DCRI THINK TANKS
FROM INSIGHT TO ACTION

Addressing Clinical Trial Deserts

October 6-7, 2021

EXECUTIVE SUMMARY

BACKGROUND

Clinical trials are intended to generate evidence on whether treatments are safe and effective—ideally evidence that is generalizable beyond those who participated in the trials. For many populations, however, participating in clinical trials is hindered by their inability to access sites that are enrolling participants. On the other hand, other populations are overrepresented in clinical trials, such as people in close proximity to academic medical centers.

The October 2021 Think Tank session on "Addressing Clinical Trial Deserts" brought together thought leaders from academia, clinical practice, the US Food and Drug Administration (FDA), industry, and clinical trial participants to share firsthand and expert perspectives on how to achieve more diverse and expanded coverage of sites where people can participate in clinical trials. The Think Tank focused on increasing access to clinical trials that require in-person interactions through the engagement of community-based health care providers, such as clinical practices, health care systems, and pharmacies not traditionally heavily involved in research. Other approaches to increasing clinical trial access, including virtual and decentralized trials, are important considerations but were beyond the scope of this Think Tank. The meeting was hosted virtually due to the ongoing COVID-19 pandemic.

WELCOME AND OVERVIEW

Cohost Harlan Krumholz (Yale University) welcomed the attendees and noted that people throughout the United States live in places where there is no access to clinical trials infrastructure or no entry points into clinical trials. This is despite clinical researchers desperately wanting access to more participants and a desire to ensure everyone can be part of a learning health care system. Cohost Charlene Wong (Duke University) invited attendees to approach this topic with humility and a commitment to listening and grounding the discussion in the experiences of participants and frontline research partners.

SESSION I: LISTENING SESSION

Panelist Zsolt Nagykaldi (University of Oklahoma Health Sciences Center) discussed clinical research participation in rural communities and the need to reorient the academic research infrastructure to better understand and build relationships with people in rural communities. Health care systems in rural communities are fragile, and they commonly experience major disruptive events, such as changes in system ownership and loss of clinicians. People in rural communities face especially high barriers to referred services like subspecialty care and mental and behavioral health care. During the COVID-19 pandemic, rural health care systems have faced an existential crisis, which has made it even more difficult for them to partner in clinical research. Principles for engaging rural communities in clinical research include the following. First, articulate the value proposition. What do we bring to the community that might enable them to participate more readily? Can we bring resources to bear, improve the capacity for providing regular health care in the community, or provide needed services that are related to the study being planned? Second, create community-friendly study designs and inclusion and exclusion criteria. A conventional randomized controlled trial may be the most rigorous design but may not be the most appropriate design for the community partners. Can we negotiate a design that is mutually acceptable and congruent with the community's needs and values? Third, create a matching set of priorities. Our top priority may be to advance science, whereas the community's top priority may be to improve the health of the population. How can we bring these priorities together and create structures of listening and cocreating that respond to both needs?

Panelist Michael Hall (University of Mississippi Medical Center) discussed the importance of including underrepresented academic medical centers in clinical trials. These centers often serve the highest-risk and most vulnerable populations. They are probably in the majority of academic centers in the country and, thus, have the potential to have the greatest impact. Representation from these centers would promote greater generalizability and a more real-world perspective on clinical issues. They also tend to be tightly linked to other rural communities, community-based clinics, and historically Black colleges and universities. However, participation in clinical research is not typically part of the institutional culture, and these centers lack clinical trials infrastructure. Effort is focused on revenue-generating activities, and there is a limited pool of trained study staff (such as study coordinators and personnel to manage pre- and postaward activities) and strained internal regulatory systems. It can also be difficult for these centers to recruit clinician-investigators who can help change the institutional culture, because they are often located in lower-income cities with large underserved populations. There is inadequate IT and informatics support in these centers, which is reflected in US patient cohorts used for training clinical machine learning algorithms. Finally, many of these centers lack research endowments and are supported by state funds subject to state laws and procedures. The Mississippi Center for Clinical and Translational Research is increasing clinical study productivity through centralized clinical research resources. We need more incentives for clinical trial activities. Sponsored centers focused on clinical trials in larger institutions would have high potential to train coordinators and trialists.

Rowena Dolor (Duke University) discussed the Duke Primary Care Research Consortium, which includes 60 community-based practices in 9 counties in North Carolina, 280 primary care clinicians, 300,000 patients, and access to a population of 3.8 million. Common barriers and challenges to these clinics participating in clinical research include lack of infrastructure, lack of clinician input on study design and procedures, and lack of experience in human subjects protection and Good Clinical Practice. Although clinic endorsement of study participation is important to patients, community clinics tend to be unaware of active studies. Moreover, clinicians are often not rewarded for time spent on research. Study budgets are insufficient for practice-based research, and study findings are rarely shared with the practices.

Esther Krofah (FasterCures) offered a patient perspective and discussed the importance of contextualizing discussion of clinical trial infrastructure by remembering that the infrastructure is situated within a fragmented and expensive health care system. We do not have a clinical trials system; rather, we have an ecosystem of actors and players responding to individual market incentives. The patient experience is about navigating the system. Those who tend to navigate the system well can benefit from the structures in place; those who cannot navigate the system or even access it lose out. We see these experiences reflected in racial and ethnic disparities in health outcomes, highlighted most recently by the COVID-19 pandemic. Building a network of networks would be one way to address fragmentation in the health care system. For example, the NIH Community Engagement Alliance (CEAL) is working directly with local partners to establish trust and build relationships. Another example is the Veterans Health Administration, which includes 106 research sites on a common IT platform, as well as patient advisory committees that engage with local communities. These could be pulled into clinical trials network. Another example is the Clinical Directors Network, a nonprofit network that supports community health care centers in participating in clinical trials networks. We need connectivity across networks to avoid creating new silos. A national network of clinical trials in community settings should have a clear plan with actionable goals. It will require funding and training, should be designed intentionally, and should align and harmonize electronic health record (EHR) platforms.

Priscilla Pemu (Morehouse School of Medicine) described Morehouse partnerships with community practices that are not affiliated with a health care system. They have had greater success with studies supported by the National Institutes of Health (NIH) than with industry-funded studies. The partnerships have been effective in recruiting Black populations, because people in the clinical trials unit are members of the community and there is trust in these relationships. The partnerships also use a community advisory board. There is a need for greater investment in infrastructure that supports community-based research outside of large academic health care systems.

DISCUSSION

Cohost Charlene Wong synthesized the panelists' contributions into several themes. First, there must be a **clear value proposition** for the community, including shared priorities and investments in meeting the health care needs of the community. Second, potential

investigators in underrepresented institutions need **greater incentives for research**, such as lower indirect costs, practice-based study budgets, clearer engagement points for clinicians, and return of results. Third, there must be **sustained relationship building with clinicians and communities**, and there should be a focus on equity to address bias in health care and research. Fourth, there is a need for **flexibility through more community-friendly clinical trial designs**, as well as early site input into designs and protocols. Finally, practice-based research sites in a fragmented health care system need the **research infrastructure** for participation, including support for regulatory personnel, pre- and postaward management, IT infrastructure, and funding.

Attendees discussed the importance of **earning trust in communities**. Trust emerges from long-term relationship building, sustained presence in communities, and investment in meeting community needs. Researchers and institutions should look beyond the short-term interests of the particular clinical trial. Rob Califf (Verily Life Sciences and Google Health) noted that the same organizations that talk about trust are engaging in routine business operations that undermine trust by failing to equitably distribute health care and research resources. The reimbursement system should be changed so that institutions are responsible for better outcomes in the populations they serve. Large academic centers' indirect costs dwarf their infrastructure investments in communities.

Richard Nkulikiyinka (Bayer AG) raised the issue of **training**. Good Clinical Practice certification can be daunting for physicians outside academic centers and a barrier to participating in clinical research. It would be worthwhile to explore offering training and certification as a benefit to physicians in community settings. Rowena Dolor noted that the Duke Primary Care Research Consortium has tried to avoid this training requirement for community-based clinicians by having only the site-level principal investigator and study coordinators handle recruitment and consent. Nevertheless, training requirements do get in the way. The National Children's Study was able to use a modified, short module on Good Clinical Practice. In other studies, the training requirement has led to months of delay. Khair ElZarrad (FDA) agreed that training should not be a blanket requirement but should correspond to the individual's role in the trial.

Maria Borentain (Bristol Myers Squibb) responded to a conversation in the Zoom chat box about the role of **decentralization of clinical trials** in building bridges with community-based clinical care and research. Industry is encouraging network building in communities by academic centers, but this has not always been successful. Esther Krofah and others agreed that decentralized and hybrid trials are an important tool but are not the sole solution. Some communities lack broadband internet access and face other barriers and would benefit from investment. Bias can also be introduced in remote tools, so we should design decentralized trials with patient input. Sean Cunningham (Janssen R&D) noted that decentralized capabilities can also include solutions that are not technology-based, such as localized care models that provide access to clinical trials outside traditional research sites.

Rob Califf bemoaned health professions education that does not instill a regard for research and continuous learning as integral to medical practice.

David Goff (NIH) shared that participants' comments resonate with his own experience with respect to efforts to engage primary care community practices in research. It is up to us to establish ourselves as **trustworthy**, to lead with the interests of the community rather than our own interests. Communities have needs, and we have a responsibility to meet those needs; as we do that in good faith, we demonstrate ourselves and our institutions as being trustworthy.

Participants discussed the role of **incentives and disincentives**. Matt Roe (Verana Health) observed that some of the more successful practice-based sites are those that are run as a small business that can generate revenue from participating in research. However, these sites generally are not located in areas that are representative of the larger population. Centralized support is needed to make this happen.

Harlan Krumholz noted that it is important for **clinicians to be partners in the research effort**. The National Registry of Myocardial Infarctions (NRMI) succeeded in this regard because frontline practitioners felt like part of the process. Ola Vedin (Boehringer Ingelheim) observed that this challenge is also applicable in Europe. Beyond financial and career incentives, working with senior, inspirational colleagues has been an important incentive. The success story in Sweden—for example, with registry-based randomized trials—is related to creating a sense of community around research. Lothar Roessig (Bayer AG) noted that attempts to use the Swedish model via the European Society of Cardiology's European Unified Registries for Heart Care Evaluation and Randomised Trials (EuroHeart) initiative have been difficult. Ola Vedin suggested that Sweden has a relatively unique infrastructure for registries. Quality registries and public registries can be merged to capture outcomes and baseline characteristics through multiple sources. What EuroHeart is doing is commendable but challenging. They are making progress by creating a baseline framework, but they do not also have the public registries.

SESSION II: POTENTIAL SOLUTIONS

Moderator Khair ElZarrad (FDA) introduced the panelists and facilitated the discussion.

Vance Bauer (OCHIN) offered an academic perspective by discussing OCHIN, a national nonprofit health IT company that provides services to a network of primary care health centers that serve low-income and underserved communities. Key lessons relate to infrastructure, study design, and study execution. With regard to infrastructure, the network offers assistance with regulatory compliance. With regard to design, engagement with health care system leadership is key to understanding their needs. The network is a strong proponent of pragmatic clinical trials and cluster randomized trials, which reduce the burden associated with altering practices' routine workflows. With regard to execution, the network uses a clinic impact fee to offset some costs of research, rather than a typical upfront startup cost with per patient costs. The network also leverages existing systems and data and centralized functions.

David Goff (NIH) offered an NIH perspective by sharing observations from a recent discussion at the 2021 National Heart, Lung, and Blood Institute (NHLBI) Advisory Council strategic retreat.

The theme of the retreat was optimizing clinical trials, and council members were asked to weigh in on the structures of clinical trial models. With regard to infrastructure and capacity development, participants stressed the importance of leveraging Clinical and Translational Science Awards (CTSA) programs and other networks to support capacity building at less experienced sites; facilitating partnerships across institutions to share resources, which also provides early-career investigators with experiences beyond what is available at their home institutions; and providing adequate funding to support inclusiveness at all levels, including support for community engagement. With regard to community and participant engagement, participants recommended being prescriptive in application requirements, such as adding a separate criterion score addressing whether the characteristics of trial participants reflect the epidemiology of the condition, as well as the diversity of the trial team and the extent to which the community is engaged. With regard to pipeline development, participants discussed providing additional funding to integrate early-career investigators into clinical trials, as is done with program project grants; providing midcareer funding and creating mechanisms for trainees to be supported; creating an academic environment that promotes the diversity in the trialist pipeline; and recognizing support from industry to develop clinical trialists. Addressing clinical trial deserts will required acknowledging that funders and funding recipients share responsibility for addressing the needs of diverse communities and may mean doing fewer trials with greater impact rather than more trials with less impact.

Ola Vedin (Boehringer Ingelheim) offered an industry perspective. First, it is important to generate awareness among patients and investigators for clinical trials. Patient engagement has typically been conducted as an afterthought, too late to have an impact. Engagement is now gaining momentum as a priority, especially engaging with patient organizations and assigning clinical trial ambassadors. It is important to increase awareness among sites, train early-career researchers and fellows in clinical trials, and partner with academic centers to offer training that is eastly accessible to early investigators. Second, we need to do better at understanding the patient journey in the specific disease being studied and to apply a diversity filter to that understanding. Real-world data will help, but ultimately we need to interact more with patients, focus groups, patient advocacy groups, and patient organizations. Similarly, we need to engage with atypical trial sites and especially their study coordinators and nurses. We also need to simplify and decentralize trials. One example is the "patient insight and engagement playbook" currently being rolled out at Boehringer Ingelheim. They are seeking to engage patients and sites much earlier in the process. The playbook is a tool to communicate throughout the clinical trial process, from planning to wrap-up. Third, we need to simplify the informed consent process and informed consent forms, avoid burdening patients and clinicians with additional visits on top of routine visits, and enable sites to focus on patient enrollment. Pragmatic protocols are key. Using existing information in routine care settings, EHRs, and local labs can help sites avoid adding new layers to routine processes.

Attendees discussed the importance of understanding the patient journey and recognizing that it looks different depending on where the patient is, especially in our fragmented health care system. Rob Califf noted that making trials practical and pragmatic is important. However, there is heterogeneity in terms of how the FDA review divisions regard efforts at simplification. On

the NIH side, there is increasing diversity in trial populations; the next phase is addressing rural populations, income diversity, education level diversity, and implications for reaching patients and engaging them in research. Rowena Dolor noted that patients in community settings want proven therapies and are more comfortable with later-phase trials. Clinical trial deserts may not be the right setting for all kinds of trials. Clinicians are sensitive to their patients' hesitation about "being experimented on," and volunteering for early-phase industry studies especially is seen as something that may not have benefit.

DAY ONE RECAP AND OVERVIEW OF DAY TWO

Adrian Hernandez (Duke University) remarked on this session being the one-hundredth in the DCRI Think Tanks series. Rob Califf noted that the goal was to create a venue where people could share their best ideas in a setting where they did not necessarily represent a particular organization. Norman Stockbridge (FDA) encouraged attendees to focus on generating specific ideas for getting things done and making change.

Cohosts Harlan Krumholz and Charlene Wong agreed that our challenge is come up with practical solutions. They offered a brief synopsis of the previous day's discussion and asked attendees to share their top "do wishes" to address clinical trial deserts (see **Table** at the end of this executive summary).

THE IMPERATIVE OF ELIMINATING CLINICAL TRIAL DESERTS

Charlene Wong introduced Nakela Cook, executive director of the Patient-Centered Outcomes Research Institute (PCORI), who gave a brief presentation on PCORI's efforts to promote patient and community engagement in research. The PCORI Engagement Rubric is built on the principle of reciprocal relationships. It provides practical guidance to ensure patient-centeredness is linked to public and patient engagement. Engagement results in more knowledge and enthusiasm for research. For communities, engagement builds trust, strengthens relationships, and increases awareness of different stakeholder perspectives. For researchers, engagement brings deeper understanding of the real-world experiences and concerns of their study populations. Best practices for building and maintaining partnerships with underserved communities include inclusive and bidirectional communication, connection through cultural or community brokers, and coaching for both investigators and partners to bridge knowledge gaps. Finally, we need to diversify the pool of investigators.

SESSION III: INNOVATIONS

Cohost Harlan Krumholz introduced this session on identifying distinct solutions from different perspectives.

Antonios Clapsis (CVS Health) offered an industry perspective by sharing an overview of CVS Health and its growing clinical research assets. Part of the CVS Health mission is to make clinical research accessible to all communities through patient engagement and recruitment, clinical

trial delivery, and real-world evidence. CVS Health has data available for 100 million patients, multiple channels for outreach, and opportunities to empirically test the efficacy of these various channels and generate lessons for expanding the availability of clinical trials. With regard to trial delivery, CVS Health is building an integrated, decentralized model. Trials are delivered through HealthHUB outpatient clinics, virtual platforms, and at-home services. These trials rely on a network of principal investigators, including both external investigators at academic centers and in communities and internal CVS-employed investigators. The national scope of the effort requires centralization of key components.

Rachael Fleurence (NIH) offered an NIH perspective and shared an overview of Say Yes! Covid Test, a public health initiative to assess the efficacy and effectiveness of home-based COVID-19 testing. The COVID-19 public health emergency has given us a glimpse of how to do research better in every domain, from design and startup to technical infrastructure. The emergency has had some unique features: a shared sense of urgency, a large of amount of resources, a contracting mechanism, and a high level of interagency coordination. For "peacetime" trials and clinical research networks, administrative ramp-up can be accelerated, and we can formalize informal collaborations that emerged during the emergency, such as those between the NIH, the FDA, and the Centers for Disease Control and Prevention (CDC). The fragmented US data system poses a challenge to electronic follow-up, but it is imperative for increasing diversity in recruitment and expanding sites. Community engagement is critical but will be difficult with less funds and different priorities. Systems will revert to the status quo. The public health emergency has provided a window into what it will it take for systems to change, and large amounts of funding may not be enough.

Brad Hirsch (SignalPath/Verily) offered a technology perspective. Technology is critical but is only one part of the suite of solutions we need. Training during and after medical school is important, but we also need to examine the economics of clinical practice. First, we need to drive efficiency at sites to enable to more sites to participate. Technology can be key here for recruitment systems and regulatory systems, but sites lack resources. Second, we need to reimagine what it means to recruit, consent, and engage patients. Trust is a big concern. Engaging local leaders is key, but not just during recruitment. These relationships must be developed over the long term. Finally, data is not just about the EHR. A variety of companies are bringing together existing data sources, including data from outside the health care system, to help identify patients.

DISCUSSION

Cohost Harlan Krumholz facilitated the discussion. He asked what attendees believe are the best ways to use the DCRI Think Tanks to galvanize action.

Rob Califf observed that it will take momentum and particular leaders who are in a position to **change policy and funding**. Financial pressures are a large part of the answer. There is plenty of money in the system, but it is misallocated. Having clear expectations from the FDA is also important. Finally, institutions with large endowments can be instigators of change. Leaders

who are in a position to make big policy decisions can have a major impact on where the opportunities and the funding are.

Antonios Clapsis noted that **requirements and incentives** are powerful. Mandating or incentivizing volumes or mixes of patients in clinical trials would have an impact. We also face the challenge of grafting a clinical research system onto a health care system. How do we create a financial model that makes it easier for health care providers to engage in research and then make this happen at a large scale? Shari Ling (CMS) said it is worth asking what clinicians need to be focusing on, given their limited time. Attendees discussed the Merit-Based Incentive Payment System (MIPS) and other approaches to provide incentives to physicians for participating and disincentives for not participating. Coverage with evidence development was a big advance. Connecting payment to the need for more evidence can be a strong incentive for changing systems.

Richard Nkulikiyinka highlighted the need for **mentorship** of less experienced sites by more experienced sites. We have recognized that most patients are not asked to participate in research. One reason might be that they receive care at clinics that are not asked to participate.

Matt Roe suggested establishing a **public-private partnership** to develop diverse trial sites. IT would be a ready-made network that multiple companies could fund and create infrastructure around. Mandates and incentives could be built around using such a network.

Esther Krofah highlighted the need for **coordination by a federal government "quarterback."** Could an interagency initiative identify interagency collaboration and leadership as a priority and identify policy opportunities to make it happen? Rowena Dolor agreed with the analogy of a quarterback to run this kind of initiative.

WRAP-UP

Cohost Charlene Wong summarized the group's discussion into "culture wishes," "policy wishes," and "practice/operations wishes." Culture wishes include patient education, activated clinicians, trust, and mentorship. Policy wishes include experienced centers mentoring inexperienced centers; requirements and incentives related to the size and makeup of clinical trial populations; and development of new financial models and coordination at the federal level. Practice/operations wishes include several discussion items related to technology and the "clinical trials industrial complex." The group should make an effort to identify and prioritize specific needs in these categories and identify the leaders and actors who can advance these priorities.

Table. Attendees' "Do Wishes" Submitted After the DCRI Think Tank Session

What is your top DO WISH and who is responsible?	What is your second DO WISH and who is responsible?	What is your third DO WISH and who is responsible?
Establish a federal clinical trials coordinating body. Responsible: US Department of Health and Human Services	Publish a clinical trial deserts report annually. Responsible: NIH	Require postmarket studies to be conducted with representative populations. Responsible: FDA
Identify policies that would support a national system for conducting rapid research based on the RECOVERY trial on critical topics for the country, including generating data for underserved/vulnerable populations on these key topics. Responsible: Federal agencies	Integrate lessons learned from the pandemic and new successful approaches that leverage technology and community engagement (including examples shared during the Think Tank) into a national, integrated approach. Responsible: A blue ribbon panel to move this initiative forward with all interested stakeholders and parties.	Question what is not working in our current system that prevents a national system from emerging. We have the resources and the brain power in the United States to do this, so the barriers are structural. Responsible: Think Tank with representation from all stakeholders.
Quickly create a proposal for developing a prototype network of community practice trial sites among primary care practices in an underserved city or region of the United States organized by leading academic medical centers Responsible: Duke University (Dr Wong) and Yale University (Dr Krumholz)	Organize the Think Tanks advisory board members to review the proposal developed by Drs Wong and Krumholz; invite the pharmaceutical industry member companies to commit to providing seed funding to support the initiation of such a network to be available to all pharmaceutical companies and FDA and CMS to facilitate rapid access to available funding sources (such as the BAA application process) to match the seed funding provided by industry. Responsibility: The DCRI team	Ensure that FDA and CMS are seriously committed to organizing and implementing the community trial site network pilot project by committing resources to provide advice, facilitate access to funding sources, offer credit for MIPS reporting requirements for sites/practices that agree to participate, and provide other aligned incentives. Responsible: Think Tank advisory board members from FDA and CMS and their associated leadership colleagues at each organization

What is your top DO WISH and who is responsible?	What is your second DO WISH and who is responsible?	What is your third DO WISH and who is responsible?
Include mentoring of at least 1 research-naive or less experienced PI/site in sponsor contracts with a National Lead/Coordinating Investigator (NCI). The mentee PI/site would preferably be in a clinical trial desert and/or rural area. The NCI or the sponsor would collaborate on selection of the PI/site(s). Responsible: Sponsor study team in negotiation of NCI contracts.	Collaborate with industry to "sponsor" ICH/GCP training through scholarship programs directed to clinical trial deserts. Responsible: Industry sponsors will need to collaborate with training providers or authorities to set up a program. Honestly no idea where to begin this journey, but willing to raise it in my organization.	Large hospitals and academic institutions already participating in clinical trials must nominate and mentor a PI/site from their rural/community clinic system as part of the site feasibility and selection process. Responsible: For industry-sponsored studies, this will need to be addressed with site development teams and their contacts with these institutions. Industry sponsors can include this in site feasibility surveys when approaching sites.
Reauthorize AHRQ (or create an NIH primary care research office) to fund a coordinating/resource center and infrastructure support for community/rural practice-based research networks. These networks could more readily pivot to participate in NIH/industry-contracted research (public-private partnerships). Responsible: DHHS, NIH Common Fund/NCATs, AHRQ, and possibly industry. Need to invest in infrastructure in these under-resourced areas.	Increase funding allocated to projects that involve practice-based research networks or community partners. For example, an R01 award could increase the direct cost from $500,000 per year to up to $1 million per year to involve key community/rural partners. Also, allow flexibility in industry-funded studies to add extra costs for recruitment of community/rural clinics, mileage, and practice reimbursement. The model of "one milestone budget fits all sites" does not work; thus, there is low engagement of practice-based research networks to do industry research. Responsible: All study sponsors (federal, nonfederal, and industry).	Change the culture of community/rural patient populations and clinics to include "evidence-generating" research. They are more comfortable with "evidence-implementation" research. Communication outreach to allow community/rural populations understand the importance of participating in clinical studies and dispel the notion that they are "being experimented on" will be needed for successful implementation of trials in these hard-to-reach populations. Responsible: Partnership between scientific community (federal/industry) and community organizations.

What is your top DO WISH and who is responsible?	What is your second DO WISH and who is responsible?	What is your third DO WISH and who is responsible?
Build a more effective national network of networks in community settings; apply what can be learned from other nations. Responsible: CEAL, VA, international collaboration with EuroHeart.	Streamline training for community/nonacademic stakeholders. Responsible: Clinical research mentors/champions.	Digitize trial setup and conduct with remote/decentralized capabilities. Responsible: Collaborative sponsorship with tech health.
Develop and easily identify networks of care between academic centers and community care. Responsible: Health care system.	Develop mobile research units (CRA, investigator, sub-investigator, imaging) able to perform remote assessments. Responsible: Partnerships between all stakeholders/private initiatives.	Develop decentralized trials and registrational endpoints. Responsible: Partnerships.