols they wished to serve as PI on. Members were also recused from voting on any protocol sponsored by any company they had ties to.

Lessons Learned

One of the most important lessons we learned is that the model of establishing an interprofessional peer-to-peer group with the purpose of reviewing protocols and overseeing their activation is highly successful. With this model, we are able to focus on the studies that most meet our clinical care priorities and ensure integration of the research activities into the clinical workflow. Assembling an interdisciplinary team of experienced researchers and clinicians has been the key factor in the successful rapid activation of multiple high impact clinical trials in a dynamic environment. This model provided the expertise needed to anticipate barriers and needs so that the clinical focus could remain on delivering high-quality patient care in an environment that is safe for patients, providers, and researchers while advancing science.

A vital component to this committee was including representatives from the clinical teams providing the patient care. Without the inclusion of the providers, the integration of trials into patient care protocols would not have been as successful. Clinical teams are able to provide perspective on the feasibility of the suggested processes. Finally, the perspective of the pathology and investigational pharmacy representatives has been an invaluable asset that PIs are not often privy to at the onset of studies. Communicating with the specimen lab and the pharmacy during the development of protocols is a step that should be encouraged for all studies moving forward. Conducting research during the COVID-19 pandemic provided unprecedented challenges and having a multidisciplinary approach to planning was essential. For instance, there were challenges in pathology related to the shortage of testing for SARS-CoV2 mRNA that limited repeated testing required for some protocols; moreover, some biological samples required specialized handling that constituted particular challenges during this crisis. Similarly, the insight of the investigational pharmacist was critical to discuss barriers related to drug preparation, possible drug-to-drug interaction, preparation of suitable placebo if applicable, and additional challenges related to the specific management of COVID-19 patients (i.e., use of long IV tubing allowing for infusion pumps to be placed outside of the patient rooms) Moving forward in non-COVID-19 related trials, these perspectives during the development of protocols could aid investigators in preemptively addressing any potential complications downstream with sample storage and drug preparation and accessibility. Assigning an interprofessional committee, housed in the CTSA, to screen and review studies could be a beneficial approach to ensuring the successful activation of trials in any institution.

Secondly, we have also learned that conducting clinical research in the midst of a pandemic requires an exceedingly high level of communication and collaboration. The committee we established was successful in ensuring that this need was met via built-in feedback loops and communication with PIs and clinical teams. This method of frequent communication and collaboration points could be transitioned into regular clinical trials procedures. While human-to-human communication is key, we would like to point out two innovative strategies that were extremely successful. The first was the creation of the COVID-19 clinical research navigator position. This navigator provided constant communication between research and clinical teams, coordinated the clinical research coordinators, led the daily huddles, and addressed any gaps that arose. The second was the repurposing and customizing of the teletracking system that was previously used to track patients through trauma care. The system was tailored to track and understand patient flow through the clinical trials. This teletracking system provided an easy view of a patient's clinical care such as COVID-19 status, isolation status, and ventilator use, as well as pertinent research status such as participation in registries and clinical trial enrollment status. Transparent and cooperative communication between clinical teams, research teams, and other relevant departments presented a smooth and organized process to patients and an efficient workflow for all involved. This efficiency is vital to both clinical and research teams, who often manage excessive demands on their time. Streamlining in this way helps to prevent unnecessary delays and administrative burdens. An additional benefit of this model is continuing a level of mentorship to researchers throughout the institution.

Finally, creating a single, agreed-upon metric for scoring studies provides multiple benefits that would be relevant for overall research operations. A consistent metric ensures that all studies are in-line with institutional missions. This tool would provide a clear standard for new studies, which would be especially useful for less experienced researchers. This standardization could also serve to provide guidance for resource allocation and prevent disagreement over such allocation as all investigators would know what factors to consider in designing protocols to meet the agreed upon metrics.

In the future, it will be important to continue to communicate and collaborate as we activate clinical research rather than relying solely upon electronic systems to support the workflow. Enlisting the guidance of experienced researchers in an interdisciplinary format provides multiple benefits as outlined previously. The benefit this would provide to the clinical research community may outweigh the barriers. Interdisciplinary teams are becoming increasingly prevalent in clinical care, and this experience has demonstrated that there is a high value in incorporating them into research, as well. Incorporating the interdisciplinary collaboration, communication with clinical teams, and community-engaged aspects of this model into normal research operations will ensure higher quality research, speedier activation, and better integration for all involved.

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Conclusion

The COVID-19 pandemic proved to be a global healthcare challenge that has driven committed healthcare teams to come forward and meet this challenge. Locally, it has also proved to be an opportunity for demonstrating efficient, evidence-based processes for prioritizing and activating clinical trials. Because of the "all hands on deck" approach from researchers and research teams and the agreement from clinical trial contracting, budgeting, and IRB leadership to prioritize these high-impact clinical trials, it has been shown that it is possible to rapidly activate clinical trials. Through a collaborative group process that included community input, we also found that it is possible to initiate multiple clinical trials rapidly without conflicting priorities and competing patient recruitment efforts. The process described in this article highlights methods developed which could be utilized for support and prioritization of clinical trials more broadly. The challenge going forward will be whether these efficient and quality-driven processes can continue beyond and outside of the pandemic.

Supplementary material. To view supplementary material for this article, please visit https://doi.org/10.1017/cts.2021.4.

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