Clinical Trial Strategies Fueled by Informatics Innovation Catalyze Translational Research
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Harris et al1 describe an innovative program fueled by informatics infrastructure from the Clinical and Translational Science Award (CTSA) program funded by the National Institutes of Health (NIH)'s National Center for Advancing Translational Science (NCATS). When the CTSA program was launched in 2006, 1 of its primary objectives was to increase accrual to clinical trials, particularly multicenter randomized clinical trials (mRCTs). This largest-ever NIH grant program (which has its own congressional line item, similar to the National Cancer Institute) is now in its 17th year of funding and has grown the CTSA network to more than 60 impactful translational sites.2 Seven years after the inception of the CTSA program, the program moved into the next phase—CTSA 2.0—which expanded clinical trials into the communities served by major academic health systems. The work described in Harris et al1 is illustrative of what can be accomplished with innovative informatics infrastructure and regulatory and governance domain experts when an NIH center funds a national need.

In the 6 years since its launch, the CTSA Trial Innovation Network (TIN), encompassing 3 Trial Innovation Centers and 1 Recruitment Innovation Center working with 60 CTSA institution program hubs has enhanced recruitment to mRCTs by "informing site selection, enhancing study design, streamlining trial initiation, and implementing decentralized approaches to trials."1 The TIN has accomplished this with innovative informatics tools, services, and rapid communication pathways, including: the Institutional Review Board Reliance Exchange,3 which is a web-based portal supporting single institutional review board documentation and coordination; electronic health record (EHR)-based identification and recruitment strategies enabled by the CTSA's research data warehouse requirements;4 ResearchMatch,5 which is a web-based portal recruitment registry to match potential participants with ongoing trials;1 and REDCap6—a web-based application that enables data capture for research studies that can be used for creating and deploying electronic consents and automatically transferring EHR data to trial databases. NCATS' vision for the CTSA program, which specifies that informatics is a required core activity, has fueled many of the successes of the TIN and the NIH's clinical and translational science enterprise in general.

Similar to the TIN, NCATS has supported several other high-impact initiatives fueled by innovative informatics approaches, such as the Evolve to Next-Gen Accrual to Clinical Trials (ENACT)7 and the National COVID Collaborative Cohort (N3C)8 and Leaf,9 which were notable developments from the NCATS Center for Data to Health (CD2H). Since 2016, Ken Gersing, MD, NCATS Director of Informatics, Division of Clinical Innovation, has overseen the programmatic direction of CD2H and other CTSA informatics initiatives.

Informatics initiatives, infrastructure, and resources have been critical in enabling mRCTs and other research to address public health emergencies like the opioid crisis and the COVID-19 pandemic. Aside from the NIH, other federal agencies have established clinical research and data networks, such as the Patient Centered Research Outcomes Research Institute's (PCORI's) Clinical Research Network (PCORNet).10 To prevent duplication of efforts, the NIH, PCORI, the US Centers for Disease Control and Prevention, the US Food and Drug Administration, and the US Department of Health and Human Services should link these pragmatic and therapeutic clinical trials networks so that they can synergize. Since informatics infrastructure like EHR recruitment via research data warehouses, ENACT, TIN, and REDCap have proven critical to these clinical trials initiatives, we must
ensure that we integrate rather than duplicate these valuable resources in other US Department of Health and Human Services programs.

Reusing deidentified EHRs on a national scale for clinical trials and in biomedical research in general has become increasingly important, and efforts to deemphasize the value of such data are unwarranted. Many COVID-19 research findings, for example, came from large-scale analyses of EHRs from multiple hospital systems conducted by N3C, ENACT, and PCORnet. Better sharing of EHRs will continue to motivate innovative collaborative research on aging, Alzheimer disease, cancer, and the opioid epidemic, as evidenced by recent requests for proposals from several federal funding agencies.

Programs such as the TIN will support the US in establishing a robust and stable infrastructure to ensure that transformative clinical trials are supported in the patient communities we serve. Importantly, when the next national or international public health crisis occurs, we will be able to share vital patient data across federal funding agencies and avoid the data silos that hampered our efforts during the COVID-19 pandemic. Both NCATS and PCORnet's clinical trial programs require informatics innovation as a core component, which has been essential to their success. Other NIH institutes and programs, such as the National Institute on Aging, the National Institute of Allergy and Infectious Disease, the Cancer Center Support Grant program of the National Cancer Institute, and the National Heart, Lung, and Blood Institute, would benefit from adopting and coordinating with NCATS and PCORnet's requirement for informatics innovation as a shared (core) service. Incorporating informatics innovation into these largest NIH agencies to create synergistic data sharing and data management shared services strategies would ensure similar national impact and innovation as NCATS's approach, as eloquently illustrated in Harris et al.1

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REFERENCES


