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Decentralized research technology use in multicenter clinical research studies based at U.S. academic research centers

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Abstract

Introduction: During the COVID-19 pandemic, research organizations accelerated adoption of technologies that enable remote participation. Now, there's a pressing need to evaluate current decentralization practices and develop appropriate research, education, and operations infrastructure. The purpose of this study was to examine current adoption of decentralization technologies in a sample of clinical research studies conducted by academic research organizations (AROs). *Methods:* The setting was three data coordinating centers in the U.S. These centers initiated coordination of 44 clinical research studies during or after 2020, with national recruitment and enrollment, and entailing coordination between one and one hundred sites. We determined the decentralization technologies used in these studies. *Results:* We obtained data for 44/44 (100%) trials coordinated by the three centers. Three technologies have been adopted across nearly all studies (98–100%): eIRB, eSource, and Clinical Trial Management Systems. Commonly used technologies included e-Signature (32/44, 73%), Online Payments Portals (26/44, 59%), ePROs (23/44, 53%), Interactive Response Technology (22/44, 50%), Telemedicine (19/44, 43%), and eConsent (18/44, 41%). Wearables (7/44,16%) and Online Recruitment Portals (5/44,11%) were less common. Rarely utilized technologies included Direct-to-Patient Portals (1/44, 2%) and Home Health Nurse Portals (1/44, 2%). *Conclusions:* All studies incorporated some type of decentralization technology, with more extensive adoption than found in previous research. However, adoption may be strongly influenced by institution-specific IT and informatics infrastructure and support. There are inherent needs, responsibilities, and challenges when incorporating decentralization technology into a research study, and AROs must ensure that infrastructure and informatics staff are adequate.

Background

The onset of the COVID-19 pandemic and associated public health measures triggered widespread restrictions on in-person research activity [1]. To resume operations, both academic research organizations (AROs) and clinical research organizations (CROs) accelerated the adoption of telemedicine, eConsent, electronic patient-reported outcomes (ePROs), and other modalities in order to engage existing study participants and resume study procedures [2]. This dramatic change in traditional procedures for conducting trials was readily enabled by the widespread availability of mobile devices, sensors, and digital communication platforms. The research community's collective experience of adopting decentralized research activities was compelling, with evidence of strong recruitment and retention outcomes. The pandemic-driven progress in decentralization now requires more intentional consideration to ensure that it is cost-effective, that the quality of decentralized research is sufficient, and that delivery frameworks, study procedures, and staff preparation are robust. For academic health sciences centers, there's a pressing need to evaluate current decentralization practices and develop appropriate research, education, and operations infrastructure to support this model of clinical research. Much of the necessary infrastructure relates to the use of technologies including digital health technologies that enable the decentralization of specific research activities, whether studies are fully or partially decentralized. However, we lack a concrete assessment of current decentralized research technology use to support assessment and planning.

We define decentralized research or decentralized clinical trials (DCTs) as research studies that use digital technologies, such as sensors, mHealth, telemedicine, and networks of local providers or home health services, to interact with participants located at a distance from the central study site. Examples of technologies and services that can be used to decentralize research activities are summarized in Table 1. These include telemedicine, remote patient monitoring, wearables, and ePROs, and reflect data collection using a range of digital

Table 1. Categories of decentralization technologies for clinical research

Category	Description	Example
eIRB	Electronic application and review system for human subject research	ERICA [17], Complion [18], HawkIRB [19]
eSource	Source document collected through electronic mechanism (outside of electronic medical record).	eSource [20], Florence [21]
Clinical Trial Management System	Information management system designed to support clinical research processes or document storage including protocol and accrual tracking, financial management, billing, compliance, reporting and trial master file documents.	OnCore [22]
e-Signature	Electronic signature; electronic indication of a person's agreement to the terms of an electronic document	DocuSign [23]
Online Payments Portal	Enables processing of electronic payments to either sites or participants	Stripe [24], ClinCard [25]
e-Patient Reported Outcomes	Outcomes reported directly by patients, electronically via web or mobile applications	Kaiku Health ePRO tool [26], PROMIS tool kit [27]
Interactive Response Technology	Technologies that enable direct interaction between participants and computer systems, via voice, web, or messaging, using structured data entry or natural language, for randomization, communication, data collection, etc . . .	Dokbot [28]
Telemedicine	Remotely delivered healthcare via telecommunications technology	Doxy.me [29]
eConsent	Electronic informed consent; uses digital technologies to facilitate informed consent process during and throughout a research study; technologies may include telecommunications, multimedia content, and digital signatures	Teleconsent [30,31], REDCap eConsent [32]
Wearables	Electronic devices incorporating biosensors, that can be worn by a patient on the body.	Fitbit [33]
Online Recruitment Portal	Online platforms that match prospective study participants with clinical research studies	Fox Trial Finder [34]
Direct-to-Patient Portals	Secure online platforms for communication and information sharing between health care organizations and patients; these platforms can also be used for study recruitment purposes.	MyChart [35,36]
Home Health Nurse Portals	Platform that enables home health personnel to access participant and protocol information, and facilitate remote data collection by home health personnel in the context of clinical research studies	Platforms are study and location dependent

communication technologies, including web and mobile applications, chatbots, interactive voice response technology, and SMS platforms [3]. Alternative definitions exist; Petrini and colleagues define DCTs as "studies in which the need for patients to physically access hospital-based trial sites is reduced or eliminated" and Santa-Ana-Tellez and colleagues advocate for the following definition: "Type of clinical research that utilizes telemedicine, mobile/local healthcare providers, and/or mobile technologies to manage participants within their usual environment. DCTs are characterized by less dependance on traditional research facilities or specialist intermediaries for data collection. They leverage tools, such as telemedicine, sensory-based technologies, wearable medical devices, home visits, participant-driven virtual healthcare interfaces, and direct delivery of study drugs and materials to participants' homes" [4,5]. Our definition and use of the term "decentralized research" is consistent with these definitions but encompasses diverse health sciences research that may not specifically constitute clinical research or a clinical trial. In a hybrid model, some study activities and procedures are decentralized, while others occur during visits to a central research site. In fully decentralized models, all study activities occur at a distance, facilitated by digital technologies and/or local services [6]. This is a distinct departure from traditional site-based research models but holds great promise for addressing recruitment, retention, enrollment, and underrepresentation in clinical trials by overcoming barriers to participation, including time, transportation, and inconvenience.

Successful hybrid and fully decentralized trials are evident in the biomedical literature, and multiple current initiatives are aimed at incorporating decentralized activities into clinical research studies [7,8]. Multiple examples of studies related to atrial fibrillation utilize remote, wearable sensor devices to collect measurements. For example, the 2015 STROKESTOP trial used remote monitoring to identify episodes of atrial fibrillation [9]. The 2016 mSTOPS trial similarly employed remote monitoring for atrial fibrillation [10]. The University of Utah-based DECAAF II trial, a hybrid multicenter international study, entailed wireless transmission of 248,099 ECGs via mobile devices and smartphones [11]. The DECAAF II team also implemented a web-based randomization process that required real-time display of enhanced MRI images to clinicians for the interventional group and collected and analyzed ablation procedure data from 3D mapping systems for each patient. The 2022 DeTAP study was a fully decentralized trial that entailed physiologic measurement of patients with atrial fibrillation on anticoagulation therapy [12]. DeTAP recruited participants via social media and traditional methods. Additionally, the study used telemedicine visits, eConsent, sensor devices, and ePROs collected via a mobile application to fully decentralize research activities. While many clinical trials are challenged by recruitment and enrollment issues [13], the DeTAP study experienced recruitment overflow, with a waiting list of over 200 patients and high retention. Further, DeTAP participants indicated a strong willingness to participate in future fully decentralized trials when surveyed at the end of the study; 69/80 (86%) agreed or strongly agreed that they were willing.

Industry adoption of decentralized research activities is sharply increasing. A 2021 survey of CROs indicated that most are planning hybrid trials that entail both in-person and remote research activities [14]. The report noted the greatest increases in specific decentralization activities in telemedicine/ mobile nursing, eConsent, and remote sites but also noted increasing adoption of remote patient monitoring, ePROs, and wearables. A 2022 Association of Clinical Research Professionals survey found that only a few respondents were conducting fully remote research studies. Still, a large proportion (38%) were implementing hybrid research studies incorporating both onsite and offsite activities [6]. Despite increasing adoption and intention to adopt decentralized research activities, respondents also described several challenges, including regulatory concerns, site integration, a lack of in-house capabilities, data security, sourcing vendors, training, data harmonization, internal buy-in, and costs.

Participant perspectives on decentralized research are not well-characterized in the biomedical literature. However, existing evidence indicates that patients are generally satisfied with remote trials and would prefer to participate in fully remote trials. Assessment of researcher perspectives is also limited; a 2021 study by Coyle and colleagues indicated there is increased burden on research staff due to the additional complexity of conducting decentralized studies, inadequate testing and design of processes, and the burden of managing and using technologies [15]. A 2022 report by the Association of Clinical Research Professionals, focused on the pragmatic implementation of decentralized clinical trials and noted "a web of multiple challenges" that included the challenges of navigating multiple systems without a common platform or sign-on process, and difficulty in funding decentralized clinical trials given sponsor budget inflexibilities [6]. A 2022 study assessed the perspective of European regulators, identifying a number of opportunities and challenges worthy of further scrutiny [16]. Opportunities included improved accessibility and geographical reach, lower participant travel burden, more complete data, and the feasibility of trials entailing rare diseases and patients with limited mobility. Challenges included increased burden to participants for communicating safety information, insufficient relationship building with participants, increased workload for both participants and researchers, hampered assessment of eligibility, and difficulty in interpreting large data sets. Additionally, some have expressed concern related to the digital divide, and the potential of decentralization to exclude patients without adequate digital literacy or technology access.

Given the widespread interest and growing adoption of decentralized research activities and current evidence indicating the promising potential for decentralization to overcome disparities in health research, there is an acute need to strengthen and expand needed support services. Research teams require support to appropriately integrate decentralized research technologies and analyze the resulting data. It is also essential that research education offerings incorporate content related to decentralized research. However, methods of decentralization vary, and we need more national data on the extent and nature of technology adoption specific to academic health sciences centers. For example, we anticipate that telemedicine has been widely adopted. Still, we need more clarity on the extent to which sensors, ePROs, and other approaches to decentralization have been adopted among academic research organizations. Therefore, this study aimed to examine the current adoption of decentralized research technologies in a sample of studies conducted by AROs.

Methods

The setting for this study was three data coordinating centers located at academic research organizations (AROs): the University of Utah Data Coordinating Center, the University of Iowa Clinical Trials Statistical and Data Management Center, and the Data Coordination Unit at the Medical University of South Carolina. All three units are AROs that coordinate data for clinical research, with a focus on multi-site clinical trials with services that include research design, clinical data management, study management, study execution, and analysis. The three sites were selected because they have existing research network collaborations that facilitated data collection, reflect varied geography, institutions, and research areas, and fulfill a similar role in coordinating clinical trials. Together, these centers initiated the coordination of 44 clinical research studies between 2020–2022, with recruitment and enrollment occurring across the United States and entailing coordination between one and one hundred sites, with almost all studies involving multiple sites. The studies are diverse and encompass many interventional trials and other prospective, observational research studies. We included all studies initiated by the three research centers during or after the year 2020 because many studies became partially or fully decentralized during 2020 due to the COVID-19 public health emergency. No studies were excluded.

We defined decentralized research technologies as those technologies corresponding to a set of thirteen (13) classifications created by the Association of Clinical Research Professionals (ACRP) based upon input from members and stakeholders who regularly recruit in clinical trials from academic institutions, private practices, clinics, and research-only sites [6]. These classifications were not formally defined in the ACRP report; we offer a brief description and at least one exemplar technology in Table 1.

During January and February 2023, each ARO reviewed their eligible studies and indicated the classes of decentralized research technologies that were used, if any. Data was collected on an Excel spreadsheet listing the specific technologies from the ACRP survey. We provided examples of each technology from studies that had already been completed for guidance. We did not collect detailed data about the specific tools or technologies that were used, or how they were used. Also, we did not attempt to determine whether the studies themselves were fully or partially decentralized. Rather we focused on the use of decentralized research technologies within the studies. We also determined whether research studies were FDA-regulated. We then used descriptive statistics to examine the current adoption of decentralized clinical trial activities. Additionally, we reviewed specific case studies of decentralized trial elements.

Results

A total of 44 trials were available for data extraction. We obtained data for 44/44 (100%) trials coordinated by the three centers. Forty-one percent (18/44) of the studies were FDA-regulated, and 66% (29/44) were interventional trials. The use of decentralized technologies in the research studies is summarized in Table 2. Three technologies had been adopted across nearly all studies (98-100%): eIRB, eSource, and Clinical Trial Management Systems (CTMS). Commonly used technologies included e-Signature (32/44, 73%), Online Payments Portals (26/44, 59%), ePROs (23/44, 53%), Interactive Response Technology

Table 2. Use of decentralized technologies in multicenter clinical trials, by FDA regulation, during the years 2020–2022

Component	Overall ($n = 44$)	FDA Regulated ($n = 18$)	Not FDA Regulated ($n = 26$)
eIRB	44 (100%)	18 (100%)	26 (100%)
eSource	44 (100%)	18 (100%)	26 (100%)
Clinical Trial Management System	43 (98%)	18 (100%)	25 (96%)
e-Signature	32 (73%)	17 (94%)	15 (58%)
Online Payments Portal	26 (59%)	10 (56%)	16 (62%)
e-Patient Reported Outcomes	23 (53%)	6 (33%)	17 (65%)
Interactive Response Technology	22 (50%)	13 (72%)	9 (35%)
Telemedicine	19 (43%)	7 (39%)	12 (46%)
eConsent	18 (41%)	11 (61%)	7 (27%)
Wearables	7 (16%)	2 (11%)	5 (19%)
Online Recruitment Portal	5 (11%)	1 (6%)	4 (15%)
Direct-to-Patient Portals	1 (2%)	0 (0%)	1 (4%)
Home Health Nurse Portals	1 (2%)	1 (6%)	0 (0%)

(22/44, 50%), Telemedicine (19/44, 43%), and eConsent (18/44, 41%). Wearables (7/44,16%) and Online Recruitment Portals (5/44,11%) were less common. Rarely utilized technologies included Direct-to-Patient Portals (1/44, 2%) and Home Health Nurse Portals (1/44, 2%).

Discussion

We determined that nearly all studies used eIRB, eSource, and CTMS, systems that support efficiency and regulatory compliance regardless of whether study participants are remote. Universal adoption of eIRB and CTMS is unsurprising given the technology availability within the United States. All studies involved the use of eSource, indicating that all trials in this study have the potential to directly enter source data within the Electronic Data Capture (EDC) compared to initially documenting study-specific data on paper. eSource has been noted to reduce transcription error and improve efficiency in clinical trials [37].

Several decentralization technologies showed common adoption across clinical trials among the three AROs: e-Signature, Online Payments Portals, e-Patient Reported Outcomes (ePRO), Interactive Response Technology (interpreted as randomization within the EDC in this publication), Telemedicine, and eConsent. Common uses of e-Signature in clinical trials include study documents (e.g., protocol), study team sign-off, database sign-off, and consent. Both e-Signature and eConsent were more common in FDA-regulated trials than in non-FDA-regulated trials. This finding is likely related to the more stringent requirements for documentation in FDA-regulated trials, including witnessed informed consent and FDA-compliant electronic signatures, as these studies entail higher levels of risk. For this manuscript, we defined Electronic Consent (eConsent) broadly as using any electronic method to obtain and document the results of the informed consent process. Methods could have been as simple as sending electronic versions of consent forms (e.g., PDFs) for signature. More complex forms of eConsent use electronic documentation and e-Signature technology in combination with telemedicine to facilitate witnessed informed consent and direct interaction between study personnel and participants (e.g., Teleconsent) [30–32,38]. Unsurprisingly, given the restrictions in research during the COVID-19 pandemic, eConsent has increased in usage.

We found that ePRO usage was more common in non-FDA-regulated studies. The mechanisms most commonly used for ePRO data collection by the three AROs in this study included texting/emailing surveys to participants or handing the participants a tablet. Less commonly used means included sending surveys from third-party sources (e.g., websites). Implementing surveys from the EDC system requires extensive user testing from the ARO to confirm the timing of automatic sending, stopping rules, reminders to the participants, and platforms used by potential end users. For example, survey testing should evaluate various platforms (e.g., computer, iPhone, android, and tablet), environments (e.g., WiFi, roaming, and cellular), and authenticity checks (e.g., confirming the identity of the participant). Automating many aspects of survey implementation reduces the risk of human error.

Telemedicine was another commonly adopted decentralization technology. Telemedicine reduces transportation and travel barriers, cost, and time required by researchers and participants. It can also facilitate eConsent in that meeting face-to-face can help researchers gauge participant understanding. Additionally, study personnel can use screen sharing to highlight and discuss parts of the consent form.

The least commonly used decentralized trial elements by the three AROs included online recruitment portals, wearables, direct-to-patient portals, and home health nurse portals. These decentralized technologies have in common that they require a fair amount of infrastructure, custom development, and support that may not be available at most AROs. Additionally, they are not applicable across all types of research studies. For instance, online recruitment portals are likely not useful for emergency trials or ancillary studies to a parent trial.

Wearables and applications, also called the Internet of Medical Things (IoMT), have many benefits, including real-time data collection, ease of participation, and the potential for more data. However, coordinating studies utilizing wearables and applications is resource-intensive and increases cost. Extra resources are required to train coordinators on wearables and applications since coordinators are typically the primary contact for enrolled participants on study-related issues. Some participants may struggle to use wearable technology, especially if the population is elderly, physically or neurologically challenged, or if participants have digital access or literacy (42). Information Technology (IT) personnel at AROs must be involved in projects to establish a secure data flow from the participant to the database. Wearables and other devices require a system of technical support. The data generated by wearables and applications must be monitored for quality, integrity, and safety, and ultimately integrated with other data sources for analysis. Site-specific budgets must account for the purchasing/replacement of wearables or applications (if needed) to allow universal participation in research unless access to the current technology is part of the eligibility criteria.

AROs have experience working with traditional partnerships such as sites, institutional review boards, and regulatory and funding agencies. However, using digital health technology such as those described requires AROs to build new partnerships for implementation. In a patient-centric decentralized research model,

the ecosystem that supports a study can be expansive with multiple technology and service partners/providers. Working with software vendors (e.g., mobile device apps, patient portals), medical device companies, and cloud providers for data storage introduces complexity and requires a thoughtful approach to mitigate technical issues, address interoperability requirements, rigorously validate data, and ensure secure data storage for all data in the ecosystem. Comprehensive risk assessments should be performed with all suppliers and service providers to evaluate security posture, including confirming that appropriate protections for patient data are in place. These risk assessments should be conducted at the start of the relationship and throughout the lifecycle for each vendor.

Healthcare data is a frequent and popular target for cyber-attacks. The growing number of interconnected devices and systems increases the risk of exposure. Wearables and other IoMT can be vulnerable touchpoints for bad actors. If successfully breached, Personally Identifiable Information, Protected Health Information, and other sensitive data about the participant/patient could be exposed. In addition, more sophisticated bad actors could trace the connection from the device through the internet to the rest of the study ecosystem, including the ARO's infrastructure. For these reasons, technical safeguards must be in place at the device level and throughout the ARO infrastructure. Examples of appropriate technical safeguards at the device level include strong authentication requirements, such as multi-factor authentication. At the infrastructure and site personnel level, preventative measures should include system hardening, software patching, malware detection, and security awareness training.

Adequate infrastructure and training are critical needs in decentralized research. Study activities often require the use of multiple and varied technologies. Technology-mediated study activities require initial configuration and testing, as well as ongoing support to both study personnel and participants. Data from diverse sources and types must be ingested, harmonized, and transformed into analysis-ready data sets. Currently, expansion of decentralized research requires growth in institutional clinical research informatics resources and support. However, there is potential to lower the infrastructure requirements through advancement of technologies that ease the conduct of decentralized research through the development of purpose-built platforms. One such initiative is the Eureka Research Platform, developed by University of California, San Francisco with National Institutes of Health (NIH) funding. The platform enables decentralized recruitment and data collection on a common platform, using a modular architecture to accommodate varied designs. The capability to use consistent, common systems and platforms across studies could reduce both cost and burden to research staff.

Decentralized research requires a new and evolving set of competencies on the part of researchers and research staff, who must address the unique considerations of online recruitment, data collection, communication, reporting, and analysis. Moreover, methodological knowledge related to decentralized research is evolving rapidly. Research training programs (e.g., PhD programs, Research-focused fellowship programs) should address the design and conduct of decentralized studies in the broader context of applied research informatics education. Research staff must receive adequate training and preparation in using decentralization technologies to plan and carry out study activities, and to optimize their communication and interaction with study participants. Additionally, some decentralized study designs may necessitate education of extra-organizational personnel who perform study activities (e.g., home health nurses local to the participant). Educational efforts must be supported by ongoing methodological research and scholarship to optimize quality, improve outcomes, and establish good practices.

Decentralized research also introduces novel statistical implications that need to be addressed through both infrastructure and education. Pre-specified data harmonization is necessary when duplicate data are collected from multiple sources (e.g., directly from the participant in addition to coordinator data entry from the medical record). Representation of the continuously collected data (e.g., the mean, highest observed value of the day) should be determined before analyses. The larger magnitude of data available through continuously collected mechanisms opens an opportunity to incorporate statistical methods (e.g., time series analyses) into clinical trials that historically have not been possible given the limited data available. Additionally, with the use of eSource, there isn't always definitive confirmation of whether outliers are valid or, in fact, data entry errors.

Study follow-ups typically have protocolized windows. Compared to pre-specified scheduled visits where participants return to the clinic, the timing of responses when data are collected remotely can correlate more with the participant's well-being. For example, participants in poor health may elect to respond to ePROs when they feel better. Statistical techniques have been proposed to account for this survey response bias [39]. Additionally, participants may not be responsive to automated reminders to complete data collection. Without attention to participant education, technology training, and support, their devices could block reminder messages. This circumstance can lead to missing data that must be accounted for with statistical input. When using decentralized technologies in clinical research, increasing centralized statistical monitoring of all data sources is critically important. Prospective and active monitoring of data accuracy and transmissions is crucial in identifying and resolving problems as soon as they arise. Moreover, statistical support and educational efforts must encompass this knowledge.

The technology, infrastructure, and "know-how" required to seamlessly collect, transform, exchange, and store data from disparate systems can be costly. While technology plays a central role in decentralized research, IT investments and budgets are typically far more limited in AROs versus counterparts in industry. University-based AROs are also confined to standard operating procedures established by the university, and potentially at the state level, which could pose additional operational complexities. There is a need for formal cost-benefit analysis of decentralized trials as the basis for organizational investment in the necessary infrastructure.

Limitations

This study reflects the adoption of decentralization technologies in studies coordinated by one of three AROs. As the adoption of decentralized technologies is likely influenced by institution-specific IT infrastructure and support for clinical research, the findings may not be generalizable to other AROs. The adoption of decentralization technologies among smaller institutions or organizations lacking appropriate infrastructure or personnel may be less. Conversely, decentralization technology use may be higher at AROs with robust IT infrastructure and support for clinical research. The studies coordinated by the three AROs are typically large, multicenter, extramurally funded studies. Some of the trials are conducted within an NIH-funded network

system that provides infrastructure for efficiency [40–44]. Additionally, studies coordinated by these three AROs are often interventional, with requirements for elements such as witnessed informed consent and an elevated need for safety monitoring. Our understanding of these considerations and their influence on the results is limited, as we did not elicit details on these characteristics. Additionally, we did not review protocols or interview ARO team members to elicit further detail on how the technologies were used or elicit the perspectives of researchers, participants, and/ or sponsors on the decentralization technologies. We adopted a classification of decentralized technologies that was created to support a survey of the Association of Clinical Research Professionals, but lack detailed information about this classification's development process, or whether it was validated.

Conclusions

We determined the extent and nature of decentralized technology use among clinical research studies coordinated by three U.S. AROs. We found that all studies initiated in 2020 or later incorporated some type of decentralization technology. eIRB, eSource, and CTMS were consistently implemented. Commonly implemented decentralized technologies included e-Signature, Online Payments Portal, ePROs, Interactive Response Technology, Telemedicine, and eConsent. Less frequently implemented decentralized technologies included Wearables, Online Recruitment Portals, Direct-to-Patient Portals, and Home Health Nurse Portals. The results indicate a more extensive adoption of decentralized technologies than found in previous research. However, adoption may be strongly influenced by institution-specific IT and informatics infrastructure and support. There are inherent needs, responsibilities, and challenges when incorporating any decentralized activity into a research study. AROs must ensure that infrastructure and informatics staff are adequate to support fully or partially remote studies. Given the growing demand for decentralized research [45], AROS must develop strategies to adequately support their use. Key next steps include the development of appropriate infrastructure and education, as well as research to better understand matters of cost and quality.

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