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Address for correspondence:

E. H. Morrato, DrPH MPH, Loyola University Chicago, 2160 South First Avenue – Bldg 120, Maywood, IL 60153, USA.
Email: EMorrato@luc.edu

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Scale-up of the Accrual to Clinical Trials (ACT) network across the Clinical and Translational Science Award Consortium: a mixed-methods evaluation of the first 18 months

Elaine H. Morrato^{1,2} , Lindsay A. Lennox¹, Elaina R. Sendro³, Anne L. Schuster¹, Harold A. Pincus⁴, Jennifer Humensky⁴, Gary S. Firestein⁵, Lee M. Nadler⁶, Robert Toto⁷ and Steven E. Reis⁸

¹Colorado Clinical and Translational Sciences Institute, University of Colorado Anschutz Medical Campus, Aurora, CO, USA; ²Institute for Translational Medicine, Loyola University Chicago, Chicago, IL, USA; ³The Chartis Group, Chicago, IL, USA; ⁴Irving Institute for Clinical and Translational Research, Columbia University, New York, NY, USA; ⁵Altman Clinical and Translational Research Institute, University of California San Diego, San Diego, CA, USA; ⁶Harvard Catalyst, Harvard University, Cambridge, MA, USA; ⁷Center for Translational Medicine, UT Southwestern, Dallas, TX, USA and ⁸Clinical and Translational Science Institute, University of Pittsburgh, Pittsburgh, PA, USA

Abstract

Introduction: The Clinical and Translational Science Award (CTSA) Program is a Consortium of nearly 60 academic medical research centers across the USA and a natural network for evaluating the spread and uptake of translational research innovation across the Consortium. **Methods:** Dissemination of the Accrual to Clinical Trials (ACT) Network, a federated clinical informatics data network for population-based cohort discovery, began January 2018 across the Consortium. Diffusion of innovation theory guided dissemination design and evaluation. Mixed-methods assessed the spread and uptake across the Consortium through July 1, 2019 (n = 48 CTSA). Methods included prospective time activity tracking (Kaplan–Meier curves), and survey and qualitative interviews. **Results:** Within 18 months, nearly 80% of CTSA had joined the data network and two-thirds of CTSA achieving technical readiness had initiated launch to local clinical investigators. Over 10,000 ACT Network queries are projected for 2019; and by 2020, nearly all CTSA will have joined the network. Median time-from-technical-readiness-to-local-launch was 154 days (interquartile range: 87–225 days). Quality improvement processes reduced time-to-launch by 35.2% (64 days, p = 0.0036). Lessons learned include: (1) conceptualize dissemination as two-stage adoption demonstrating value for both CTSA hub service providers and clinical investigators; (2) include institutional trial into dissemination strategies so CTSA hubs can refine internal workflows and gather local user feedback endorsement; (3) embrace designing-for-dissemination during technology development; and (4) sustain adaptive dissemination and customer relationship management to keep CTSA hubs and users engaged. **Conclusions:** Scale-up and spread of the ACT Network provides lessons learned for others disseminating innovation across the CTSA Consortium. The Network is primed for embedded implementation research.

Introduction

The Clinical and Translational Science Award (CTSA) Program is a Consortium of nearly 60 academic medical research centers across the USA funded by the National Center for Advancing Translational Science (NCATS) within the National Institutes of Health. Over \$500 million is spent annually to support the program's infrastructure and mission to accelerate the translation of clinical research into practice and to improve the health of Americans [1]. Individual CTSA Program hubs provide an integrated research and training environment for translational science and catalyze the development, demonstration, and dissemination of methods and technologies that improve research efficiency and ultimately the population impact of health innovation [2].

Multisite clinical trials play a critical role in the translation of medical innovation to practice. Efficient mechanisms for planning and completing multisite trials are major unsolved problems in translational medicine. One of NCATS' stated strategic goals is to “enable efficient clinical hypothesis generation and testing, facilitate participant recruitment for research, and enable straightforward cross-comparison of data sets” [3]. In response to this charge, the Accrual to Clinical Trials (ACT) Network was funded by NCATS to develop a federated clinical informatics data network of medical research sites across the CTSA Program Consortium [4]. The network aims to support participant accrual to multisite clinical trials by improving cohort discovery and trial design when inclusion and exclusion criteria and site selection are determined.

Through its “hub-and-spoke” structure, the CTSA Program Consortium provides a natural network for promoting the spread and uptake of new clinical and translational innovation and research methods to improve healthcare delivery and health outcomes [5]. As noted in the *NCATS Strategic Plan* [3]: “CTSA hubs are expected to develop and demonstrate solutions to translational roadblocks individually, as groups of hubs, or as a network whole; in all cases, dissemination of successful solutions throughout the network, and to the translational research community as a whole, is an explicit goal and expectation” [5]. Collaborative Innovation awards aim to financially support the dissemination of validated solutions developed at one hub to other hubs and to test innovations in different hub settings and adapt the innovations for further dissemination within and outside the CTSA Program Consortium [6]. To date, the science of dissemination across the Consortium – including, understanding factors affecting speed of diffusion and characteristics of CTSA hubs as institutional adopters and local disseminators of translational research innovation – has been understudied.

Dissemination of the ACT Network among CTSA Program hubs began January 2018. Its dissemination represents a natural experiment for understanding the diffusion and national scale-up and spread of a clinical informatics innovation among academic medical institutions in the USA. This paper focuses on lessons learned during the CTSA hub dissemination and adoption process. Our intent is to elucidate how we operationalized dissemination of the ACT Network and stimulate dialog on potentially effective models and strategies for other teams disseminating research innovation across the CTSA Program Consortium. In addition to presenting current-state learning, we identify areas for further study.

Materials and Methods

A comprehensive mixed-methods program evaluation was conducted to characterize the first 18 months of national dissemination of the ACT Network for the time period January 1, 2018–July 1, 2019.

Dissemination Product: The ACT Network

Fig. 1 shows the geographic reach of the CTSA hubs participating in the ACT Network. The ACT Network data platform is a HIPAA-compliant clinical informatics tool for clinical researchers to query de-identified electronic health record (EHR) data and iteratively explore and validate cohort feasibility in real time at their desktops [4]. Investigators can identify potential partners for multisite studies and support study feasibility for funding proposals and IRB submission. The network has created governance and regulatory frameworks and a common data model to harmonize EHR data across institutions.

The network uses widely adopted informatics tools: Informatics for Integrating Biology and the Beside (i2b2) data repositories linked by the Shared Health Research Information Network (SHRINE) platform [7,8]. SHRINE provides a federated query and response system that enables investigators to query EHR data housed in i2b2 repositories across multiple independent institutions [9,10]. For the ACT Network, new functionality in SHRINE was developed that supports a true hub and spoke network topology, eases network setup and management, enables a distributed data steward model, better error reporting for users, and improves administrative reporting.

Dissemination Audience: The CTSA Consortium and Local Clinical Investigators

The ACT Network is being disseminated in partnership with 57 CTSA hubs representing nearly 100% of the CTSA Program Consortium. Each CTSA hub serves a variety of academic clinical and translational researchers extending reach to 100s and 1,000s of investigators and research staff per hub.

Centralized Dissemination Responsibility: ACT Network Project Team

The ACT Network project team is a national multidisciplinary consortium comprised of 40 individuals representing 23 CTSA institutions and organized into 5 workgroups: Data Governance, Regulatory, Technology, Data Harmonization, and Dissemination and Evaluation (see Online Supplement for organizational structure). The Executive Committee includes work group leads (or co-leads), NCATS sponsorship, and a national project manager. The committee meets biweekly to share progress against annual tasks and milestones, to discuss cross-work group priorities, for example, technology rollouts or release of updated governance documentation.


The Dissemination and Evaluation workgroup meets weekly to discuss operational activities of the dissemination launch strategy in addition to the process for evaluating the ACT tool and its usage across the CTSA Consortium. A full-time communications profession (LL) and project management professional (ES) are dedicated to the project. This work group sought regular strategic input from a Dissemination Advisory Board comprised of experts in dissemination research and practice; marketing; and in pharmaceutical and health informatics commercialization (see Online Supplement).

De-Centralized Dissemination Responsibility: CTSA Hubs

The ACT Governance document prescribes local team roles, including site lead, site operations coordinator, data steward, and dissemination lead (see Online Supplement). Each CTSA hub received funding to technically configure a local i2b2 data instance and join the ACT-specific SHRINE network, that is, technical readiness for dissemination. Each hub then received \$25,000 annually to sustain their data node and support local outreach and user support.

Conceptual Framework

ACT launch and dissemination strategies were based on the PCORI Dissemination and Implementation Framework [11] and systematic application of diffusion of innovation theory for accelerating the adoption of biomedical interventions and technologies by individuals and institutions [12–16]. Diffusion theory rests on the established fact that people typically learn of innovations through mediated channels of communication but then turn to trusted or expert interpersonal sources for advice about whether to adopt or not. ACT dissemination was conceptualized as a two-stage adoption process. The first stage of dissemination and implementation is the acquisition and activation of CTSA hub sites (i.e., formation of the data network and dissemination “distribution channel”). The second stage is the acquisition and activation of local clinical investigators using the data network (i.e., network “customers” and “end users”). Table 1 summarizes assumptions and strategies to engage stakeholders and to actively accelerate



The ACT Network
Powered by NCATS CTSA Program

The ACT Network lets researchers explore and validate feasibility for clinical studies across the NCATS Clinical & Translational Science Award (CTSA) consortium, in real time, from their desktops. ACT is secure and HIPAA-compliant.

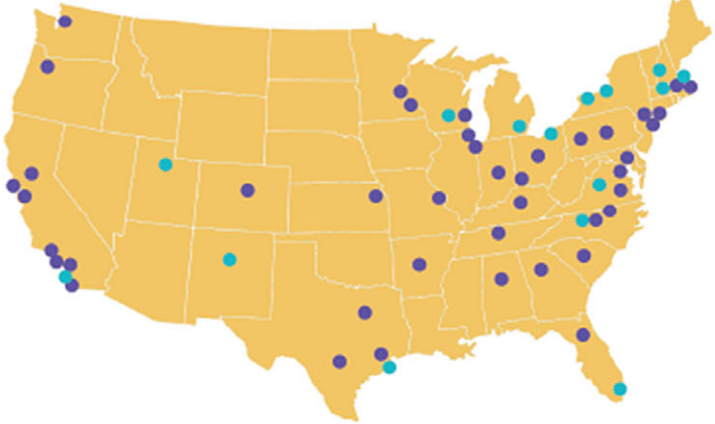
EXPLORE PATIENT POPULATIONS
Learn about your patient population in depth and in real time, from your desktop.

CHECK FEASIBILITY OF CLINICAL STUDIES
Iteratively test and refine inclusion and exclusion criteria to confirm the feasibility of your clinical study.

FIND PARTNER SITES
Search for patients across the CTSA network to identify potential partners for multi-site studies.

DEMONSTRATE FEASIBILITY
Access easy-to-download results for use in funding proposals and IRB submissions to demonstrate the feasibility of your clinical study.

125 MILLION PATIENTS
42 SITES CONNECTED
AND GROWING.



Connected to ACT:

- Boston University
- Children's National
- Columbia University
- Duke University
- Emory Univ./Morehouse Univ.
- Harvard University
- Indiana University
- Johns Hopkins University
- Mayo Clinic
- Medical College of Wisconsin
- Medical University of South Carolina
- New York University
- Northwestern University
- Ohio State University
- Oregon Health & Science University
- Pennsylvania State University
- Stanford University
- University of Alabama at Birmingham
- U. of Arkansas for Medical Sciences
- University of California, Davis
- University of California, Irvine

Staging for ACT:

- Case Western University
- Dartmouth College
- Scripps Research / Scripps Health
- Tufts University
- University at Buffalo
- University of Massachusetts
- University of Miami
- University of Michigan
- University of New Mexico
- University of Rochester
- University of Texas Medical Branch
- University of Utah
- University of Virginia
- University of Wisconsin-Madison
- Wake Forest University

- University of California, Los Angeles
- University of California, San Diego
- University of California, San Francisco
- Univ of Cincinnati/Cincinnati Children's
- Univ of Colo/Children's Hosp. Colorado
- University of Florida
- University of Illinois-Chicago
- University of Kansas
- University of Kentucky
- University of Minnesota
- University of North Carolina at Chapel Hill
- University of Pittsburgh
- University of Southern California
- UTHealth Houston
- UT Health San Antonio
- UT Southwestern
- University of Washington
- Vanderbilt University Medical Center
- Virginia Commonwealth Univ.
- Washington University In St. Louis
- Well Cornell Medicine

CONTACT

ACTNetwork@pitt.edu

ACCESS

www.ACTNetwork.us

Fig. 1. The ACT Network (as of July 1, 2019).

Table 1. The ACT Network dissemination strategy and hypotheses using diffusion of innovation theory as the conceptual framework

Diffusion element	Theory*	Working assumptions for the diffusion of the act network	Dissemination strategies to support adoption among CTSA sites
Innovation	Adoption occurs faster by <ul style="list-style-type: none"> Decreasing perceived complexity of the innovation Increasing compatibility with existing systems and workflows Providing mechanisms allowing for trial use Making adoption observable to other potential adopters Increasing perceived relative advantage versus status quo or other alternatives 	Local dissemination will require a team-based approach integrating activities between several CTSA leads and cores (i.e., clinical informatics, clinical study support, biostatistics research study design services, and communication and marketing), each with competing demands. Our grant financially supports clinical informatics technical readiness and maintenance. However, local CSA are generally not well resourced to develop dissemination messaging, materials, and training resources <i>de novo</i> for innovation coming from outside their institution. Each CTSA has a different comparative set of clinical informatics tools being used locally for cohort discovery. ACT's dissemination will be more successful if we target messaging to clinical investigator subgroups (i.e., customer segments) where there is the greatest unmet need and if we showcase use case scenarios demonstrating value in those research areas.	<ol style="list-style-type: none"> Decrease dissemination complexity by providing prepared messaging and adaptable communication materials and by launching a centrally maintained ACT Network website Increase compatibility with local CTSA workflows by initiating dissemination Quick Start planning calls with each CTSA team and by enabling locally facing co-branded versions of the ACT Network website Provide quick-start How-To videos on the website to promote trial use, individually and as part of local training activities Regularly communicate institutional adoption of the ACT Network by stage of adoption Participate in the I-Corps@NCATS program to conduct customer discovery interviews and refine ACT's value proposition positioning
Communication	Mass communication creates awareness and knowledge. Interpersonal communication is more effective in persuading individuals to change behavior (i.e., adopt new innovation). Transfer of ideas occurs faster among peers with shared professions, education, and/or social status.	Dissemination needs to be multi-channelled and needs to intentionally foster interpersonal communication between the ACT team and local CTSA dissemination members. Local communication needs to be adaptable in order to match individual CTSA communication norms and preferences. Local CSAs represent the natural peer-to-peer distribution channel to reach local clinical investigators because they have greater local reach and higher credibility than ACT's national dissemination team because of geographic proximity and shared institutional culture.	<ol style="list-style-type: none"> Use the monthly ACT Network and CLIC-CTSA newsletters to raise awareness and maintain knowledge about the ACT Network Use ACT Network technology workgroup meetings; dissemination Quick Start conference calls and follow-up email/phone support; and the annual i2b2 and SHRINE network face-to-face meetings to provide sufficient interpersonal interaction. Have each CTSA site be the primary disseminator to its local users using co-branded communication materials to promote peer-to-peer sharing within shared institutions
The individual adoption process	Voluntary adoption occurs in stages over time. Diffusion typically follows an S-shaped curve (i.e., a logistic function). For technologies, there is often a diffusion gap between early adopters (technology enthusiasts and visionaries) and the early majority (the pragmatists). Early technology adopters seek evidence of innovation and performance. Later adopters seek evidence of practical solutions that are proven to work.	ACT Network dissemination was not resourced to support achieving technical and dissemination readiness across all CTSA sites simultaneously. Speed of diffusion will follow the rhythm of the academic calendar year (semesters) and NIH grant submission cycle (three per year). We will need to measure and assess the adoption stages to identify opportunities for improving the process. Dissemination messaging, and key support points, will need to adapt over time to meet different informational needs of early adopters versus later majority of adopters.	<ol style="list-style-type: none"> Disseminate the ACT Network in a series of waves as CTSA sites achieve technical readiness. Establish metrics to evaluate adoption stages and to quantify the time-based diffusion process; identify opportunities for improvement Emphasize network characteristics and performance capabilities early in dissemination. Showcase successful use case stories later in dissemination. Promote other mechanisms for early CTSA sites to share practical and proven approaches for later-adopting CSAs.

(Continued)

Table 1. (Continued)

Diffusion element	Theory*	Working assumptions for the diffusion of the act network	Dissemination strategies to support adoption among CTSA sites
Social setting	<p>Individuals are more likely to adopt an innovation if more members of their personal network have adopted the innovation.</p> <p>Opinion leaders within social systems tend to be early adopters, especially if the system norms favor change.</p>	<p>The CTSA Consortium is a national academic medical research network that favors adoption of new clinical and translational research tools. Clinical data informatics is a priority area.</p> <p>CTSAs renew their funding every 5 years and are highly attuned to the priorities of NCATS, the funding agency. NCATS views cross-institutional collaborations favorably. However, the CTSA Consortium is a de-centralized network with local decisional autonomy. Although the dissemination of the ACT Network is funded by NCATS, participation is voluntary.</p> <p>Leaders of the Recruitment Innovation Centers (RICs), Trial Innovation Centers (TICs) and the National Center for Data to Health (CD2H) are informatics experts and opinion leaders external to the ACT Network team within the CTSA social system.</p>	<p>A. Seek endorsement of the ACT Network by NCATS leadership.</p> <p>B. Establish active presence at the annual CTSA Principle Investigators Meetings and regularly communicate dissemination progress (including the number of CTSAs participating) to the network of CTSA directors.</p> <p>C. Identify opportunities for shared partnerships with the Trial Innovation Network (RICs and TICs) and the CD2H initiative.</p>

*Adapted from Dearing et al [12]; Moore [14]; and Greenhalgh et al [15]

CTSA stands for Clinical Translational Science Award; NCATS for the National Center for Advancing Translational Science, National Institutes of Health

the dissemination and adoption of the ACT Network among CTSA hubs.

Dissemination Materials and Activities

Communication included mass media and interpersonal channels. For example, mass communication materials included a monthly newsletter, short quick-start training videos, and adaptable materials for use at the local CTSA level (e.g., sample messaging and graphics). A dissemination kickoff call with each CTSA hub team was held and the central ACT team served a customer relationship management role interacting frequently with hubs to support them through the dissemination planning process. Materials, including the website, were co-branded to promote peer-to-peer sharing within shared institutions.

Evaluation Methods

This evaluation reports on dissemination findings for sites participating in the network as of July 1, 2019 (n = 48 CTSA hubs) and summarizes learning for the first stage of adoption: acquisition and activation of CTSA hubs. Unless where noted, IRB approval was not required because the evaluation project was carried out as quality assurance and did not meet the definition of research per the Department of Health and Human Services regulations. Mixed-methods (grouped by diffusion element) were used to assess dissemination processes and quality of activities.

Adoption process

Dissemination team members (LL, EM) created an Excel database to track dates that local CTSA hubs or the central ACT Network team completed an adoption stage and/or dissemination milestone

activity. Stages of adoption were (1) Governance Agreement: Initiated; (2) Governance Agreement: Completed; (3) Technical Readiness: Initiated; (4) Technical Readiness: Completed, (5) Dissemination: Planning Initiated; (6) Dissemination: website/URL ready; and (7) Dissemination: Local Launch. Primary analysis focuses on the dissemination process (stages 4 and onward). The Online Supplement provides additional Kaplan–Meier curves that pertain to the adoption stages that preceded dissemination (stages 1–3).

Dissemination activity milestones included (a) date the central ACT dissemination team sent an email invitation to each CTSA site to initiate local dissemination planning; (b) date CTSA teams participated in a kickoff conference call; (c) date the ACT dissemination team sent each CTSA site a dissemination readiness checklist for the site to complete and return electronically; (d) date the CTSA site returned their completed dissemination readiness checklist; (e) date the ACT dissemination team delivered a website/URL to each CTSA site that allowed end user at that site to directly access the ACT Network; and (f) date the CTSA first launched the ACT Network, either locally or publicly.

Kaplan–Meier curves were used to analyze time intervals between date of email invitation to initiate local dissemination and date of first launch and for two dissemination subphases: (1) date of email invitation to date of the hub's kickoff conference call and (2) receipt of the dissemination readiness checklist to date a functional local website/URL was available for end users to access the ACT Network. The median number of days and interquartile range (IQR) were calculated for each curve. Fitted loglogistic curves were predicted and plotted for the data. For CTSA hubs that launched the ACT Network locally, a histogram was used to visualize the time relationship between the date a functional website/URL was ready and the date of first launch.

Data from the date-tracking spreadsheet were used to categorize and assess the duration of dissemination subactivities by locus of responsibility: centralized (national ACT Team); de-centralized (local CTSA hub); and parallel activity. Based on continuous process improvement feedback from CTSA hubs, adaptations were made to streamline and integrate dissemination readiness with technical readiness work processes. The log-rank test was used to compare Kaplan–Meier curves between sites launching using the original dissemination planning process (phase A) versus improved processes (phase B).

Stata/SE 14.2 was used for graphical display and descriptive analysis of the date-tracking data and for statistical comparison (College Station, TX: StataCorp LLC).

For purposes of understanding sites' experiences with ACT implementation, two evaluators (HAP, JH) conducted interviews with early institutional adopters of ACT. Interviews took place from December 2018 to April 2019. Semi-structured interviews took place by phone, which lasted approximately a half-hour. Interviews were audio-recorded and transcribed by a member of the research team. The Columbia University Institutional Review Board approved study activities. Transcripts were analyzed for common themes.

Communication

Mass communication evaluation included longitudinal tracking of open and click-through rates for the monthly ACT Newsletter and comparison to higher education and health professional industry averages reported by Constant Contact®. Frequency of interpersonal communication between the ACT Network dissemination team (LL) and each CTSA hub was tracked from date of technical readiness to date of first launch and categorized by channel: WebEx, telephone, email. Descriptive statistics were performed to estimate the median (IQR) email exchange rate per CTSA hub.

An internet-based survey was administered to the dissemination point person at each CTSA hub that had achieved local launch as of October 1, 2019 (77% response rate, 24 out of 33 CTSA hubs) to ascertain blinded feedback on ACT's dissemination approach and communication materials. Three questions were open-ended and responses were qualitatively analyzed for common themes. There was one six-part close-ended question asking respondents to indicate how much they agreed or disagreed (on a four-point scale ranging from strongly disagree to strongly agree) that each of six different dissemination elements were valuable to their site's local launch. An evaluator (AS) calculated mean scores and the number and percent of respondents who indicated that they "agreed" or "strongly agreed" that an element was valuable.

A dissemination team member (LL) solicited feedback from CTSA hub communicators during the September 19, 2019 CLIC (Center for Leading Innovation & Collaboration) Quarterly Communications call. The purpose of CLIC is to serve the CTSA Program through coordination, transparent communication and to make the work and accomplishments of the CTSA Program visible to all stakeholders. Open-ended questions included "how did you use the communication materials?"; "what are your thoughts about the customizable toolkit approach?"; and "what other tools or resources can help, when launching NCATS-funded innovation at individual CTSA hubs?" Notes were taken to record participants' responses and analyzed for common themes.

Innovation

In-depth interviews were conducted by dissemination team members (LL, EM) among a convenience sample of CTSA stakeholders

and clinical investigators to refine dissemination messaging and communication of the ACT Network's value proposition. Interviews were conducted as part of the 5-week I-Corps@NCATS training program (September–October 2018) hosted by the UC Davis Clinical and Translational Science Center [17]. Interview methods and questions followed the I-Corp™ customer discovery process and elicited understanding of the most critical jobs-to-be done by stakeholders and the greatest pains (problems) to be solved, and gains (motivations) to be achieved through cohort discovery [18,19]. Notes were taken to record participants' responses and analyzed for common themes.

Social setting

Activities engaging the CTSA Program Consortium at the system-level, for example, presentation at the CTSA Director meetings, were catalogued. NCATS communication to CTSA hubs concerning the ACT Network was monitored to assess messaging.

Results

Adoption Process

Fig. 2 presents the scale-up of the ACT Network among CTSA Programs by stage of dissemination (Fig. 2A) and the exponential growth in network queries over time (Fig. 2B). As of July 1, 2019, 41 CTSA hubs had achieved technical readiness, that is, gone live on the national production network. Among CTSA hubs achieving technical readiness, 66% (27 out of 41) had launched the tool to local users. The median time from technical readiness to local launch was 154 days (IQR: 87–225 days). Eight CTSA hubs were planning to disseminate the platform locally after the July 1, 2019 cutoff date. One CTSA decided to achieve technical readiness for multiple clinical data nodes at their hub before initiating local dissemination. Five CTSA hubs share clinical informatics data with the ACT Network but have deferred local dissemination given competing priorities and/or until evidence of utility (i.e., social proof).

Fig. 3 presents the time-based analysis of the dissemination process. Fig. 3A shows the Kaplan–Meier curve for the time from invitation to initiate local dissemination to date of the team kickoff conference call ($n = 40$ CTSA hubs). The median time to the kickoff conference call was 36 days (IQR: 21–49 days). Fig. 3B shows the Kaplan–Meier curve for the time from the date the dissemination readiness checklist was emailed to the site to the date the local website/URL was functional allowing end users to directly access the network ($n = 40$ CTSA hubs). The median time from checklist to dissemination readiness was 99 days (IQR: 57–188 days).

Fig. 3C is the histogram showing the time relationship between when the CTSA's website/URL was functional and the date when they first launched the ACT Network locally ($n = 27$ CTSA hubs). Nine CTSA hubs (33%) elected to soft-launch to local users prior to having the public-facing website functional. Soft-launch methods varied by CTSA and included piloting the network among a few target users to launching the network to internal CTSA support groups (mediators) that provide study design and recruitment services to clinical investigators. A minority of CTSA hubs (22%, 6 out of 27) initiated local dissemination via a broad launch to all membership.

Interviews with early-adopting CTSA sites (20 hub personnel at 9 institutions) elucidated training and technical support needs from data stewards and site operations team members. Most said

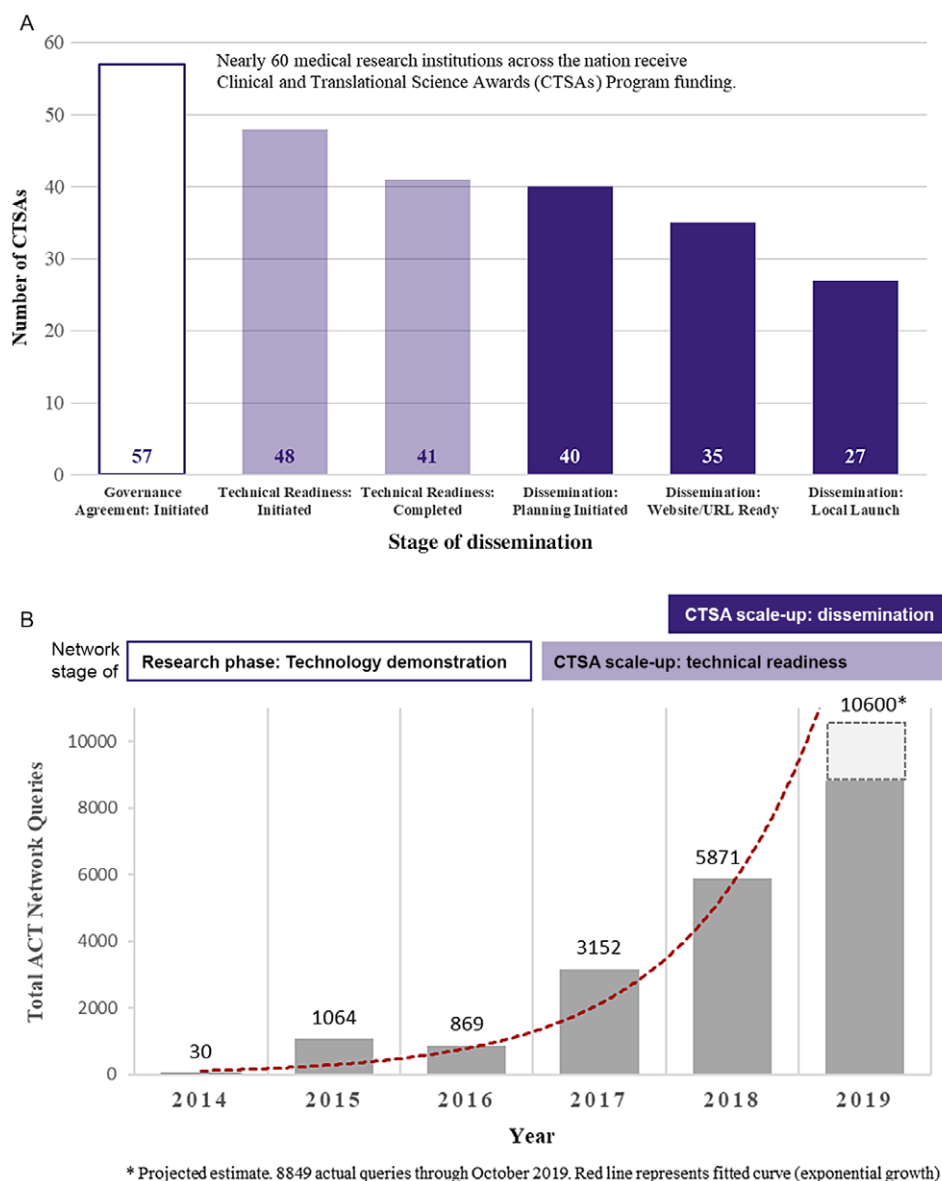


Fig. 2. Scale-up and spread of the ACT Network among CTSA Programs. A. Institutional adoption (number of CTSAs) by stage (as of July 1, 2019). B. ACT Network usage (number of queries) over time.

the technology was not difficult to learn with a minimal amount of training. For many,

The most helpful thing [about training] was getting to know the people in the project, to know who and introduce myself; so they have a face to go with ... building rapport. [clinical informatics professional, CTSA site]

Perceived need for training resources targeting clinical investigators varied by CTSA site.

When rolling out, we had researchers here look at it [some tech savvy and some not] and give us feedback to see if videos were appropriate and sufficient or if we needed to develop additional training. The feedback we got was that it was self-explanatory and didn't feel additional training necessary. [clinical informatics professional, CTSA site]

Yes, the i2b2 interface is simple and we have clinical data navigators who can help the researchers ... I still think it is important [to get training] on

how to do complex queries, otherwise [people may be] using system in immature ways. [clinical informatics professional, CTSA site]

Communication

In terms of mass communication, the ACT Newsletter has a membership list of over 500 individuals representing CTSA principle investigators, clinical informatics leads, ACT data stewards and site operations coordinators, marketing/communication professionals and other stakeholders. Engagement with newsletter content has been relatively strong given industry norms for this communication channel. Mean open and click-through rates (e.g., to access new training videos) were consistently higher than higher education and health professional industry averages (open rate: 36% vs. 22% and 18%, respectively; and click-through rate: 20% vs. 8% and 7%, respectively). Analysis of interpersonal dissemination

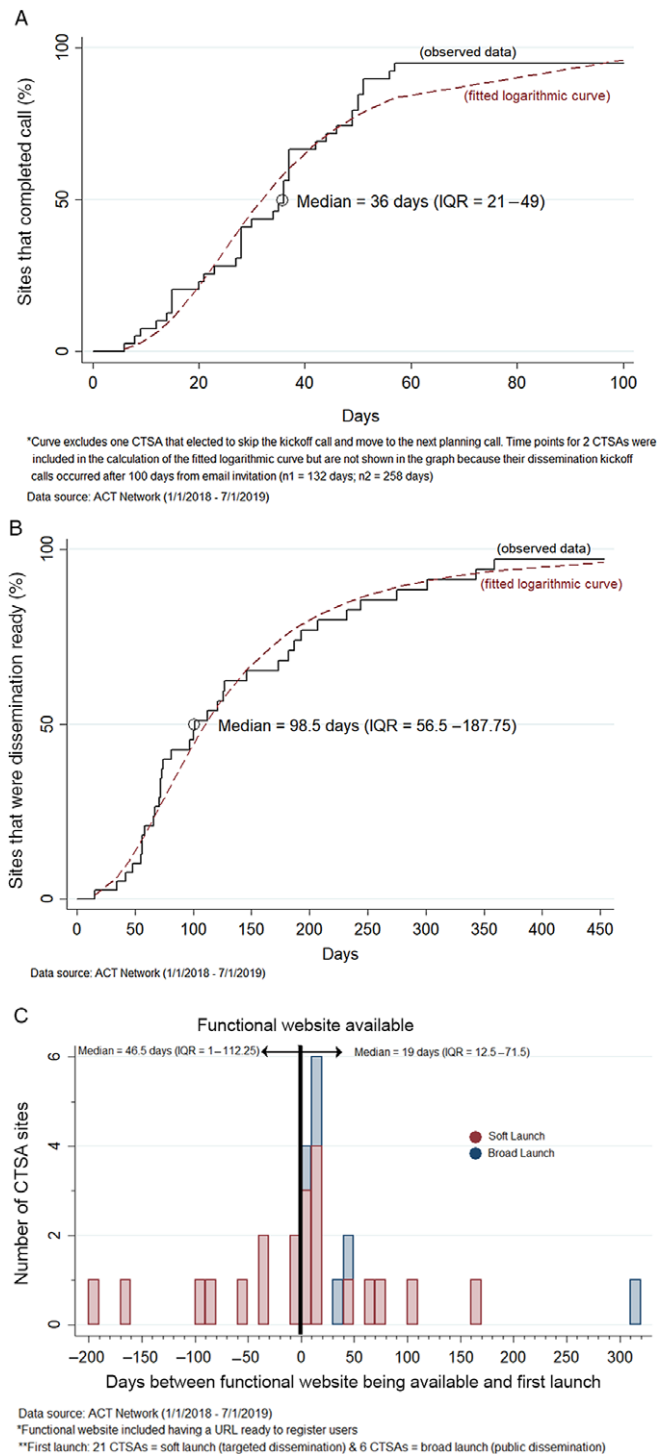


Fig. 3. Time-based analysis of three different stages of the ACT dissemination process. A. Time from the date the invitation to initiate local dissemination planning was emailed to the CTSA (following technical readiness) to the date of the team kickoff conference call (n = 40 CTSA). B. Time from the date the dissemination readiness checklist was emailed to the CTSA to the date the local website/URL was functional (dissemination ready) (n = 40 CTSA). C. Time between the date the local website/URL was functional and the date the CTSA launched the ACT Network locally (n = 27 CTSA).

communication between the national ACT dissemination team and the 27 CTSA Program hubs who achieved local launch averaged showed 1 WebEx team kickoff, 1–2 follow-up phone calls, and 29 (IQR: 24–39) email communications per site.

Fig. 4 shows the break down in time allocation on dissemination planning and preparation activities (points of interpersonal communication) between the local CTSA and national ACT team varied between CTSA hubs (n = 27 CTSA). Sites were stratified into two groups: before (n = 14) and after (n = 13) dissemination process improvement changes were implemented. Quality improvement efforts were associated with a 64-day (35.2%) reduction in median time to local launch: 118 days versus 182 days (p = 0.0036).

Table 2 summarizes survey feedback on the dissemination materials and approach used by the ACT Network. Overall, feedback on the dissemination process was positive. The items receiving consistently high value were the dissemination kickoff call, dissemination toolkit and co-branded, and centrally maintained local websites. Having dedicated support from the central team was critical. Areas for improvement focused on sustaining dissemination, including more training resources, success stories, and continued outreach strategies.

Feedback from the CLIC quarterly communicators call was similar in nature. Two illustrative quotes were

The materials were very helpful; the project manager *could have* developed these materials independently but ACT was 1 of 30 other initiatives/programs so having these launch materials helped move ACT up in the queue. Local response to ACT has been positive but slow. The kickoff call was very helpful and having a full-time ACT communicator to support the process seems essential for a national launch like this. [communications professional, CTSA site]

need testimonials/faculty champions to encourage use post-launch. [communications professional, CTSA site]

Innovation

Table 3 summarizes feedback obtained from customer discovery interviews (n = 35) to understand how best to message and demonstrate two-sided value to both CTSA hub partners (n = 13), clinical investigators (n = 17), and other stakeholders involved in academic clinical trial research (n = 5).

CTSA hub clinical trial support and service providers seek satisfied users of their services. For them, the ACT Network could provide a “first stop” where clinical investigators can either answer their own questions or become better prepared for a clinical trial service consult. Cohort discovery needs of clinical investigators varied by career stage. Early-career investigators felt the pain of increased institutional scrutiny on meeting patient accrual targets and timelines. For them, the ACT Network could provide a self-service platform for real-time credible estimates to guide decisions about designing or joining a study. Senior clinical investigators have an established track record and personal network for conducting cohort discovery, so this is a lower perceived need. Instead, the desire to be viewed as a good mentor was more salient and they did not want to be perceived as “out of touch” with technology. Based on these insights, we hypothesize that providing training to help early-career investigators use state-of-the-art clinical informatics tools responsibly (thereby alleviating the burden on individual senior investigators to provide this mentorship directly) would provide value.

Social Setting

NCATS publicly supported the ACT Network. The team was invited to present at the CTSA Principal Investigator (PI) Webinar and present in-person project updates at the 2018 and

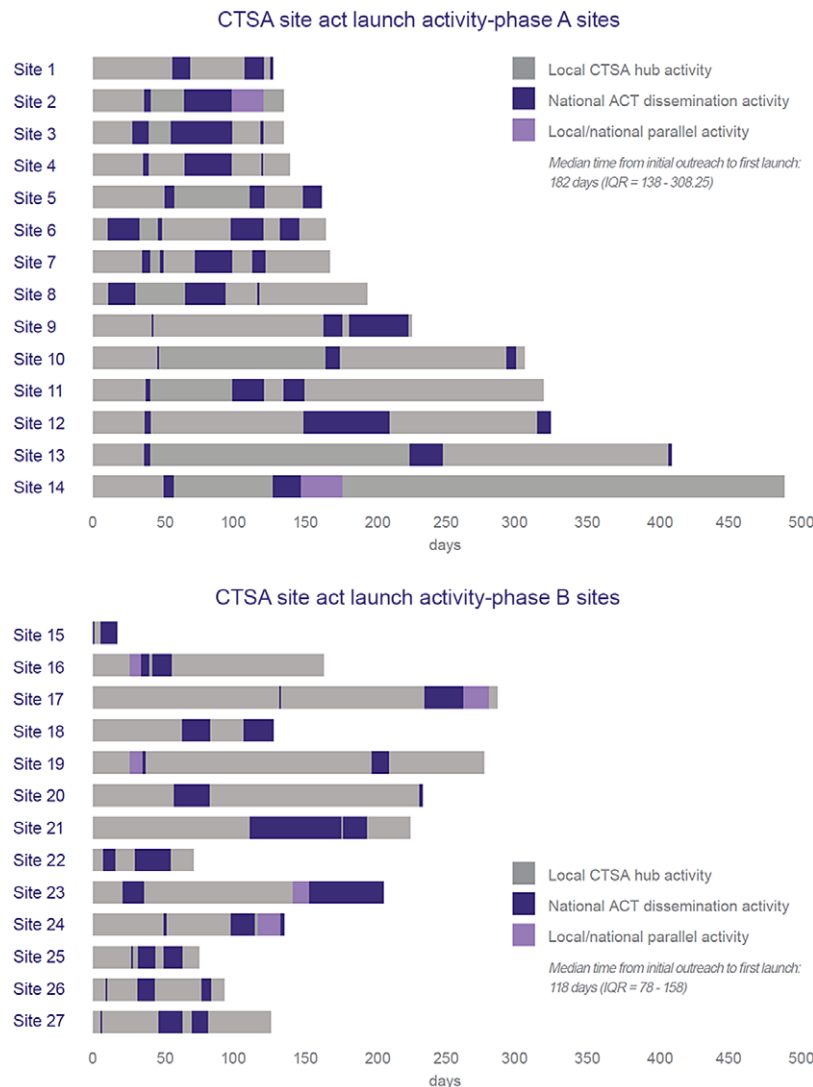


Fig. 4. Comparison of the duration and locus of responsibility for dissemination planning activities by CTSA hub achieving local launch (as of July 1, 2019) (data show duration of dissemination readiness activities for CTSA hubs that launched the ACT Network to local users ($n = 27$ CTSA sites)). Sites are listed in order of launch date. Bar length represents time from technical readiness to launch and is subdivided based on locus of activity: centralized (ACT Team) versus de-centralized (CTSA hub). Phase A used original dissemination readiness processes. Phase B used improved processes based on quality improvement feedback. In Phase A, all sites had the same technical readiness date and joined the production network in unison. In Phase B, sites had varying technical readiness dates).

2019 Fall and 2018 Spring CTSA Meetings reaching PIs and other CTSA hub leadership. At the 2018 Spring CTSA Meeting, the ACT team had a live demonstration table to showcase the platform. At the 2019 Spring CTSA Meeting, the ACT team presented at the Workforce Development Domain Task Force to seek feedback and explore the potential for adjacent value of the network for informatics training. The ACT Network dissemination team participates regularly in the quarterly CLIC-CTSA Communicators' meeting and is mentioned regularly in the monthly CLIC newsletter to CTSA Program leadership.

However, NCATS has messaged that network participation is optional. In an email to CTSA PIs and administrators in June 2018, NCATS stated that it "views the ACT Network project as an exciting and innovative experiment ... [however] NCATS is cognizant of the competing demands for hubs resources ... [and] wants to clarify that participation by the hubs in the ACT Network is voluntary ... and no criteria related to the participation in the ACT Network is used in the funding opportunity

announcement." As a result, some CTSA sites have stated "we want to be good citizens" but are unclear on the degree of local dissemination outreach that is expected by NCATS.

Discussion

The spread and uptake of the ACT Network demonstrates that the CTSA Program Consortium is an institutional network incentivized and primed to participate in the national dissemination and adoption of clinical and translational research innovation to improve healthcare delivery and health outcomes. Within 18 months, over 80% of the CTSA Consortium had joined the data network and two-thirds of CTSA sites that had achieved technical readiness reached the first phase of adoption by launching the network to local users. Over 10,000 ACT Network queries are projected for 2019; and by 2020, nearly all CTSA sites will have joined the network. The ACT Network adds to the armamentarium of NCATS-supported translational research tools adopted among

Table 2. CTSA site feedback on the dissemination and communication approach used by the ACT Network

ACT dissemination and communication approach		
<i>Thinking about the ACT dissemination approach, which elements did you LIKE MOST and would recommend for future dissemination of NCATS-supported innovation across the CTSA Consortium? [open-ended, unaided]</i>		
(10 mentions)	Dissemination Toolkit. “Samples of text”; “Templates”; “Supporting documentation . . . built ahead of time and allow for us to quickly customize and launch”; “Informational videos”	
(7 mentions)	Website. “Co-branded local ACT landing page”; “Website is maintained and updated by ACT”; “took some of the ‘heavy lifting’ off of the sites”	
(7 mentions)	Dissemination Process. “Kick off planning call”; “low effort for us, a clear process”	
(5 mentions)	Support. “Dedicated support from the central team”; “one contact”; “willingness to help”	
<i>Thinking about the ACT dissemination approach, which elements did you LIKE LEAST? Or what other dissemination materials or tools do you wish had been provided? [open-ended, unaided]</i>		
(5 mentions)	More Training Resources. “technical documentation”; “end-user training slides”; “[more] detailed tutorials”; “[support of] continuous education”	
(4 mentions)	More Dissemination Outreach Strategies. “More support/reminders for other outreach methods”; “more focus on digital tools . . . social media graphics, bite-size videos”	
(4 mentions)	Proven Evidence. “Successful launch plans”; “Success stories”; “real world examples”; “not straight forward to integrate ACT in with all the other local resources”	
(3 mentions)	Disliked Not Feeling Ready. “[not] enough pre-dissemination communication”; “we weren’t quite ready for dissemination”; “timeline was a challenge for us (we were short staffed)”	
How much do you agree or disagree with the following statement: “This element of the ACT dissemination approach was valuable during my site’s local launch and dissemination of ACT to end users. ” [strongly disagree (1); somewhat disagree (2); somewhat agree (3); strongly agree (4)]		
Dissemination element	Mean Score	Percent Agree, “somewhat” or “strongly” (n)
<i>Supporting mass communication activities</i>		
Templates, graphics, and suggested language for use in local emails, websites, and newsletters	3.54	91.2% (22)
Templates for co-branded flyers and info sheets	3.29	91.2% (22)
Customized local ACT website, co-branded with ACT and developed and maintained by ACT	3.33	87.5% (21)
ACT-branded flyers and information sheets	3.13	83.3% (20)
ACT video tutorials: ~3 min animated videos on topics like “Getting Oriented to ACT,” “Running ACT Queries,” “Interpreting and Using ACT Query Results,” and “Understanding the ACT Data Structure”	3.29	79.2% (19)
<i>Supporting interpersonal communication activities</i>		
Dissemination kickoff conference and additional planning phone calls as needed	3.45	100% (24)

Twenty-four CTSA respondents (77.4% survey response from among the 31 sites that have locally launched ACT through October 1, 2019)

CTSA hubs, namely, REDCap for data management, i2b2 informatics software, and SMART IRB Master Reliance Agreement enabling single IRB review [20–22]. To our knowledge, this is the first systematic evaluation of the diffusion process of a new translational research tool being actively disseminated across the CTSA Program Consortium of academic medical research centers.

Early dissemination findings are consistent with what diffusion theory predicted. We observed the classic S-shaped adoption

curves demonstrating that institutional adoption is a time-based process. In our case, timing appears consistent with academic quarterly and semester workflows and pace of new program implementation. As we gained experience and CTSA hub feedback, we improved our dissemination planning and quick-start processes reducing time-to-launch by 35% (approximately 2 months). Feedback from CTSA hub partners underscored the criticality of interpersonal communication, both with the central ACT

Table 3. Summary of customer discovery learning

	DISSEMINATION AUDIENCE for the ACT NETWORK (target customer)		
	DISTRIBUTION CHANNEL PARTNER	END USER: Academic Clinical Investigator	
	CTSA hub service providers	Early/mid-career investigator	Senior/established investigator
Jobs to be done	Provide high-value, cost-effective clinical study consulting services to local investigators Collaborate in cross-CTSA clinical informatics initiatives and networks	Get my local clinical research initiated (get funding) and get promoted	Conduct my high-impact R01 clinical research (maintain funding) Support and mentor early-career investigators. Influence on the adoption of new clinical research tools and solutions.
Pains to be solved: cohort discovery	Concerned about customer satisfaction of local researchers/CTSA members. Users often desire concierge service. However, CTSA have limited resources to provide the customized consulting services that they'd like to do. To optimize efficient use of available resources, want to triage users more to self-service platforms as the first step.	Higher perceived need and urgency. Feel pressure of increased institutional scrutiny on patient accrual. Weighing eligibility criteria trade-offs to balance scientific validity and feasibility needs. Want to form new multi-institutional collaborations, but hesitant about reaching out to unknown people. Weigh financial, time, and social costs benefits of joining "other people's trials."	Generally lower perceived need, especially for studying common conditions. Often already participating in research networks. Infrastructure in place for effective cohort discovery and patient accrual (even if labor-intensive). Greater perceived need for rarer conditions, studies with more complex eligibility criteria or in clinical areas new to the investigator.
Emotional gains to be achieved	Greater job satisfaction. Less work on basic tasks, more time on complex questions and consults ("the part of the job I enjoy most")	Seeking control. Prefer to get answers themselves, and sensitive to inaccuracy and bias in "guesstimating" patient cohorts. Seeking greater confidence in defending own study designs and knowing which trials to join, or not.	Seeking social standing as a good mentor. Aware of newer informatics tools for cohort discovery, even if they don't personally use them. May be skeptical of using electronic health record data for clinical research, but they don't want to be perceived as "out of touch" with technology.
Illustrative quotes	"A self-service tool has the advantage of making investigators more knowledgeable about their patient cohorts almost by stealth, [even if] they're just there to get data for their funding proposal."	"Our estimates are probably in the ballpark, but you don't want to base your entire R01 career on ballpark." "When I'm approaching potential collaborators, I want to do my homework and stand out."	"The last thing I need as a physician is another system to learn." "I don't even care that much about my own diagnostic coding. I'm just trying to get through the screens." (EHR data skepticism) "to do multi-site studies you need experience-based understanding of your population and a strong professional network." (can't just rely on informatics tools and skip these steps)
Targeted value proposition	... a "first stop" where clinical investigators can either answer their own questions or become prepared for a CTSA service consult better than my current concierge service model	... a self-service platform ("for when I'm ready to work on it") providing real-time credible estimates to guide decisions about designing or joining a study better than current methods of estimating.	... clinical informatics tools and training to help early-career investigators use state-of-the-art clinical informatics tools responsibly better than using technology on their own.

dissemination team and within CTSA hubs, in navigating the adoption process. Given competing priorities at the local CTSA hub level, the perceived value of reducing dissemination complexity (e.g., by including a kickoff planning call and dissemination readiness checklist; having a centrally supported website; and providing pre-developed messaging) was high and facilitated adoption. Efforts to support compatibility with local institutional systems (e.g., co-branded materials and websites) were also valued. Lastly, rapid institutional adoption was enabled by the CTSA Program's social system in which cross-institutional collaboration and adoption of clinical informatics innovation is incentivized.

The spread and uptake of the ACT Network is an example of real-world adaptive dissemination. To sustain CTSA implementation

and grow usage, the ACT Network is now moving beyond the first stage of CTSA institutional adoption to the next stage of dissemination and end user adoption and use. For this stage, demonstrating value and relative advantage for local users will be critical. The next wave of dissemination strategies are grounded in diffusion of innovation theory and based on CTSA hub partner feedback to date.

First, we are identifying success stories and seeking local faculty champions to demonstrate and provide the social proof of ACT's utility and value. This is a critical evidentiary need necessary for "crossing the chasm" in technology adoption as adoption moves from early adopter/visionaries motivated by being "first movers" motivated by the technology itself to early majority/pragmatists

who are motivated by “practicality” and evidence of utility [14]. In this context, it is important to show ACT’s value relative to a changing and dynamic competing alternative landscape, including other regional and national health data networks and technology solutions being used and adopted by CTSA Programs, such as PCORnet [23]), EPIC Slicer-Dicer tool and Cosmos Platform [24,25], TriNetX [26], and Leaf [27]. Selecting stories and messaging that are most relevant to early-career clinical investigators, the audience segment we have identified with the greatest perceived unmet need and readiness to adopt new informatics tools, appears warranted based on customer discovery insights. We are also exploring opportunities for providing adjacent value to meet other CTSA Program hub needs, such as developing and helping to spread platform-agnostic training and educational tools supporting cohort discovery. The i2b2 and SHRINE development teams are pursuing product upgrades to improve end user experience (i.e., further reduce perceived complexity). Lastly, as part of the CTSA Program social system, the ACT Network is building partnerships with other groups disseminating translational research innovation within the same ecosystem, such as, the CD2H (Clinical Data to Health) [28] and Trial Innovation Network [29,30] centers.

Based on our initial operational experience disseminating the ACT Network within the CTSA Program Consortium, we offer the following pragmatic considerations for others designing and planning for dissemination across the CTSA Consortium (see Box).

1. *Conceptualize dissemination as a two-stage adoption process.* This means demonstrating value and targeting dissemination strategies and materials for both CTSA hub service providers and clinical investigators. At the start of ACT dissemination, CTSA hubs had not planned how they would migrate from an informatics research team implementing ACT to a cross-disciplinary team disseminating ACT. To address this gap, we integrated dissemination readiness checklists earlier into the technical readiness process. Customer discovery, as taught in the I-Corps program [17,19] was also used to identify target segments and areas of most urgent unmet needs to focus value creation, including dissemination messaging. Ideally, designing-for-dissemination methods, such as I-Corps and the National Cancer Institute’s SPRINT program [31] should be embraced early to inform technology development and sustainability [32].
2. *Engineer-in CTSA hub trial into the dissemination strategy.* In retrospect, the strong preference by CTSA hubs to proceed with a “soft launch” of ACT before broad dissemination to local investigators is not unexpected given diffusion theory and “public beta testing” practices commonly used in the launch of software and digital technologies. Goals of trial included seeking feedback to refine internal workflows and to gather early user feedback and endorsement.
3. *Embrace adaptive dissemination and the tech start-up world’s “get-keep-grow” philosophy to customer relationship management [33].* In other words, sustained scale-up and spread is not “one and done” dissemination; instead, it requires continuous effort to keep CTSA hubs and users engaged. Dissemination must remain responsive to changing external environments and customer needs. As such, sustained activity should be anticipated and budgeted accordingly given high demand for interpersonal communication and outreach.

Box. Key considerations for disseminating innovation across the CTSA Consortium

1. **Conceptualize dissemination as a two-stage adoption process.** This means demonstrating value and targeting dissemination strategies and materials for both CTSA hubs (service providers) and clinical investigators (end users).
2. **Engineer-in CTSA hub trial into the dissemination strategy.** The goals of trial include seeking feedback to refine internal workflows and gathering early user feedback and endorsement. These practices reflect diffusion of innovation theory and “public beta testing” practices commonly used in the launch of software and digital technologies.
3. **Embrace adaptive dissemination and the tech start-up world’s “get-keep-grow” philosophy to customer relationship management.** In other words, sustained scale-up and spread is not “one and done” dissemination; instead, it requires continuous effort to keep CTSA hubs and users engaged.

The scale-up and spread of translational research tools and workforce development programs across the CTSA Program Consortium is ripe for further research to advance the science of adaptation and translation. Future research direction can include developing a CTSA-specific Adaptome [34] to describe and create a common data platform to systematically capture information about variations in the scale-up and spread of translational research innovation across CTSA institutions and contexts. This knowledge can guide translational research tool developers and the dissemination and implementation research communities engaged in the CTSA Program [35,36].

In addition, because the CTSA Program Consortium is a dynamic complex system, lessons learned from systems theory, and its application in healthcare [37] and public health [38], can also inform future research. This includes enabling a learning network by managing systems knowledge about scale-up, understanding the Consortium’s unique social networks, and developing methods for analyzing adoption behaviors and processes. The business-to-business (B2B) marketing literature is another relevant resource because it also focuses on the challenge of introducing new products-services into complex institutional entities involving multiple layers of decision-makers, adopters, and end users [39]. For example, we might conceptualize the ACT team as the “manufacturer,” the CTSA hub “institution” as the top-level adopter, and individual researchers as the ultimate “consumers/end users”; with this framing, the ACT Network has developed a “distribution channel” [40] with the CTSA hub “institution” acting as a “retail intermediary.”

In summary, we describe the initial dissemination experience of the ACT Network and encourage dialog on effective models and strategies for disseminating translational research innovation across the CTSA Program Consortium. Limitations of the evaluation should be noted. First, it represents one case experience and findings may not be generalizable.

Second, the scope of the evaluation focused on CTSA hub dissemination from the time point of technical readiness define as going live on the production network. Kaplan–Meier figures are

presented in the Online Supplement about the time-based analysis of the earlier stages of adoption: the governance agreement and technical readiness processes. The median time to complete (1) the governance agreement was 49 days (IQR: 23–134 days) and (2) technical readiness was 1,217 days (IQR: 1,126–1,217) for Phase A sites and was 477 days (IQR = 260–488) for Phase B sites. It should be noted, though, that the threefold increase in technical readiness for Phase A versus Phase B sites was affected by the fact that Phase A sites participated in early pilot development of the network, and there was a significant time lapse between NCATS proof-of-concept funding and dissemination funding when the production network was activated. Given the duration and variation in technical readiness timing, a root cause analysis would also be informative for accelerating the development and adoption of future informatics innovation. Further evaluation is also underway to understand the adoption process of clinical investigators and end users. Our aim is to leverage the Act Network as a learning collaboratory to advance the science of CTSA institutional uptake of innovation and improve its research efficiency and impact on health outcomes and healthcare delivery. The Network is primed for partnership-based embedded implementation research.

Supplementary material. To view supplementary material for this article, please visit <https://doi.org/10.1017/cts.2020.505>.

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