

**A Content Analysis of CTSA Websites: The Identification and Evaluation of CTSA
Program Hub Website Content Standards for Knowledge Management of NCATS
CTSA Program Goals and Initiatives.**

By

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Abstract

Between 2014 and 2018 the NIH has awarded \$2.2 billion to U.S. Academic Medical Centers to build a national network of clinical and translational science program hubs that serve to meet key goals and initiatives designed to effectively and efficiently move scientific discoveries from bench to bedside. In 2018 there were 58 Clinical and Translational Science Award (CTSA) institutions called program hubs. Each CTSA program hub has a corresponding website highlighting its CTSA centered programs and activities. These websites are a critical communication gateway to promote the funding sources goals and initiatives.

This original research evaluated the NIH funded Clinical and Translational Science Award (CTSA) program hub websites for content, navigability, and interactivity.

Four of the five NCATS goals are thoroughly and consistently represented among the CTSA Consortium with workforce development, patient and community engagement, and quality and efficiency of research being the top three. Informatics is thoroughly and consistently represented, but not always clearly identified on the home page. The most underrepresented goal is integration of special and underserved populations which was identified on only 60% of CTSA program hub websites.

The most common focus of the eight CTSA program initiatives is the Trial Innovation Network in CTSA program hub websites. The Smart IRB comes in a distant second. The remaining six initiatives are severely underrepresented.

The identification of these gaps among the CTSA program hubs presents an understanding of content management and website functionality among the consortium from 3 principal approaches. First it creates an understanding of CTSA program hub content alignment with its funding source goals and initiatives. Such an understanding presents an opportunity to promote ways to create a better aligned consortium with improved collaboration pathways by the funding source through program hub website content standards. Second, it creates an opportunity for program hubs to understand and respond to the messaging their websites are presenting as it relates to the funding source. Third, it provides an opportunity to identify specific program initiatives and goals the CTSA institutions independently chose to highlight which can open a dialog to the better understanding the value of the program initiatives as they relate to the needs of CTSA program hubs. Ultimately, CTSA websites through content alignment should lead to an improved user experience.

Chapter I

INTRODUCTION

Statement of Problem

Websites are a critical communication gateway for businesses, organizations and institutions. Higher education websites including academic medical centers rely heavily on websites for distance learning, interactivity among campuses, and stakeholder and community engagement. In this evolving web-based environment, website content and design are crucial for user engagement. Poorly developed websites can result in less than optimal interactivity among intended users while more mature websites have been found to positively influence visitor attention. [1] Literature relating to the evaluation of website content has been scarce.[2]

The purpose of this original research is to evaluate the National Institute of Health (NIH) funded Clinical and Translational Science Award (CTSA) program hub websites for content, navigability, and interactivity. The funding agency, leadership body, and program hub will benefit from CSTA institution website evaluations because this novel approach will reveal content management standards not previously understood or identified. This research will leverage the goals and initiatives developed by the CTSA's

leadership body, National Center for the Advancement of Translational Science (NCATS), by applying them as content variables in a customized website ranking system. The unique and novel integration of NCATS goals and initiatives within a website ranking system will create a landscape of content alignment levels between each CTSA program hub website and NCATS directives.

The CTSA program hub consortium consists of 58 diverse academic medical center translational science programs aligned by NIH funding to support the advancement of collaborative, efficient, and expedient basic science research that leads to effective clinical implementation. Since 2014, \$2.2 billion has been awarded to these hubs for this purpose. NCATS assesses the value of these awards through a set of common metrics relying predominantly on scientific productivity including, grant funding and publications. [3]

The effectiveness of this research as an innovative approach to award assessment is predicated upon the fact that it focuses on the foundational need to build and improve access to scientific discovery information and resources. Scientific discovery begins with a prerequisite of resources that foster research that include training, collaboration, funding, administrative support, data, technology, and research participants.[4] Providing researchers with the knowledge to acquire and leverage each of these components nurtures scientific productivity and along with it, scientific translation. In a digitally based environment, the optimal way for CTSA program hubs to disseminate valuable resources and information (content) related to scientific productivity is through a program hub website. Existing CTSA program hub websites reflect each institution's unique approach and contribution to translational science and the National CTSA Program.

The NCATS CTSA program provides little direction on website development or subsequent content management. Despite the substantial investment in CTSA program hubs, no systematic, comprehensive evaluation of their website hubs as content dissemination systems has been conducted thus far. Presently, no website development content standards exist. It is not known whether content in these websites represent the whole of the NCATS CTSA goals and program initiatives. It is also not known whether the websites that are representing the NCATS / CTSA goals and initiatives are effectively being presented by way of navigability, interactivity, and user support.[5]

Research Objective

The principle objective of this research is to demonstrate the utility of a content ranking system that leads to CTSA institutional website content management standards. These standards set up a foundation for the electronic dissemination of information and resources that are developed to empower users to promote translational scientific productivity. This research aims to:

- Develop a CTSA website content ranking system that effectively captures the components of its leadership body's goals and program initiatives and optimizes its presence in CTSA program hub website platforms.
- Evaluate CTSA program hub website content with the content ranking system across the 58 CTSA funded hub websites.
- Report the results of the CTSA website content evaluation and their implications.

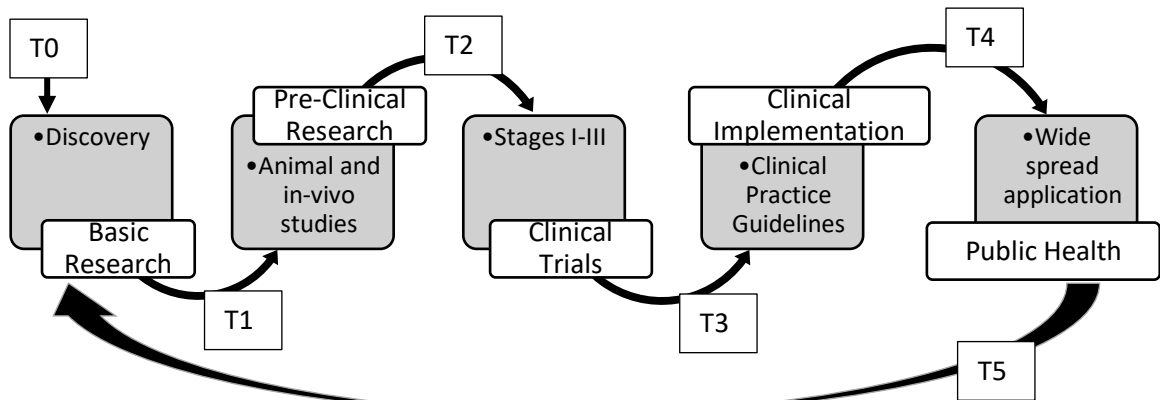
Background

Translational Science

Translational Science (TS) is the process of transforming biomedical research into improved health outcomes. [6]It involves a cross disciplinary movement of a biomedical hypothesis into a laboratory discovery and along a continuum of research development and human trial procedures. The goal of translational science is to have the results of human trials inform clinical practice on a nation or world-wide level. Clinical practice outcomes can then either support and implement the original findings (and lead to improved public health outcomes) or lead to unexpected outcomes that should ultimately re-inform basic science.

Formal translational phases link the 5 ascending stages of research, which are discovery, animal and in vivo, human trials, standards or practice guideline development, and public health outcomes. These linkage points are defined by “T” levels T0 - experience and discovery, T1 Basic Research to Pre-Clinical Research, T2 - Pre-Clinical Research to Clinical Trials, T3 Clinical Trials to Clinical Implementation, T4 Clinical Implementation to Public Health, T5 Public Health Applications to informing Basic Science. (See **Figure 1**. Translational Phases). [7]

Figure 1. Translational Phases



While T levels correspond with Clinical Trial Science phases, they are not always linear. Each of these T levels (T0-T5) requires: a qualified workforce, informatics tools (to assist in every phase of translation), laboratory facilities (to investigate the hypothesis), research data and analysis (that might lead to the support of that hypothesis), institutional capacity (to get the tested hypothesis approved for clinical trials and treatment), community support (to conduct robust human trials that will test the safety and efficacy of the hypothesis on humans), bio-statistical resources (to be able to validate the efficacy of the hypothesis), and the ability to disseminate the results of successful trials and report on unexpected events in treatment outcomes. It is for these reasons that translation of a treatment discovery from bench to bedside has been known to cost billions of dollars and take up to 14 years.[8] [9]

The above domains, being outside the expertise of a single biomedical researcher, are the backbone of translational science. By these definitions, translational science integrates a variety of experts, technologies, and resources.

CTSA Funding

The National Institute of Health (NIH) through the National Center for Advancing Translational Sciences (NCATS) distributes Clinical and Translational Science Awards (CTSA) to create institutional clinical and translational research program hubs at Academic Medical Centers (AMC). These hubs are funded not only to strengthen the capabilities of the awarded institutions, but to create translational science collaboration resources and pathways for award recipients as a consortium. The award is designated to (1) support collaboration in translational science; (2) improve efficiency of clinical translational research; and (3) develop and implement translational science training.[10] The 58 recipients are tasked to overcome systematic translational scientific barriers within the AMC model. Data interoperability, biomarker qualification processes, regulatory science, clinical research networks, patient recruitment, electronic health records for research, synchronized IRB's, clinical diagnostic criteria, clinical outcome criteria, adaptive clinical trial designs, reduced intervention adoption time, methodology for measuring intervention health impact, data transparency, project management integration, team science, health outcome improvement, education/training, and collaborative structures are identified by the NIH as such barriers.[10]

NCATS and the CTSA program

In 2013, the Institute of Medicine (IOM) reported a consensus study that provided recommendations on the suitability of the CTSA Program's mission and strategic goals and whether adjustments were necessary. [11] This report confirmed that the CTSA Program should lead the nation in advancing innovative and transformative clinical and translational research that improves human health. It also reported that the realization of

this premise required the CTSA Program to reshape its goals to reflect those the National Center for Advancing Translational Science (NCATS). [11] NCATS focuses on CTSA program goals and CTSA initiatives.

There are 5 structural NCATS goals for the CTSA funded institutions.

NCATS Goal #1.

The first goal is to train, cultivate and sustain the translational science workforce. One of the main barriers to improving the health outcomes is a shortage of qualified clinical and translational research (CTR) investigators.[11] Providing the resources that strengthen the future of the biomedical researchers is a key NCATS/CTSA program goal.[12]

NCATS Goal #2.

The second goal is to engage patients and communities in every phase of the translational process. Community engagement is considered a mechanism that increases research participation and reinforces the dissemination of findings to stakeholders. Including community engagement to NCATS / CTSA goals raises the profile of community engagement in biomedical research to improve translation.[13]

NCATS Goal #3.

The third goal is to promote the integration of special and underserved populations in translational research across the human lifespan. Underserved and special populations have access to too few primary care providers, high infant mortality, high poverty, shortages of primary medical, dental or mental healthcare. They can be groups

that face economic, cultural, or linguistic barriers to healthcare.[14] They can include, but are not limited to groups like Native Americans, migrant workers, children, prisoners, the elderly, and the homeless.[15] The rapidly changing environment in healthcare offers great challenges, especially to special and underserved populations.[16]

Translational science that includes special populations leads to an identification of differences in disease progression and treatment. NCATS designation of this topic as a goal reminds CTSA hubs that successful efforts to translate science include special and underserved populations. Program hub inclusion of this goal should intrinsically lead to quantifiable improved health outcomes for society as whole rather than overlooking those populations historically underserved. [17]

NCATS Goal #4

The fourth goal is to innovate processes that increase the quality and efficiency of translational research, particularly of multisite trials. The NIH looks to the CTSA Program to improve quality and build plans that ensure safe and ethical human subject research within study design, feasibility assessments, recruitment practices, timely closure of futile studies, research study workflow, analysis, and dissemination of results.[10]

NCATS Goals #5

The fifth goal is to advance the use of cutting-edge informatics. The NIH sees informatics as a high priority, all-encompassing role that leads to the transformation of translation at the CTSA Program hubs and nationally across the entire CTSA continuum. The NIH emphasizes that “informatics resources, support, expertise, training,

collaboration and innovation are critical to a successful translational research environment.”[10] The CTSA program hub website is the gateway informatics tool in the translational informatics tool-kit.

CTSA Program Initiatives

The National CTSA Program under NCATS direction has also developed 8 specific program initiatives for the awarded CTSA hubs. These initiatives focus on accelerating research agreements, accruing research participants, distributing awards for innovative collaborations, building common program evaluation metrics, supporting a program coordination center, building an informatics ecosystem, streamlining the IRB process, and promoting innovation in the clinical trial process. Each initiative is implemented by a specific title, tool, and or website.

ARA4US

The Accelerated Research Agreements website (<https://www.ara4us.org/>) is the first of 8 program initiatives highlighted on the National CTSA website. It is funded by the National Institutes of Health (NIH) Clinical and Translational Science Award (CTSA) program, grant (2U54TR000123). This initiative introduces accelerated research agreements acceptable to participating institutions that serve to expedite the study initiation process.[18] Turnaround times for clinical trial contract agreements are a crucial metric in the translation of research. Master agreements are a highly effective and successful strategy for significantly reducing the average time to complete contract terms. [19]

ACTS Network

The second of eight program initiatives is the Accrual to Clinical Trials Network (<http://www.actnetwork.us/national>). This initiative, known as the ACT Network, is a national network of sites that share electronic health record data in order to increase patient participation in high priority clinical trials.[20] It offers real-time network queries that provide aggregate counts of patients who meet clinical trial inclusion and exclusion criteria from participatory CTSA program hubs. [19]

Collaborative Innovation Suite of Awards (CCIA)

The third CTSA program initiative is the Collaborative Innovation Suite of Awards (CCIA). These awards stimulate team-based research across the CTSA Program.[21] The CCIA projects receive CTSA Program funding through two funding opportunity announcements: (1) The PAR-15-172 Collaborative Innovation Award (U01) which is designed to stimulate innovative research among the CTSA continuum program hubs, and (2) The PAR-16-343 is a limited competition of the CCIA which is designed to capture the utility and feasibility of the proposed innovation.[19] The CCIA's are intended to foster investigator-initiated research collaboration by encouraging teams from three or more CTSA Program hubs to work together to develop, demonstrate and disseminate innovative, experimental approaches that overcome translational science roadblocks.

Center for Leading Innovation and Collaboration (CLIC)

The fourth program initiative is the Center for Leading Innovation and Collaboration (CLIC). Operation of the program is awarded to a specific CTSA program hub. As of 2019, CLIC operates out of the University of Rochester. CLIC provides

support to the CTSA Program and its institutional hubs through coordination, transparent communication, actionable metrics, network analytics and innovative collaboration tools. It also looks to highlight the efforts and accomplishments of the CTSA Program to all stakeholders.[19]

Common Metrics

The fifth CTSA program initiative is the Common Metrics initiative (CM) which falls within CLIC's purview. While NCATS developed and implemented a set of common metrics for use by the CTSA Program hubs as a tool for collaborative strategic management, CLIC is the program that runs it. The Common Metrics initiative (CM) aims to capture data related to important functions and activities of the CTSA Program.[19] The CM implements and reports on specific metrics that are common across all CTSA hubs.[22] Common metrics thus far relate primarily to scientific productivity such as scholarly publications and KL2 and TL1 funding.

National Center for Data to Health (CD2H)

The sixth identified CTSA program initiative is the National Center for Data to Health (CD2H). CD2H supports the informatics ecosystem needed for CTSA functionality. It identifies translational science challenges consortium-wide then builds and implements solutions that include informatics infrastructure and community integration.[19]

Smart IRB

The seventh CTSA program initiative is the SMART IRB platform (<https://smartirb.org/>). In 2016, the NIH released its final policy on the use of a single

Institutional Review Board (IRB) for multi-site research. The purpose of the policy was to restructure the IRB review process involving multi-site research to be more effective and expedient. Funded by NCATS and supported by the CTSA program, SMART IRB is a web-based platform designed to ease common challenges associated with initiating multisite research. [19]

Trial Innovation Network

The eighth initiative is a web-based platform called the Trial Innovation Network (TIN) (<https://trialinnovationnetwork.org/>). It is a clinical trial collaboration opportunity. It offers pathways to efficiently complete clinical trials by combining Trial Innovation Centers (TIC) and one Recruitment Innovation Center (RIC). The TIN is designed to leverage the expertise and resources of the CTSA Program. It connects investigators to the other CTSA hubs and program initiatives including SMART IRB, ARA4US, and the ACT Network.[19]

Each of the NCATS goals and CTSA program initiatives are expected to be implemented to make the CTSA funding program a success in its efforts to translate discoveries in to successful clinical outcomes. A focus on these goals is also expected strengthen the CTSA network capacity.

Content regarding the NCATS goals and CTSA program initiatives are highlighted and promoted on both the NCATS website (<https://ncats.nih.gov/ctsa>) and the National CTSA Program website (<https://ctsa.ncats.nih.gov/>). The institutional CTSA program hub websites, as representatives of the awards, have the virtual infrastructure for further dissemination of the five NCATS goals and eight program initiatives. Individually

the institutional program hubs also have the opportunity to present their unique approach to understanding and implementing them. It is unknown whether the CTSA program hub websites are being developed along these lines. No research exists to define the specific content elements that constitute effective CTSA program hub website design and NCATS goals and initiatives.

Website Value in Translational Science Informatics

Informatics plays a vital role in the translation of research. Modern informatics methodologies and techniques support the continuum of clinical and translational research. While informatics in translation can be as complex as building algorithms to genomic datasets that help hypothesis generation[23][24], or aligning Electronic Health Record (EHR) data in order to create patient registries and clinical data repositories [25][26], its role in basic knowledge management and information retrieval is also valuable to researchers and institutions.[27]

The CTSA Informatics Domain Task Force has identified six informatics goals for improving clinical and translational science. The first is to create a diverse data ecosystem. The second is to enhance informatics training. The third is to support research networking to access experts. The fourth is to ensure interoperability of digital assets. The fifth is to facilitate the innovation of informatics technology. The final goal is to support the CTSA consortium-wide initiatives for multi-site clinical trials.[28]

Funding has insured the CTSA institutions have a variety of informatics resources for researchers and the consortium, but the collection, storage and presentation of these resources can make a difference to translational science end users. The frontline of translational science for every CTSA is predicated upon the presentation and access to

clinical and translational science services and tools. Websites are an informatics tool vital to presentation and access to clinical and translational services and tools.

A Snapshot of CTSA Program Hub Websites

CTSA institutional program hub websites presently provide a variety of information and resources that help facilitate NCATS goals. CTSA program hub websites generally disseminate information and tools on topics ranging from training, collaboration, and community outreach to research methods and biomedical informatics. Information within these CTSA websites has been leveraged to conduct research into CTSA content, capabilities and characteristics both on an institutional level and consortium level.[2–5] While research is being conducted using content culled from the websites as a data source, there are no CTSA website development protocols or direction in funding applications, NCATS goals or CTSA initiatives that look to ensure all the program hubs are presenting the data that is being identified.[10][29][29]

As a mean to this knowledge management end, each member of the CTSA consortium present a website as an information arm of their program hub. These websites provide valuable infrastructure, programs, and resources supporting translational science.[30] Each CTSA Hub delivers an array of components to areas of research expertise, including: informatics tools, training, biostatistics, clinical trial design, funding assistance, and community engagement. Since CTSA Institutions gain valuable input from NIH and other federal agencies, industry, and private and community organizations they are also expected to use their hubs to share its own resources and information with researchers, community partners, students, other CTSA institutions, and NCATS

counterparts.[31] NCATS makes a strong point to address the purpose of hubs to provide links to one another:

“Under NCATS’ leadership, the Clinical and Translational Science Awards (CTSA) Program supports a national network of medical research institutions — called [hubs](#) — that work together to improve the translational research process to get more treatments to more patients more quickly. The hubs collaborate locally and regionally to catalyze innovation in training, research tools and processes.”[32]

While a CTSA program hub represents the Clinical and Translational program at each AMC, the primary method of presentation for CTSA institutions is through the virtual representation of the CTSA Website. The website is the AMC’s virtual CTSA hub designed with the intent to highlight the sponsored institution’s clinical and translational research program strengths while also offering access to its unique brand of tools and resources. Website designs among the CTSA recipients are heterogeneous in nature. In an informal cross-sectional sampling of 20 of the 58 CTSA Websites conducted for background purposes of this research, a variety of themes and access priorities existed. (See: **Table 1.** Snapshot of CTSA Hub Designs by Theme) Websites (among the 20 sites preliminarily investigated) highlighted themes such as: (1) Researcher Goals, (2) Program Offerings (3) Faculty Achievement (4) Upcoming Events, (5) Clinical and Translational Research Roadmaps, (6) Program Successes and (7) Student Recruitment. Throughout the spectrum of website hubs reviewed, at least one of each of the

components of the NCATS / CTSA objectives (cultivate and train a TS workforce, engage patient communities, promote integration of the underserved patient, innovate processes, advance the use of cutting-edge informatics) were addressed in each of the 20 sites searched. There were indications of information consistency. Although all the sites offered access to informatics tools, the sites themselves did not always make that access seamless. For example, informatics was listed on the main toolbar for only 1 of the 20 sites while 4 offered a portal to informatics through “resources”, 6 offered a portal to informatics through “services”, and 1 offered a portal to informatics through “resources and services.”

This heterogeneity in websites serves to fill any clinical and translational research gaps on the consortium level but ensuring the thoroughness of a single website as an independent comprehensive clinical and translational informatics tool is important. CTSA program hub websites present vast resource opportunities to clinical and translational research and should therefore be evaluated under a set of common standards and assessed through general website scoring system designed to inform the CTSA program hubs and the funding institution on strengths, limitations.

Table 1. Snapshot of CTSA Hub Designs by Theme

CTSA Program Hub	HUB Introductory Theme	Tool Bar Topic 1	Tool Bar Topic 2
<i>CTSA hub 1</i>	Assist in Researcher Goals	Research Commons	Training Academy
<i>CTSA hub 2</i>	Highlights Program Offerings	About	Services
<i>CTSA hub 3</i>	Staff Working	About	Translational Research
<i>CTSA hub 4</i>	Program Highlights	Home	Research Services and Tools
<i>CTSA hub 5</i>	Informative	Home	Researcher Resources
<i>CTSA hub 6</i>	Quick Links	Research	Researcher Resources
<i>CTSA hub 7</i>	Building Research Teams	Home	CTSC Programs
<i>CTSA hub 8</i>	Faculty Highlights	Home	About Us
<i>CTSA hub 9</i>	Faculty Highlights	Home	About
<i>CTSA hub 10</i>	Promotional Message	Our Work	Programs
<i>CTSA hub 11</i>	Tiled portals	Home	Program and Services
<i>CTSA hub 12</i>	Varied Messaging	About Us	Clinical Trials
<i>CTSA hub 13</i>	Events	About	For Researchers
<i>CTSA hub 14</i>	Student Recruitment	Home	Community
<i>CTSA hub 15</i>	Varied Messaging	About	Research Services
<i>CTSA hub 16</i>	Clinical Research Roadmap	Home	Request
<i>CTSA hub 17</i>	Varied Messaging	What we do	News and Events
<i>CTSA hub 18</i>	Asking for help	About	Center Programs
<i>CTSA hub 19</i>	Varied Messaging	Home	About
<i>CTSA hub 20</i>	Directory Search	About	Services

Website Scoring Tools

Health information website scoring tools generally focus on a set of general principles. Principles considered by medical library resources include authorship, accuracy, currency, coverage, design, referral to other resources, purpose, audience value of content and navigation as essential items in their online publication regarding evaluating internet resources.[33] User engagement strategies in website design most often focus on are navigation, graphical representation, organization, interactivity and design, content utility, purpose, simplicity, and readability[34]. But recommendations in website design for engagement strategies also require the consideration of the unique needs of the organization [29] [5].

This research focuses on three specific principles of web evaluation: *content utility, interactivity and design*, and *navigability*. An evaluation of CTSA websites based on “content utility” determines: whether information exists to attract the intended users, whether that information is current and whether the content is relevant to the purpose of the website. [34] Appraising the CTSA websites on “interactivity and design” addresses the user’s ability to engage with the website and explore the content through a variety of interactions. It also includes the user’s ability to access tools to that enable them to comment or ask questions. [35] Looking at the CTSA websites based on “navigability” addresses ease of access to content such as determining how many clicks information is located from the point of the home page.[5] These three website scoring concepts are specifically related to alignment with the funding goals and program initiatives. They are included in this research to help to create minimum common standards for CTSA program hub website evaluations.

Need for Study

The CTSA program hub websites serve as an information repository for a multi-billion-dollar funding program by the National Institute of Health. NIH funding implies that the information contained in these websites should distribute content that supports a diverse audience including students, researchers, primary investigators, other CTSA program hubs, the local community, and even special and underserved populations. A better understanding of program hub website content can pinpoint funding successes and identify innovative approaches to NCATS goals and CTSA program initiatives. It can identify the goals and programs most highlighted among the consortium. It can also identify those overlooked by the consortium. Such information can inform of the direction and needs on both the program hub level and the consortium level.

This type of evaluation requires a ranking system to fairly assess the content without placing too much burden on the program hub. It needs to provide room for heterogeneity while focusing on a set of content standards that should be met across the consortium.

Such a ranking system can also serve as the foundation for CTSA program hub website development guidelines. Before research into the use of CTSA program hub website content as an indicator of its hub overall practices, resources, functions, or capabilities can be considered robust, a content analysis of the knowledge management in the existing CTSA program hub websites is necessary.

Purpose

To conduct a content analysis of CTSA program hub websites designed to determine how information diversity and accessibility align with NCATS / CTSA goals and program initiatives that can generate a ranking system that presents a comprehensive understanding of hub alignment with funding agency goals and program initiatives.

Chapter II

REVIEW OF RELATED LITERATURE

Rational for a Review of Related Literature

This literature review will identify any existing literature that uses Clinical and Translational Science Award (CTSA) program hub website content to assess or promote NCATS CTSA Program Goals. The CTSA program hub websites are public digital gateways to CTSA institutional hubs for researchers, collaborators, administrators, and the community. Understanding website functionality and its potential ensures NIH investment in translational science is being leveraged at every opportunity by CTSA funding recipients.

Literature Review Objective

The objective of this literature review was to identify and evaluate published research articles that highlight the use of CTSA institutional websites as a research tool or data source for translational science research.

Literature Review Methods

Inclusion and Exclusion Criteria

All U.S. based studies and reports from 2006 through the present that addressed the use of websites of individual CTSA Institutions in their research or as a tool to promote or address translational science issues were included in this review.

Since the CTSA began in 2006, material dated prior to 2006 was excluded from the search process for the literature review but was considered for background information. Translational research articles that did not involve a CTSA component as a major subject in the publication were also excluded. Articles that did not address the use of a CTSA website were also excluded from this review.

Literature Search Methodology

A multifaceted search was engaged for this literature review process that included 4 search stages.

Search Stage 1

Stage 1 included a review of PubMed, Science Direct, and Cochrane Library accessed through the Rutgers University Library. This search used a combination of search terms, qualified as “All Fields”, using Boolean operators in PubMed, Cochrane Library, ScienceDirect databases advanced search tools. The goal was to generate broad results. The search equation used the following combination of terms and Boolean Operators (CTSA OR “Clinical and Translational Science Awards”) AND (website OR “web site” OR “web sites”).

The following search syntax was used to align with the search equation:

1. “Clinical and Translational Science Awards” [All Fields]
2. CTSA [All Fields]
3. #1 OR #2
4. website [All Fields]
5. “web site” [All Fields]
6. “web sites” [All Fields]
7. #4 OR #5 or #6
8. #3 AND #7

This search generated twenty-seven ($n=27$) results. Five studies were identified through the PubMed search ($n = 5$); Two additional studies were identified through a Science Direct search ($n = 2$). Twenty more studies were identified through a Cochrane Library Database search ($n = 20$).

Search Stage 2

The Stage 2 search included a pearl growing technique [36] that followed the Stage 1 search process to assist in identification of additional topic specific records. The pearl growing process used the top five (5) best matched articles from Stage 1. Each of the 5 articles were investigated for additional articles using supplemental database functionalities including “related articles”, “relevant articles” or “cited by” articles. An additional 6 articles were identified through this pearl growing method.

Search Stage 3

Stage 3 included a web-based search of the NCATS (<https://ncats.nih.gov/ctsa> and <https://ncats.nih.gov/ctsa/about/hubs>) and CTSA (<https://ctsacentral.org/>)¹ websites to identify potential records or related reports. No articles were identified through this method.

Search Stage 4

Stage 4 included targeted journal searches in the *Journal of Clinical and Translational Science*, *Journal of American Medical Informatics Association*, and *SAGE Journals* databases using the referenced search equation [(“CTSA” OR “Clinical and Translational Science Awards”) AND (website OR “web site” OR “websites”)]. An additional 95 articles were identified.

Intermittent searches for the purposes of updating records were conducted on a monthly basis with the final search performed in early October 2018. The primary search period was from November 2017 through January 2018.

Literature Search Results

Publication titles were reviewed from the multifaceted search (number of articles identified $n = 128$) for inclusion and exclusion criteria. Articles were imported into Mendeley (Bibliographic Software) including, available PDF's, abstracts, database, and date imported. Mendeley identified three ($n=8$) duplicates or non-full text records from

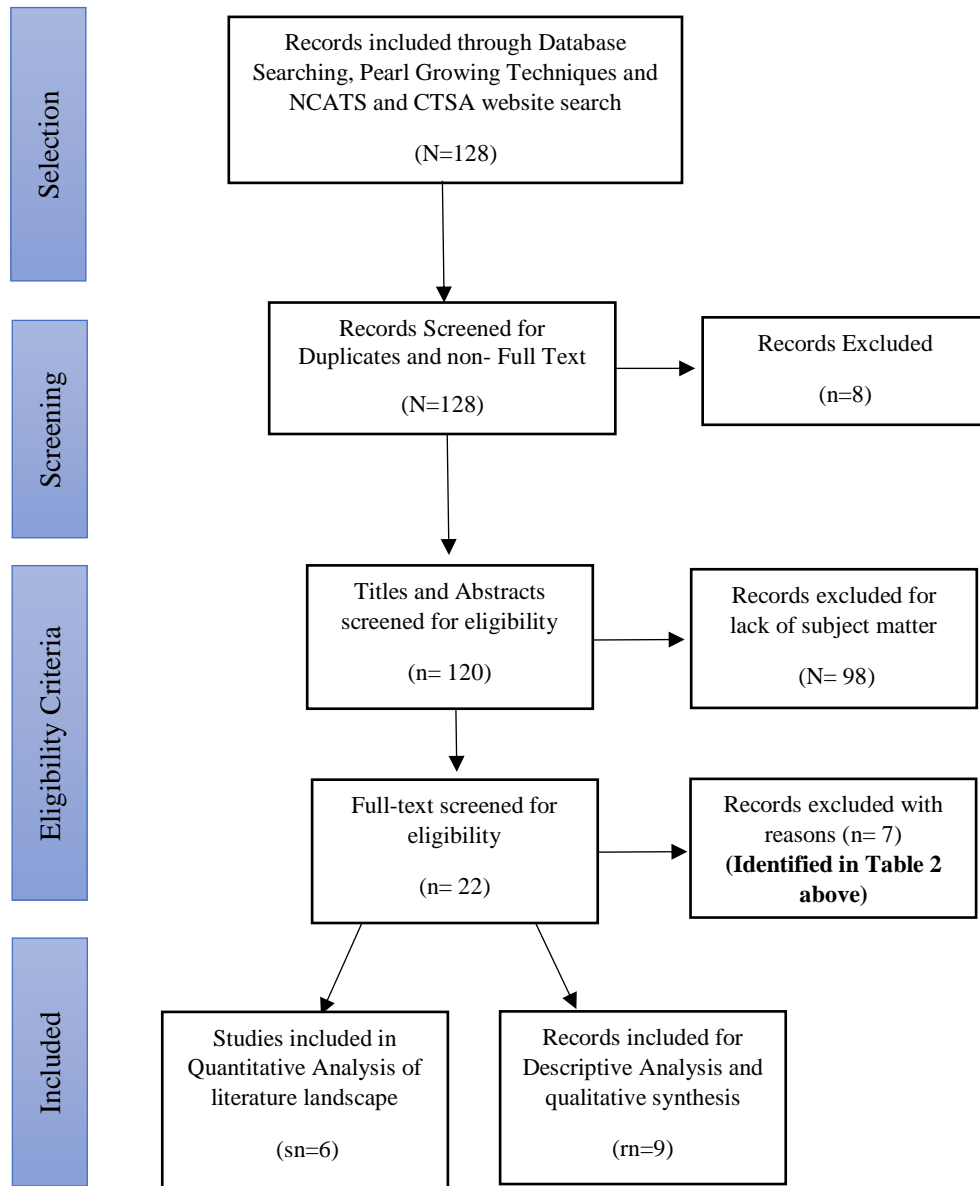
¹ This website no longer exists.

the 128 imported studies ($n=120$). The review of titles and abstract alone excluded additional articles ($n=98$). A more thorough full-text review of the remaining 22 records identified an additional seven articles for exclusion based on a lack of relationship of the specific subject matter to the objective of the review ($n=7$) (See **Table 2**. Excluded articles with reasons). The remaining records ($n=15$) were categorized into 2 main groups: (1) Studies (sn): articles that used extracted data or information from a CTSA website or a group of CTSA Institutional websites as the foundation of performing research ($sn=6$) and (2) Reports (m): articles that described the use of CTSA websites as an informatics communication or resource tool in the translation of science ($m=9$). (See **Figure 2**. PRISMA Flow Diagram). Study characteristics were broken down for quantitative analysis and synthesis, while reports were identified for descriptive analysis and subject matter synthesis.

Table 2. Excluded articles with reasons

<i>Authors</i>	<i>Year</i>	<i>Title</i>	<i>Reason</i>
<i>Meurer, W. J., Quinn, J., Lindsell, C., Schneider, S., & Newgard, C. D.</i>	2016	Emergency Medicine Resources Within the Clinical Translational Science Institutes: A Cross-sectional Study.	Website referenced for data was the CTSA National website not CTSA Individual websites.
<i>Eldredge, J. D., Kroth, P. J., Murray-Krezan, C., Hantak, C. M., Weagel, E. F., & Hannigan, G. G.</i>	2015	How accurately does the VIVO Harvester reflect actual Clinical and Translational Sciences Award-affiliated faculty member publications?	Research was about the VIVO Harvester's (a research networking system) capabilities in identifying CTSA Publications references to national CTSA website not CTSA individual.
<i>Smits, P. A., & Denis, J.-L.</i>	2014	How research funding agencies support science integration into policy and practice: an international overview.	Focused on data in funding websites rather than CTSA Individual Websites.
<i>Kennedy, B. M., Katzmarzyk, P. T., Johnson, W. D., Griffin, W. P., Kennedy, K. B., Cefalu, W. T., & Ryan, D. H.</i>	2013	Perceptions Community Residents Have about Partner Institutions and Clinical Research.	Only asked in a questionnaire if the internet/ websites were a good way to communicate to research participants.
<i>Carter-Edwards, L., Cook, J. L., McDonald, M. A., Weaver, S. M., Chukwuka, K., & Eder, M. "Mickey."</i>	2013	Report on CTSA Consortium Use of the Community Engagement Consulting Service.	This involved a CTSA supported, but independent website about consulting services.
<i>Melvin, A. J., Edwards, K., Malone, J., Hassell, L., & Wilfond, B. S.</i>	2013	Role for CTSA's in Leveraging a Distributed Research Infrastructure to Engage Diverse Stakeholders in Emergent Research Policy Development.	Discussion was about an additional website for online responses not related to the CTSA Institutional website
<i>Knafl, K., & Grey, M.</i>	2008	Clinical Translational Science Awards: Opportunities and challenges for nurse scientists. Nursing Outlook, 56(3), 132–137.e4.	Researchers investigated the National CTSA website, not the Individual CTSA recipient websites.

Figure 2. PRISMA Flow Diagram



Data Collection

An Excel spreadsheet was used for the collection, organization, and descriptive analysis of data extracted from relevant articles for the purposes of reporting. There were 2 different data collection and organization protocols, one for studies the other for reports.

Studies

The first data collection protocol was for the identified studies that used individual CTSA Institutional websites as a data source for a research topic. The organization processes for each relevant study article included a customized data extraction process that looked to identify a standard group of key elements from each study: (1) The study's NCATS CTSA Goal. (2) The type of data searched in the CTSA institutional website. (3) The number of CTSA institutional websites searched. (4) The number of sites that had the needed data. (6) The outcomes reported from the research.

Reports

The second data collection protocol was for identified reports that referenced single CTSA Institutional websites as performing a specific translational informatics functionality either as a portal to Clinical and Translational Science Award tools and resources or as a direct information source. The organizational process for each relevant report article also included a customized data extraction process that looked to identify a standard group of key elements from each report: (1) NCATS / CTSA Goal (2) Tool or Functionality Promoted (3) Description (4) Website used as portal or direct tool. (5) Target Audience.

Results

Summary of Studies

The studies were summarized using the standard group of key elements identified for data extraction and summarized in a table (See **Table 3.** Study Summary Table). In 5 of the 6 studies, researchers relied on CTSA member individual website content to mine necessary data. [37–41] One (1) of these studies employed a mixed method approach to data acquisition and only relied on CTSA member individual website content for CTSA institutions that did not respond to a user survey.[41] One (1) study used a survey to learn about CTSA website content rather than review the websites.[42]

In 5 of the 6 studies, researchers reviewed individual CTSA websites for the purposes of determining the number or percentages of CTSA institutions that had specific data. One (1) study instead reviewed the individual websites to develop a broader picture of what the CTSA Consortium offered as a group.[38]

The percentage of CTSA websites that had the needed data of the researchers ranged from 32% to 100%. The median and mean scores for CTSA websites having the needed data was 66% and 66.5% respectively. One study did not provide specific information for assessment.

Table 3: Study Summary Table

First Author	Year	Title	NCATS CTSA Goal	Data searched on website	# of CTSA websites reviewed	# of Responses to Survey	# of websites with data	Outcomes reported
Flood-Grady, E.	2017	A content analysis of Clinical and Translational Science Award (CTSA) strategies for communicating about clinical research participation online.	4, 2	Clinical Research (CR) Content that aimed to: 1. enhance understanding of CR, 2. educate individuals about CR participation and opportunities, 3. recruit participants into studies was considered relevant to the research question and collected as data.	62	NA	55	The number and percentages of CTSA Individual sites providing information regarding patient recruitment. To who and type of information disseminated.
Rosenblum, D.	2012	Access to core facilities and other research resources provided by the CTSA.	4, 5	Number and category of core facilities and other research resources offered by CTSA on Website	60	NA	60	List of 170 Generic services in 7 categories among the 60 websites. Connected via CTSACentralOrg. No breakdown or analysis.
Plottel, C.S.	2014	Designing and implementing INTREPID, an intensive program in translational research methodologies for new investigators	1, 4	CTSA short term educational program offerings in clinical research methodologies	62	NA	20	The range of educational offerings (1) one to several days, (2) more extensive programs (6-8 weeks), (3) part time but longitudinal over one or more semesters.
Fenton, S. H.	2015	Informed Consent: Does Anyone Really Understand What Is Contained In The Medical Record?	2, 3, 4	Templates on informed consent clearly posted on institutional websites and whether they were in different languages.	"each CTSA" or matching IRB website	NA	No clear indication where data came from: CTSA or IRB	17 Institutions' clearly posted Informed Consent Documents
Holbein, M. E. B.	2014	Recommendations from the IND/IDE Task Force of the CTSA Consortium.	1, 4	CTSA Sponsor-Investigator Training Materials for IND / IDE offered online.	NA	60	At least 1 of 34 reported	CTSA Institutional training methods for sponsor-investigators.
Byington, C. L.	2014	The CTSA mentored career development program: supporting the careers of child health investigators.	1, 3	1. Year of CTSA 2. Evidence of KL2 of other CDA program. 3. Number of Positions each year. 4. Child Health PI's who received support through CTSA	21	NA- websites were used to collect data for survey non-responders	16 - KL2; 10 - Child health PI's	Percentage of CTSA KL2 Awards for Child Health Investigators within total KL2 Awards

Footnote 1. NCATS CTSA Goal Key:

1. Cultivate and train a translational science workforce.
2. Engage patients and communities in every phase of the translational process.
3. Promote the integration of underserved populations in the research continuum.
4. Innovate processes to increase the quality and efficiency of translational research.
5. Advance the use of cutting edge informatics [14]

All 6 studies included research that fell within at least 2 categories of the 5 NCATS CTSA Goal topics. The category most investigated was translational research processes where 5 of the 6 studies investigated how CTSA websites looked to improve the quality and efficiency of translational research. Three (3) studies investigated how CTSA's cultivated and trained the clinical and translational science workforce. Two (2) studies investigated how CTSA's engaged patients and communities in the translational research process. Two (2) studies investigated how CTSA's promoted the integration of underserved populations. One (1) study investigated ways the CTSA's used their websites to advance the use of cutting-edge informatics.

The first study identified CTSA program hub website content aimed at potential clinical trial participants. The authors indicate this study was the first to evaluate online CTSA community engagement on clinical research participation strategies through CTSA sponsored websites. Findings suggest that CTSA's communicate about CR participation primarily with investigators through their program hub websites, patients appear to be a secondary audience. The researchers in this study investigated content that enhanced the potential participants' understanding of clinical research, educated these users on clinical research participation and opportunities, and recruited them into studies. The researchers found 89% of the CTSA program hub websites provided this information online. This research also identified seven CTSA program hub websites that did not include information about clinical research participation. The authors ultimately concluded that CTSA program hubs needed to identify their target audience and develop website content and design strategies accordingly. Clinical research participation content falls primarily under community and patient engagement NCATS goals when addressed to the

participants and falls under quality and efficiency in methods and processes NCATS goals when the content is directed at investigators.[37]

The second study identified investigated the number and category of core facilities offered by CTSA program hub websites throughout the CTSA continuum. This was done through on central access point: CTSAcentral.org. This researched focused on the bulk of the offerings made available through access to all CTSA program hub websites, rather than break down how the content was distributed throughout each website. It instead offered a list of overall generic services offered among the consortium. This specific study, published in 2012, highlighted the fact that there was a centralized access point for the CTSA hubs as a new opportunity for coordination. Interestingly, the CTSAcentral.org website no longer is supported by the funding body, nor is it in existence.[38]

The third study investigated CTSA program hub website content for short term educational offerings in clinical research methodologies. It identified these offerings in 32% of the CTSA website program hubs. The CTSA website review was not a major topic in this publication, instead it was used as the justification for the information presented in the publication. The authors used a review of CTSA websites to identify gaps in short term education programs for potential clinical and translational science researchers at different levels. [43]

The fourth study investigated website content for posted Informed Consent templates. The Informed Consent templates were the data source and topic of the research. The CTSA program hub websites were used as the starting point to collect the data. There was no clear indication that all the CTSA program hub websites were

searched. The study did report finding 17 CTSA program hub websites posting Informed Consent templates. These templates were then assessed for their language relating to “medical records”. [40]

Rather than investigating the CTSA program hub websites, the fifth study surveyed CTSA program administrators about their online offerings for investigator training materials. This was a regulatory approach to support the protection of human subjects. The CTSA Regulatory Key Function Committee surveyed each CTSA program hub to determine if they offered training materials for Investigational New Drug/ Investigational Device Exemption IND / IDE online. It determined 56% of the CTSA program hubs provided this type of investigator training content online. This research is unclear on specific CTSA program hub website content. It provided one example of a specific CTSA program hub that distributed the material directly through their CTSA program hub website. Two other examples presented were from awarded CTSA programs, but training and materials were identifiably distributed through their main university website, not the CTSA program hub.[44]

The sixth study described the landscape of CTSA Mentored Research Career Development Awards (CDA) and evaluated participation and outcomes of child health investigators in these programs. While a survey was the primary data collection source, for all nonresponding institutions, the authors conducted a structured review of the institution’s CTSA program hub website. Researchers were required to conduct a website review of 21 CTSA program hub websites that did not respond to the survey. This study reported that 16 of the 21 websites reviews included details on their KL2 Awards to

determine the percentage of KL2 Awards that were for child health investigators within the total KL2 awards. [41]

There were no studies that inquired about any of the eight CTSA Program Initiatives.

Summary of Reports

The reports ($n=9$) were also summarized using the standard group of key elements identified for data extraction and summarized in a table (See **Table 4. Report Summary Table**). All nine articles reported using their Institutional CTSA website as either a portal or a tool to promote clinical and translational science as outlined through NCATS goals. A CTSA program hub website is used as a *portal* when it provides links to other sites, tools, or programs. A CTSA program hub website is used as a *tool* when it provides the functionality within its web design like providing an online application or database, or interactive training pages. In 8 of the 9 articles, authors reported on CTSA institutional website as either a translational informatics portal or providing informatics functionalities. Four of the articles reported the use of their website for engagement, on either the collaborator or patient level, such as advocacy, education, or subject enrollment. Two (2) articles reported the use of their CTSA website for the cultivation and training of a clinical and translational science workforce. Four (4) articles reported on the use of their CTSA website for the purposes of increasing the quality and efficiency of translational research. None of the articles reported how their sites were used to promote the integration of underserved populations.

Table 4. Report Summary Table

First Author	Year	Title	NCATS / CTSA Goals	Description	Website as Portal	Website as Tool	Target of Website
Printz, C.	2015	In the NEWS: A ROUNDUP OF NEWS AND INFORMATION FROM OUR COMMUNITY.	2, 5	Researcher can gather clinical notes as data using this tool.	EMERSE (Electronic Medical record Search Engine)		Researchers
Winkler, S. J.	2014	A Distributed Model: Redefining a Robust Research Subject Advocacy Program at the Harvard Clinical and Translational Science Center.	2, 5	Research Subject Advocacy expertise, education, and resources.		Research Subject Advocacy Page	research subjects, researchers, research coordinators, and research nurses
Brenda G. Fahy, M.D., F.C.C.M.	2011	Crossing the Chasm: Information Technology to Biomedical Informatics	5	eWorkBench is a complex biomedical informatics tool distributed to the research community and AMC Health care community through the University of Kentucky's CTSA website (CCTS)	eWorkBench		researchers
Hazard, M.	2011	CTSA-IP: a solution to identifying and aggregating intellectual property across the NIH Clinical Translational Science Award (CTSA) consortium of biomedical research institutes.	5	Open Access IP Search Tool that aggregates and promotes technologies. 1 Year 16,000 visits and 30,000-page views. No Longer Functioning IP	CTSA IP		Researchers looking for tools
Sajdyk T	2015	Project Development Teams: A Novel Mechanism for Accelerating Translational Research.	1, 4, 5	How to conduct an online Project team development application through the Indiana CTSA hub webpage		Hub Webpage is the tool. Online Application Process	Researcher (PI)
Pienta, K. J.	2011	The CTSA's Are Transforming the Way Academic Medical Institutions Approach Translational Research: The University of Michigan Experience.	1, 2, 4	Create a home for study coordinators to promote education and share of best practices. Including a web-based participant registry to help match interested patients and volunteers with open studies.	To link to patient registry tool	To educate and share knowledge.	Patients, Investigators, new researchers
Hogle, J.A.	2014	Success case studies contribute to evaluation of complex research infrastructure	4	CTSA Institutional Website was used to identify researchers for case studies to determine the level of success of CTSA program implementations.		To identify PI's for research	Researchers, administrators
Nahm, Meredith	2011	Design and implementation of an institutional case report form library	4	CTSA institutional website was used to demonstrate the implementation of a web-based case report form.	For informatics demonstration		Clinical research administrators
Weber, G.M.	2011	Diret2Experts: A Pilot national network to demonstrate interoperability among research.	2	CTSA institution used component of their CTSA website, a RNS, to expand engagement through RNS system interoperability.		For expanding the researcher engagement opportunities	Researchers

Footnote 1. NCATS CTSA Goal Key:

1. Cultivate and train a translational science workforce.
2. Engage patients and communities in every phase of the translational process.
3. Promote the integration of underserved populations in the research continuum.
4. Innovate processes to increase the quality and efficiency of translational research.
5. Advance the use of cutting edge informatics [14]

All the reports identified a CTSA institutional website as a tool to leverage or disseminate CTSA capabilities and functionality. The access point and/or warehousing of these capabilities was the CTSA institutional website. The target audience for these publications included researchers, clinical research administrators, IT programmers, community collaborators, and research subjects.

The articles that reported on the use of CTSA institutional websites for clinical and translational functionality included topics such as: (1) the introduction of an informatics tool that searches clinical notes to identify clinical data for research. (2) the promotion of an online research subject advocacy program. (3) the introduction of an informatics tool portal that allows researchers flexible, efficient and effective means of collaboration and interaction with data. (4) the promotion of a team development project tool. (5) the introduction of a research participant registry and study promotion and education tool. (6) the promotion of an independent informatics tool registry that could connect to all CTSA websites.

The first report highlighted an informatics tool on a CTSA program hub webpage called EMERSE. EMERSE was identified as an Electronic Medical Records Search Engine that empowered researchers to gather clinical notes for data research purposes. This data query system speeds searches through clinical notes stored in patients' electronic health records. Data known to be compiled in these records include biomarkers, side effects, infections, and clinical outcomes.[45]

The second report highlighted the value of including a research subject advocacy (RSA) page on a CTSA program hub website. The webpage provided expertise, education and resources to a diverse audience including research subjects, investigators, research coordinators, and research nurses. This research used the CTSA program hub public facing RSA webpage to redefine research subject advocacy from a role vested in an individual to a “replicable and scalable, distributed model of advocacy focusing on functions that support heightened protections and respect for research subjects.” [46]

The third report highlighted a complex biomedical informatics tool offered through a CTSA program hub website called eWorkbench. This report provides accessibility of this tool through a CTSA program hub website. It explains that this type of access allows users, including CTSA program hub faculty and staff and collaborators, to more efficiently collaborate and conduct research. The report also shows the inclusion of this tool on their website allowed it to be more freely distributed among the research community.[47]

The fourth report highlighted a tool that harvested and aggregated the tools offered by CTSA consortium websites and stored them on an independent website. In the first year of this website’s offering it recorded 16,000 visits and 30,000-page views. This webpage is no longer available. [48]

The fifth report focused on the use of its website as a research team development tool. It provided an online application process that promoted activities relating to team development. Investigators are instructed to access their institution’s CTSA program hub webpage and click the “Research resources” link. They are then instructed to click the “Project Development Teams” link. The Project Development Team link provides access

to information investigators would need to submit an online Project Development Team application.[49]

The sixth report laid out concrete organizational plans and investments to improve infrastructure of translational research at a CTSA program hub. It identifies the use of the CTSA program hub website as a home for study coordinators to promote education and best practices along with the use of web-based participation registries to help match interested patients and volunteers with open studies. [50]

The seventh report uses an institutional CTSA program hub website as a component to evaluate clinical and translational research infrastructure. It identifies the CTSA website as one piece of a resource and guide to administrations in assessing institutional progress. It highlighted the use of a CTSA program hub website as a tool to identify principle investigators for case study research that would lead to the determination of success levels of the CTSA program. [51]

The eighth report highlighted the use of a CTSA program hub website as a distribution model for web-based case report forms. The report praises its improved accessibility of the CRFs with this type of distribution.[52]

The ninth report highlighted the use of the research networking system component of a CTSA program hub website to aid in the expansion of research collaboration opportunities through research networking system interoperability among other CTSA institutions' and universities' websites.[53]

No reports identified any of the eight CTSA program initiatives in their website offerings or functionality.

Conclusion

The 15 peer reviewed articles, both studies and reports, identified in this review reference the use of CTSA institutional websites as an instrument in the translation of science at Academic Medical Centers either as a data source or a tool distribution source. The use of the websites described in the articles aligns specifically with NCATS goals. There were no identified reports or studies that aligned with the CTSA program initiatives. The identified studies focused on understanding how CTSA websites provided data as a group that could inform clinical and translational research initiatives on an administrative level through an understanding of what is being offered or reported throughout the continuum. The identified reports were an individualistic approach where institutions reported on presenting their CTSA offerings through their program hub websites.

This research shows that CTSA institutional website functionality and content contributes to the CTSA body of research and the advancement NIH translational science goals.

Discussion and Research Gaps

All CTSA institutions have a website that have the capabilities to provide a variety of clinical and translational science portals that include useful tools and content, and interactive opportunities. This systematic literature review shows that researchers already interact with CTSA institutional website content across the continuum. CTSA Institutional program hub website are being mined for data in this vein. The data being mined is directly related issues within the five defined NCATS program goals. There is

no literature indicating the CTSA program hubs were intended to be utilized in this manner. There is no literature indicating CTSA program hubs rely on a common set of content standards for their website development. Reported findings from this literature review indicate CTSA institutional websites are being highlighted from 2 approaches. The first approach investigates CTSA institutional websites to gain a better understanding of the composition and characteristics of the consortium as a whole. The second approach reports on a single institution's CTSA program hub website content to inform researchers of available functionalities, information, or tools.

There is no literature that examines the potential CTSA individual websites offer to the clinical and translational research community as a tool or as a data mining resource. There is no literature that examines potential website content that should exist across the CTSA continuum to best validate and leverage this type of research. While the literature indicates that researchers are specifically investigating content topics related to the five NCATS goals, no literature in this area uses or characterizes website content related to the eight CTSA program initiatives such as the Common Metrics Initiatives (CMI), SMART IRB, Trial Innovation Network, NCATS National Center for Data to Health (CD2H), Trial Innovation Network, ARA4US.org, or Collaborative Initiative Awards.

In the literature reviewed, all the literature addressed content utility, only one addressed interactivity and design, and none of the literature addressed the subject of navigability.

Chapter III

METHODS

CTSA institutional websites were evaluated for information or tools that align with the five NCATS / CTSA Goals and eight CTSA nationally identified program initiatives. Each NCAT goal and CTSA initiative was subsequently ranked by information diversity level (text, tool, interactivity) and navigation level (click distance from the home page).

Population Identification

A list of 58 CTSA Program Hubs was obtained from the National Center for the Advancement of Translational Science website. Google queries were used to obtain website URLs for each CTSA institutional website. Each CTSA institutional website was visited and content related to NCATS program goals and CTSA program initiatives were evaluated on three scores: (1) a content score, (2) a data diversity score, (3) a navigation score.

Evaluation Domains and Categories

The research evaluated two specific evaluation domains within each website, NCATS goals and CTSA initiatives. The first set of categories include the five program

goals identified by NCATS identified at <https://ncats.nih.gov/ctsa/action>. The second set of evaluation categories includes the eight initiatives identified by the national CTSA identified at <https://ctsa.ncats.nih.gov/initiatives/>. (See Table 5. Evaluation Categories)

Table 5. Evaluation Categories

NCATS Program Goals	CTSA Program Initiatives
1. Education and training	1. ARA4US.org
2. Patient and community engagement	2. ACT Network
3. Integration of special and underserved populations	3. Collaborative Innovation Suite of Awards
4. Innovation of methods and processes	4. Common Metrics Initiative
5. Advancement of Cutting-Edge Informatics	5. CTSA Program Coordination Center (CLIC)
	6. CTSA program data to health coordinating center (CD2H)
	7. SMART IRB
	8. Trial Innovation Network (TIN)

Variables and Scoring

There were three variables measured that relate to the above evaluation categories of this data collection process: content score, data diversity level, and navigation level.

Content Score

The first variable to determine was the content score (CS) for each evaluation domain. The content score was a simple yes or no evaluation it addressed the issue of

CTSA program hub website content utility. It answered the question: Does the NCATS program goals and initiative content exist? If content on the NCAT Goal or CTSA Program Initiative exists, then CS=1. If content did not exist, then CS=0.

Data Diversity Level

The second variable was the data diversity level (DL). The data diversity level was based on the interactivity and design concept. It reported on how many different formats the content identified from the Content Score were represented. The DL was assessed by the sum of the number of three different formats: information, tool, and resource. *Information* was defined as a text format that was descriptive and non-interactive information. A *tool* was content that allowed the user to interact with the website on related content or use the website to complete a task (e.g., an online form). *Interactivity* represented information that identified contact emails or phone numbers for personnel that could provide additional information. If one out of three of the information formats was identified, then the DL = 1. If two of the three information formats were identified, then DL=2. If three of the three information formats were identified, then DL = 3.

Navigation Level

The third variable measured was the data navigation level (NL). It addressed the navigability of the content. This variable measured how many clicks content was found in relation to the CTSA website home page. An evaluation domain that was identified on the home page was scored the maximum 5 points, NL=5. Each click further from the home page dropped the NL 1 point. The remaining NL scoring was as follows: NL=4 when the evaluation component was 1 click from the home page. NL=3 when the

evaluation component was 2 clicks away from the home page. NL=2 when the evaluation component was greater or equal to 3 clicks from the home page. NL=1 when access to the evaluation component required a login. (See **Table 6-** Study Variable Table).

Table 6. Study Variable Table

<i>Evaluation Domains</i>	<i>Evaluation Categories</i>	<i>Content Score (CS)</i>	<i>Data Diversity Level (DL)</i>	<i>Navigation Level (NL)</i>
<i>NCATS / CTSA Goals</i>	Workforce Development (WD)	1=yes; 0=no	1-3	1-5
	CTSA Engagement (ENG)	1=yes; 0=no	1-3	1-5
	Promote Underserved Populations (UP)	1=yes; 0=no	1-3	1-5
	Translation quality and efficiency (QE)	1=yes; 0=no	1-3	1-5
	Informatics (INF)	1=yes; 0=no	1-3	1-5
<i>CTSA Program Initiatives</i>	Common Metrics Initiative (CMI)	1=yes; 0=no	1-3	1-5
	SMART IRB (IRB)	1=yes; 0=no	1-3	1-5
	Trial Innovation Network (TIN)	1=yes; 0=no	1-3	1-5
	CD2H	1=yes; 0=no	1-3	1-5
	Collaborative Initiative Awards (CCIA)	1=yes; 0=no	1-3	1-5
	Accelerated Research Agreement (ARA4US)	1=yes; 0=no	1-3	1-5
	Accrual to Clinical Trials (ACT)	1=yes; 0=no	1-3	1-5
	CTSA Program Coordinating Center (CLIC)	1=yes; 0=no	1-3	1-5

Ranking System

Individual CTSA program hub websites were ranked for each evaluation category. The scores from the three variables in an evaluation category were plugged into

a formula in order to rank the thoroughness of that domain's representation on a CTSA program hub website. Each of the 13 evaluation categories were ranked in each of the 58 CTSA program hub websites. Based on the below formula the category score range was 0-15.

Category Ranking (CR) Formula = CS x DL x NL

Once each evaluation category is ranked within both evaluation domains in a CTSA program hub website, 2 additional rankings were calculated for the website. The first was the overall ranking for the NCATS goals which was the sum of the five category scores for the NCATS Goals. The NCATS goal overall ranking ranged from 0-75. The second was the sum of the category scores for the eight CTSA initiatives. The CTSA initiative overall ranking ranged from 0-120.

Each CTSA program website had individual category scores for all five NCATS goals and all eight CTSA initiatives in addition to an overall NCATS goal score and an overall CTSA initiative score.

For ease of interpretation, the ranking system was divided into three levels of content representation:

Level #1

The score for a level # 1 content representation required a score between 10-15 for any single category, 50-75 for the entire NCATS goal domain, or 80-120 for the entire CTSA initiative domain. Level #1 can be achieved for any single category with two possible combinations of interactivity and design and navigability for the content. The first combination was that the category being evaluated had included more than one

format to represent the information (text, linked information, interactive content) and was found on the home page. The second combination the content could be represented for a level #1 would be if the information offered included related text, linked information, and interactive content and was found no more than one click away from the home page.

Level #2

The score for a level #2 content representation must be between 5-9 for any single category, 25-49 for the entire NCATS goal domain, or 40-79 for the CTSA initiative domain. Level #2 can be achieved through 3 combinations of “interactivity and design” and navigability for a single category. The first combination is that there is that one form of the content in the category exists on the website and is accessible on the home page. The second combination is that 2 forms of content are available on the website and they are between 1-2 clicks away from the home page. The final combination is that 3 forms of content exists, and it is either 2 clicks away from the home page or identified through a free text search.

Level #3

The score for a Level #3 content representation must be between 1-4 for any single category, 1-24 for the entire NCATS goal domain, or 1-39 for the entire CTSA initiative domain. Level #3 can be achieved through 3 combinations of “interactivity and design” and navigability for a single category. The first combination is that there is that one form of the content in the category exists on the website and is not accessible on the home page. The second combination is that 2 forms of content are available on the website and they can only be identified through a free text search or can only be accessed

through a user login. The final combination is that 3 forms of content exist, and it can only be accessed through a user login. (See **Table 7: CTSA Program Hub Website Individual Ranking System Ranges**).

Table 7: CTSA Program Hub Website Individual Ranking System Ranges

<u>Level #1 Content Representation</u>	<u>NCATS Goal Single Category (Score 10-15)</u>
	<u>NCATS Goal Entire Domain (Score 50-75)</u>
	<u>CTSA Program Initiative Single Category (Score 10-15)</u>
	<u>CTSA Program Initiative Entire Domain (Score 80-120)</u>
<u>Level #2 Content Representation</u>	<u>NCATS Goal Single Category (Score 5-9)</u>
	<u>NCATS Goal Entire Domain (Score 25-49)</u>
	<u>CTSA Program Initiative Single Category (Score 5-9)</u>
	<u>CTSA Program Initiative Entire Domain (Score 40-79)</u>
<u>Level # 3 Content Representation</u>	<u>NCATS Goal Single Category (Score 1-4)</u>
	<u>NCATS Goal Entire Domain (Score 1-24)</u>
	<u>CTSA Program Initiative Single Category (Score 1-4)</u>
	<u>CTSA Program Initiative Entire Domain (Score 1-39)</u>

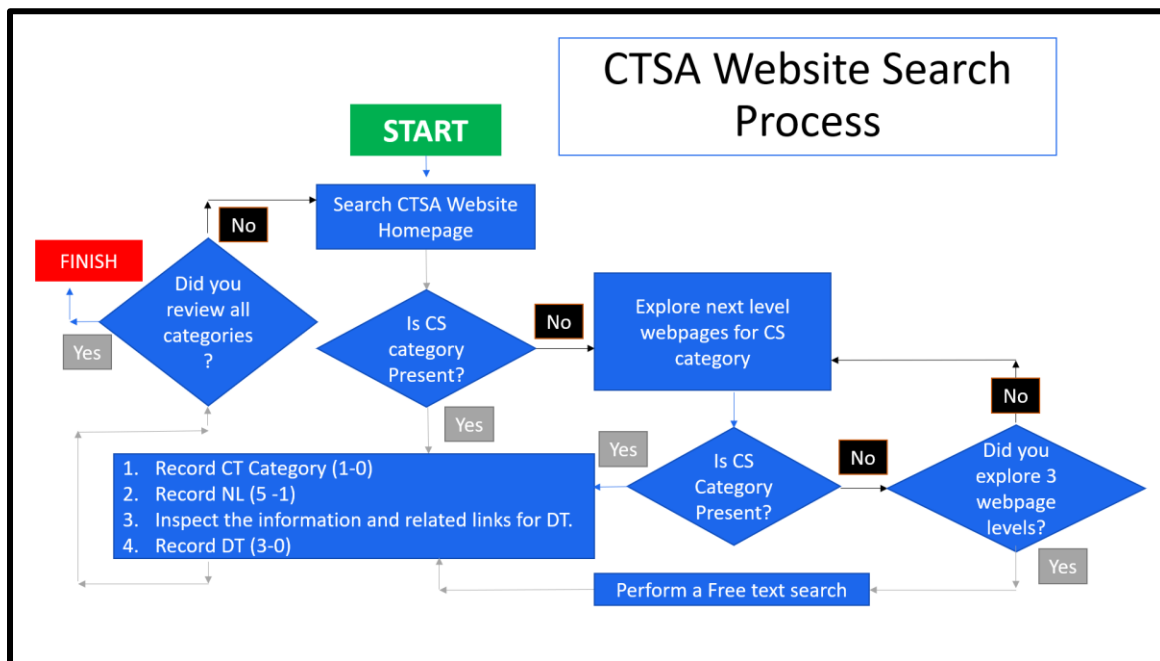
Data Collection Process

An excel database designed to store NCATS program goal and CTSA program initiative information on CTSA Program Hubs was created for data collection. The google search conducted to capture the uniform resource locator (URL) of each identified CTSA Program Hub was recorded in the existing excel spreadsheet. Using the URL found through the Google Search, each CTSA Program Hub website identified by NCATS was accessed and evaluated. A screen shot of each CTSA Program hub home page was taken and stored in a separate PowerPoint file before the website content evaluation began in order to capture and archive the sample. Content evaluation data

collection began with a review of the publicly accessible web content at the home page main toolbar level. Further evaluation continued to a thorough section-by-section examination of the remaining webpages in the site.

Each CTSA program hub website was searched for information, resources, and tools within 13 evaluation categories (five - NCATS / CTSA Program Goals; eight - CTSA Program Initiatives). The search process was conducted by searching only one evaluation category at a time. Once content was identified for a specific evaluation category (Content Score -CS), it was then evaluated and scored for the diversity of the information (Data Diversity Level - DL) and accessibility of that information (Navigation Level - NL). If it was not present on the home page, then the homepage links, side bars, headers, and drop-down menus were explored for information on the evaluation domains further into the website. Once the evaluation domain was identified through this search process beyond the home page, a content score, data diversity and navigation level were recorded. If an evaluation domain was not identified within three navigation levels of the website, a free text search was performed in the website's search box. If the evaluation domain was identified through a free text search, a content score, data diversity and navigation level was recorded. Each evaluation domain was searched in the same manner until all evaluation domains were assessed. Once a website evaluation was complete, the search began on the next CTSA program hub website. Results were recorded on the existing Excel spreadsheet. (See **Figure 3. CTSA Website Evaluation – Website Search Process**).

Figure 3. CTSA Website Evaluation – Website Search Process



Validation

Validation of Content Category Variables

The content validation process to validate the 13 content categories (five NCATS goals and eight CTSA Initiatives) began with search of the NCATS CTSA home page. The NCATS as the directing body identified the 5 specific goal categories used in this research and mentioned 5 of the 8 CTSA program initiatives. The national CTSA program had a webpage of its own linked from the main NCATS page. This National CTSA website identified the 5 Program initiatives highlighted by NCATS but also included three additional program initiatives. This search process was the foundation for the identification of the 13 categories in the content evaluation. Once the 13 categories were identified through the institutional websites, a review of 2 National Institute of

Health Funding Opportunity Announcements (FOA) for the Clinical and Translational Science Awards was conducted to validate the use of these categories as variables. Funding opportunity PAR-15-304 represented the Clinical Translational Science Award (U54). Funding opportunity PAR-18-940 represented funding for the Clinical and Translational Science Award (U54) with a clinical trial option. A review of these funding opportunities validated the 5 NCATS goals as a component of award recipient activities. Three of the 8 program initiatives were also identified as award related components in the 2 FOAs. The FOAs also made direct reference to the goal of strengthening the CTSA as a network. This directive was used to justify the use of all 8 CTSA program initiatives identified on the National CTSA website. Stakeholders in website content and development in 6 CTSA program hub institutions were consulted on the category choices and confirmed the value of the 13 content categories. This process ensured the 13 categories selected reflect the related activities in the CTSA consortium.

There is no criterion-related validation because the measurement this evaluation will determine its alignment with the 13 NCATS / CTSA goals and initiatives. Content either exists or it does not. It is not predicting an outcome. Variables relating to data type and navigation levels are also dependent on yes or no inputs

Methods for Validation of Results

All CTSA websites were rated according to the scoring system by the primary researcher. A second researcher was recruited to evaluate a random sample of the websites using the same system. A 10% randomly selected sample of websites was used.

The second researcher was trained using the algorithm as a guide with the primary researcher as supplemental trainer. The second researcher was given one random website

to rate independently. Both the main researcher and the second researcher reviewed the algorithm using the first website as an example. The second researcher then scored another randomly selected website. Another discussion session followed with further clarifications. The second researcher then rated the final 4 with the algorithm.

Concordance rate was calculated and websites with discordant rating were re-examined and discussed by both the first and second observer in order to reach a consensus.

Validation Results

A total of 58 websites were evaluated and scored by the primary researcher. A total of 6 websites were evaluated and scored by the second researcher. Following the scoring by the second researcher and comparing the 3 different scores for the 13 categories in 6 websites (254 total scores), 221 (87%) were found to be concordant and 33 were discordant. Discordant websites were reviewed together by both main researcher and the second researcher and the consensus was reached in all (100%).

Supplemental Data Collection

Supplemental content was recorded and collected when the search process led to exemplar website functionalities or evaluation domain content. Additional screen shots were taken of any exemplar webpages representing of any evaluation domains or any unique website design or functionality deemed that way by the main researcher. Screenshots were stored in the existing the PowerPoint program and notes on interesting content or functionality was recorded in the existing excel spreadsheet.

Chapter IV

RESULTS

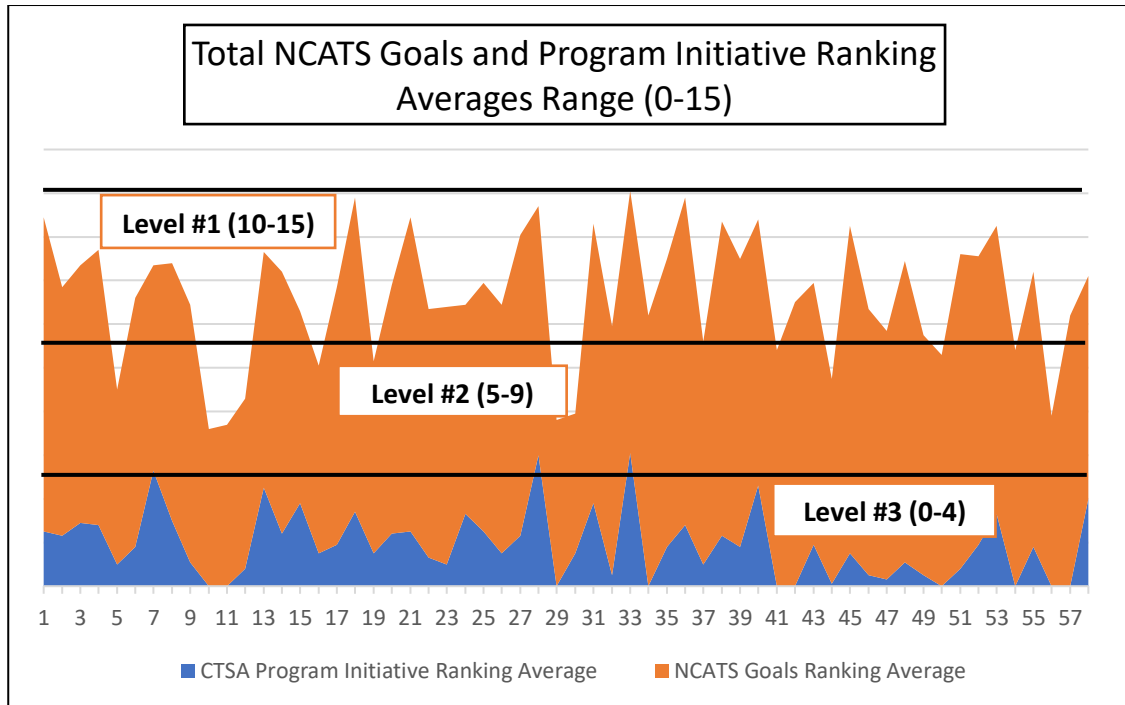
There were 58 CTSA program hubs that received CTSA funding in 2018 with a UL1 Award and linked KL2 or TL1. More than half of the funded academic medical centers were state schools ($n=39$). They represented 27 states across the U.S. Funding awards in 2018 ranged from \$3,996,732 to \$22,863,488.

NCATS Goals and CTSA Initiatives Snapshot.

The total average of all five NCATS goal category rankings among the 58 CTSA program hub websites was 11.4 (SD = 3.5) (possible range 0-15). This means the NCATS goal category ranking fell within the highest representation Level #1 . The average individual rankings for each of the NCATS goals averaged between 5-14. *Integration of Special and Underserved Populations* was the lowest ranking category with an average ranking of 5.5 (SD = 5.4) and *Education and Training* was the highest ranked category with an average of 14.1 (SD = 2.5) The total average of all eight CTSA initiative category rankings among the 58 CTSA program hub websites was 1.9 (SD = 2.0) (possible range 0-15). This average CTSA initiative category ranking fell within the lowest representation Level #3. (See **Figure 4.** Total NCATS Goals and Program Initiatives Rankings (Range 0-15))

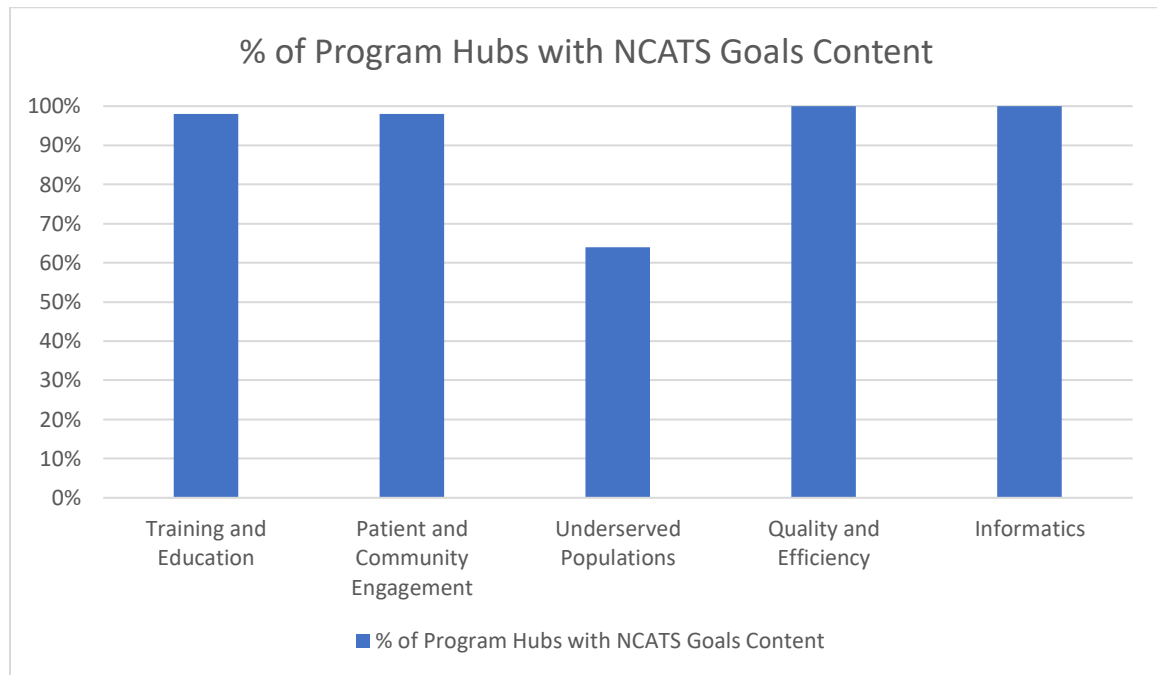
The average individual ranking for each of the CTSA initiatives was 1.9 (SD = 2.0). The lowest average ranking was for *ARA4US.org* at .2 (SD = .83). *The Trial Innovation Network* was ranked the highest with an average of 6.2 (SD = 5.1).

Figure 4. Total NCATS Goals and Program Initiatives Ranking Averages (Range 0-15)



NCATS goals were represented by over 98% of the CTSA program hub websites in 4 of the 5 categories (See **Figure 5.** Percentage of Program Hubs with NCATS Goals Content). Integration of Special and Underserved Populations was the only evaluation category represented by 64% of the CTSA program hub websites. The diversity of content (data diversity level) implemented by the program hubs websites averaged between 2 and 3 different types of data for 4 of the 5 NCATS evaluation domains

Figure 5. Percentage of Program Hubs with NCATS Goals Content



(See **Figure 6.** Average Data Diversity Level for NCATS Goals). The *Integration of Special and Underserved Populations* category had a data *Diversity Level* average 1.5 (SD = 1.3) that was one complete data diversity level below each of the other four categories. The *Navigation Level* for the **Integration of Special and Underserved Populations** also had the lowest average 2.3 (SD = 1.9). (See **Figure 7.** Average Navigation Level for NCATS Goals) The average NCATS Goals overall rankings show that **Training and Education, Patient and Community Engagement, and Quality and Efficiency** in research are the top 3 categories. Informatics is thoroughly and consistently represented as well but slightly lower than the top 3. The NCATS Goal category that need more content is the integration of special and underserved populations. (**Figure 8.** Average NCATS Goals Overall Ranking).

Figure 6. Average Data Diversity Level for NCATS Goals

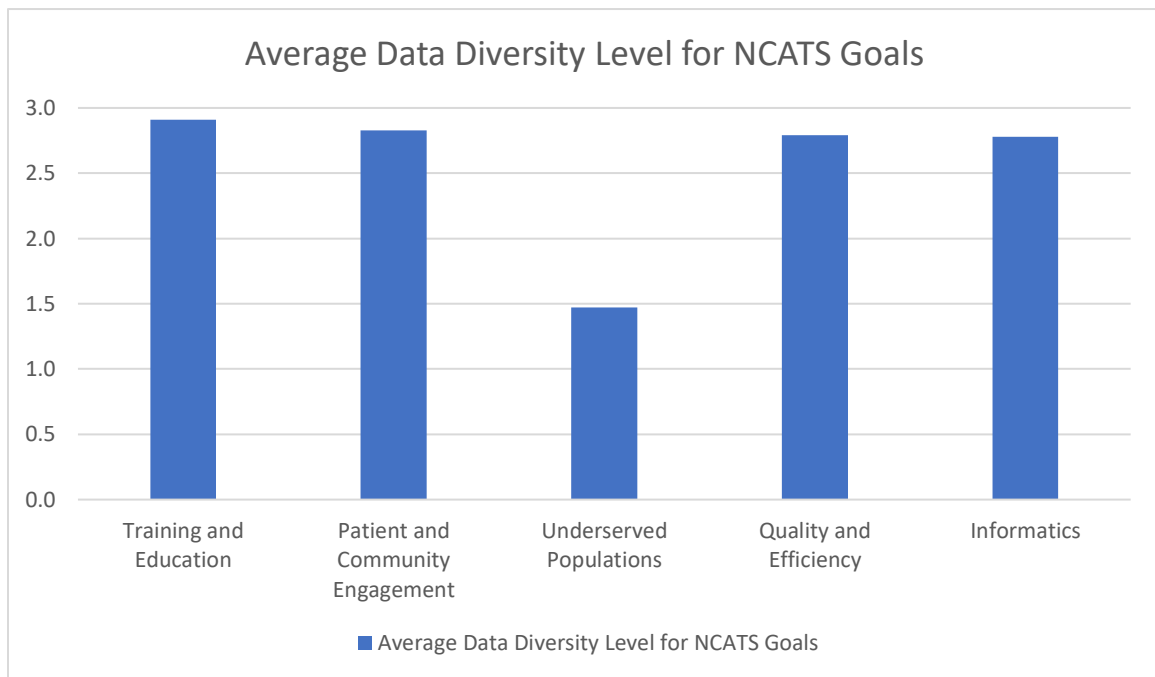


Figure 7. Average Navigation Level for NCATS Goals

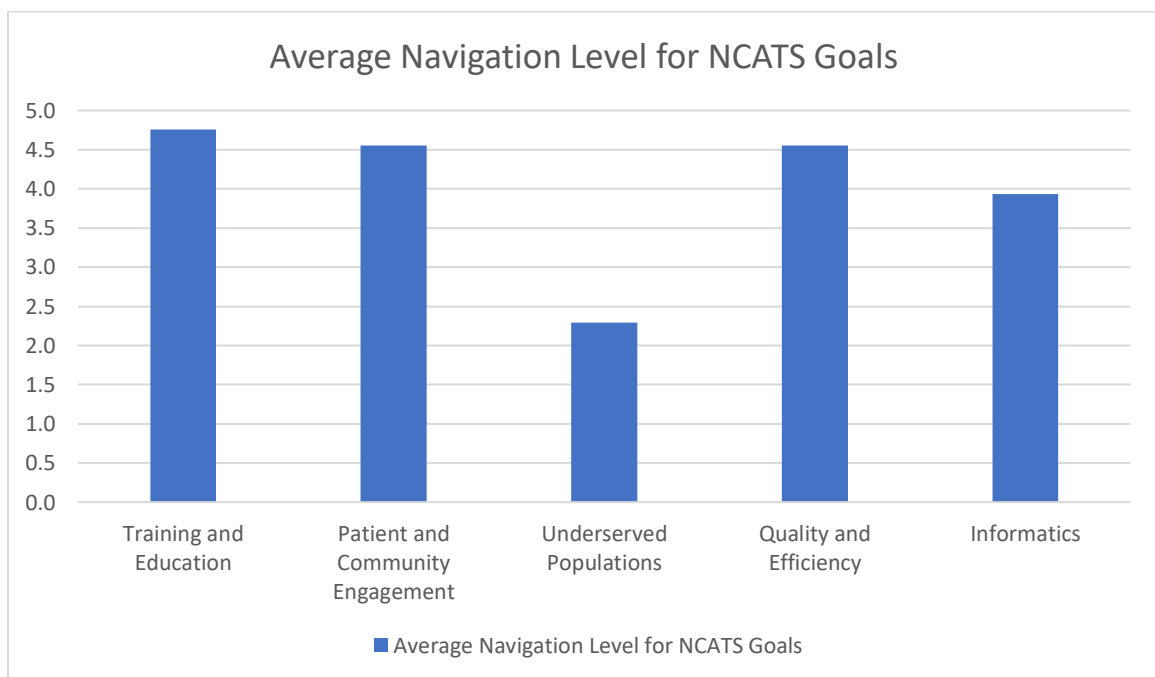
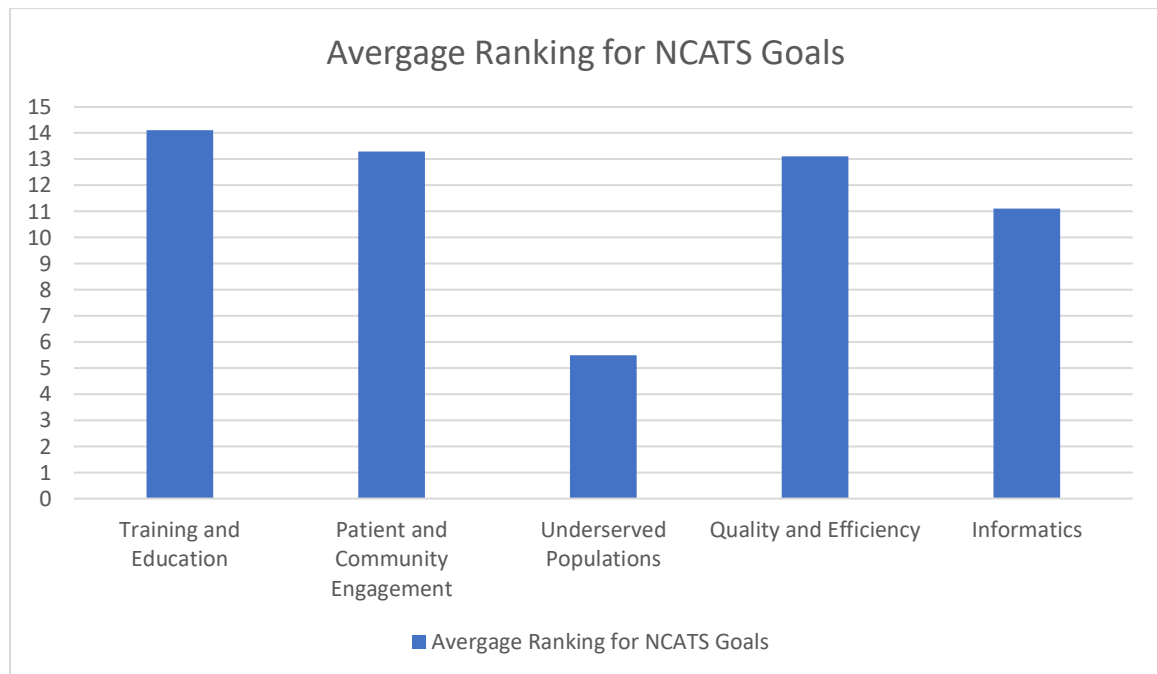


Figure 8. Average NCATS Goals Overall Ranking



NCATS Goal #1

The overall category ranking for translational science **Training and Education** across the CTSA continuum was at the highest level (Level #1) with an average of 14.1 (SD = 2.5) out of a range of 0-15. The *data diversity* of this category showed that among the CTSA program hub websites, average *data diversity* was high with a score of 2.9 (SD = 0.4) out of a range of 0-3. The *navigation level* was high, averaging 4.8 (SD = 0.8) out of a range of 0-5. (See **Table 8.** NCATS #1 Training and Education Overall Scores)

Table 8. NCATS #1 Training and Education Overall Scores

<i>NCATS #1 Training and Education Overall Scores</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	2.9	4.8	14.1	Level #1
<i>Mode</i>	3.0	5.0	15.0	Level #1
<i>Median</i>	3.0	5.0	15.0	Level #1
<i>Standard Deviation</i>	0.4	0.8	2.5	

NCATS Goal #2

The overall category score for translational science **Patient and Community Engagement** across the CTSA continuum reached Level #1 representation with an average of 13.3 (SD = 3.4) out of a range of 0-15. The data diversity of this category showed that among the CTSA program hub websites it was high with a score of 2.8 (SD = 0.5) out of a range of 0-3 data points.. The navigation level was high, averaging 4.6 (SD = 0.9) out of a range of 0-5. (See **Table 9.** NCATS Goal #2 Patient and Community Engagement).

Table 9. NCATS Goal #2 Patient and Community Engagement

<i>NCATS Goal #2 Patient and Community Engagement Overall Scores</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	2.8	4.6	13.3	Level #1
<i>Mode</i>	3.0	5.0	15.0	Level #1
<i>Median</i>	3.0	5.0	15.0	Level #1
<i>Standard Deviation</i>	0.5	0.9	3.5	

NCATS Goal #3

The overall category score for **Promoting Special and Underserved Populations** across the CTSA continuum barely reached a Level #2 with an average of 5.5 (SD = 5.4) out of a range of 0-15. The data diversity of this category showed that among the CTSA program hub websites this category needs more content diversity with only a score of 1.5 (SD = 1.3) out of a range of 0-3 data points. The navigation level was low as well, averaging 2.3 (SD = 1.9) out of a range of 0-5. (See **Table 10**. NCATS Goal #3 Special and Underserved Populations)

Table 10. NCATS Goal #3 Special and Underserved Populations

<i>NCATS Goal #3 Special and Underserved Populations</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	1.5	2.3	5.5	Level #2
<i>Mode</i>	0.0	0.0	0.0	Level #3
<i>Median</i>	1.0	3.0	0.0	Level #3
<i>Standard Deviation</i>	1.3	1.9	5.4	

NCATS Goal #4

The overall category score for translational science **Processes that Promote Quality and Efficiency** across the CTSA continuum was represented at Level #1 with an average of 13.1 (SD = 3.3) out of a range of 0-15. The data diversity of this category was high at 2.8 (SD = 0.6) out of a range of 0-3 data points. The navigation level was high, averaging 4.6 (SD = 0.8) out of a range of 0-5. (See **Table 11**. NCATS Goal #4 Process promoting quality and efficiency).

Table 11. NCATS Goal #4 Process promoting quality and efficiency

<i>NCATS Goal #4 Process promoting quality and efficiency</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	2.8	4.6	13.1	Level #1
<i>Mode</i>	3.0	5.0	15.0	Level #1
<i>Median</i>	3.0	5.0	15.0	Level #1
<i>Standard Deviation</i>	0.6	0.8	3.3	

NCATS Goal #5

The overall category score for translational science **Cutting Edge Informatics** across the CTSA continuum was represented by Level #1 with an average of 11.1 (SD = 2.8) out of a range of 0-15. The data diversity of this category was high with an average of 2.8 (SD = 0.5) out of a range of 0-3 data points. The navigation level was high, averaging 3.9 (SD = 0.7) out of a range of 0-5. (See **Table 12.** NCATS Goal #5 Cutting Edge Informatics Overall Scores)

Table 12. NCATS Goal #5 Cutting Edge Informatics Overall Scores

<i>NCATS Goal #5 Cutting Edge Informatics Overall Scores</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	2.8	3.9	11.1	Level #1
<i>Mode</i>	3.0	4.0	12.0	Level #1
<i>Median</i>	3.0	4.0	12.0	Level #1
<i>Standard Deviation</i>	0.5	0.7	2.8	

CTSA Program Initiatives

At least one of the eight CTSA program initiative was represented by 83% of the CTSA program hub websites. CTSA program initiatives were not represented at all in 17% of the CTSA program hubs websites. Each of the eight program initiative categories was represented in at least one CTSA program hub. The Trial Innovation Network and Smart IRB were the best represented CTSA initiative evaluation categories by being present in 72% and 46% respectively of the CTSA program hub websites. (See **Figure 9. Percentage of Program Hubs with CTSA Program Initiatives**). The diversity of content (data diversity level) implemented by the program hubs websites averaged no more than 1 type of data for 7 of the 8 CTSA initiative categories. The Trial Innovation Network averaged more than one type of data represented in its category (report mean and SD). (See **Figure 10. Average Data Diversity Level for CTSA Program Initiatives**). The average navigation levels of the data for the CTSA program initiatives were less than 2 for 7 of the 8 CTSA initiatives meaning most initiatives were only identified through a free text search or more than 3 clicks away from the home page. The Trial Innovation Network navigation level was greater than 2 making it easier to identify than the other CTSA initiatives. (See **Figure 11. Average Navigation Level for CTSA Program Initiatives**). In average over all ranking, the Trial Innovation Network was the only category that qualified as having a Level #2 representation among CTSA program hub websites. The remaining 7 CTSA program initiatives are at Level #3. (**Figure 12. Average over CTSA program initiative ranking**)

Figure 9. Percentage of Program Hubs with CTSA Program Initiatives

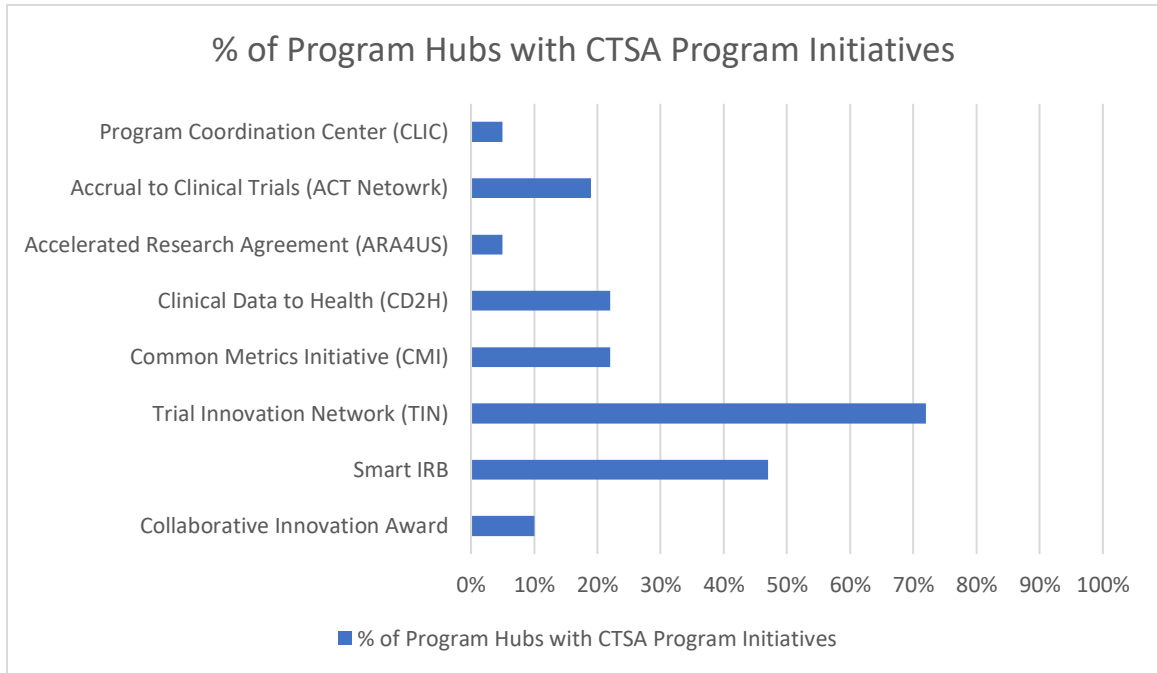


Figure 10. Average Data Diversity Level for CTSA Program Initiatives

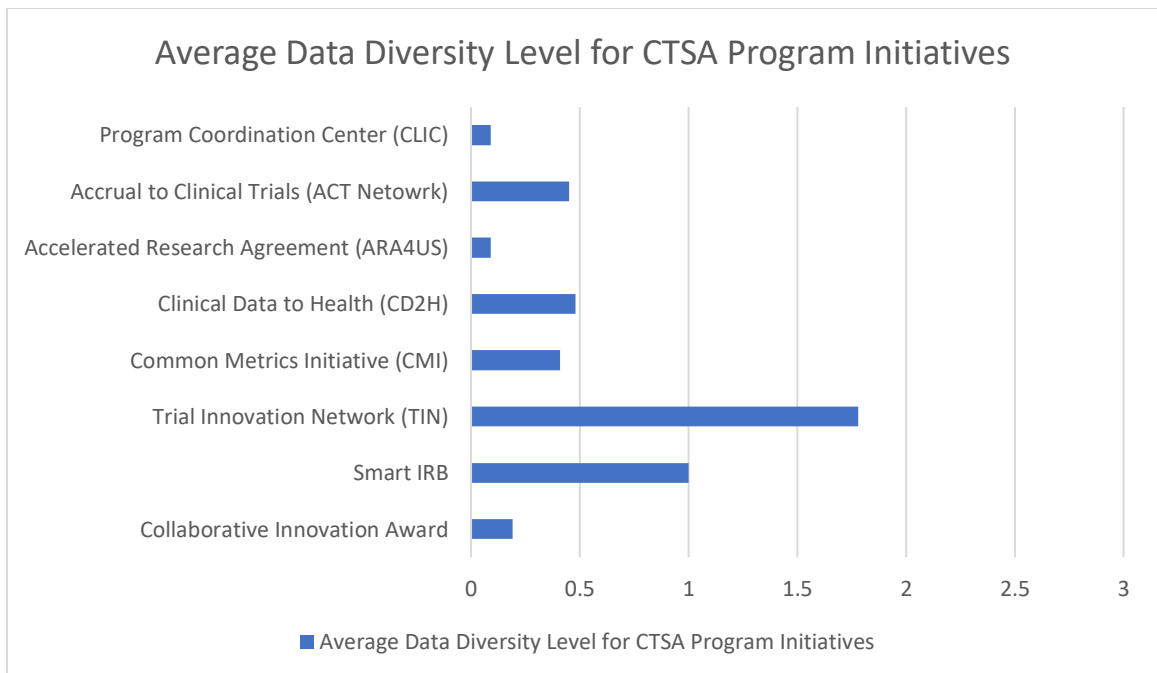


Figure 11. Average Navigation Level for CTSA Program Initiatives

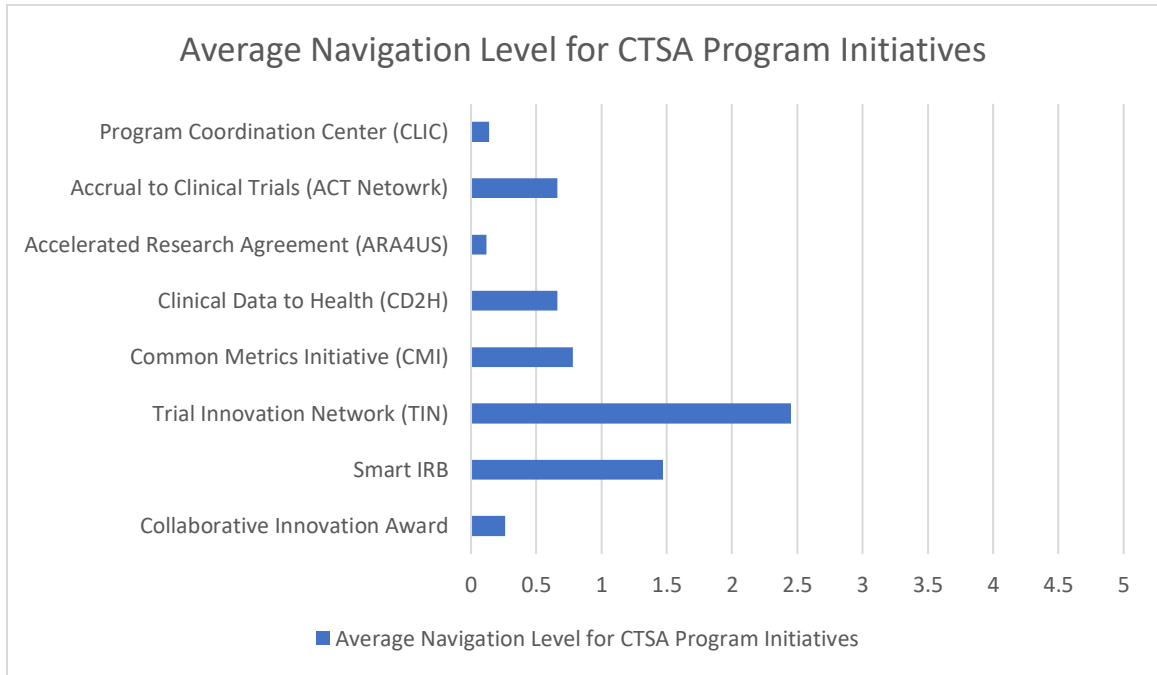
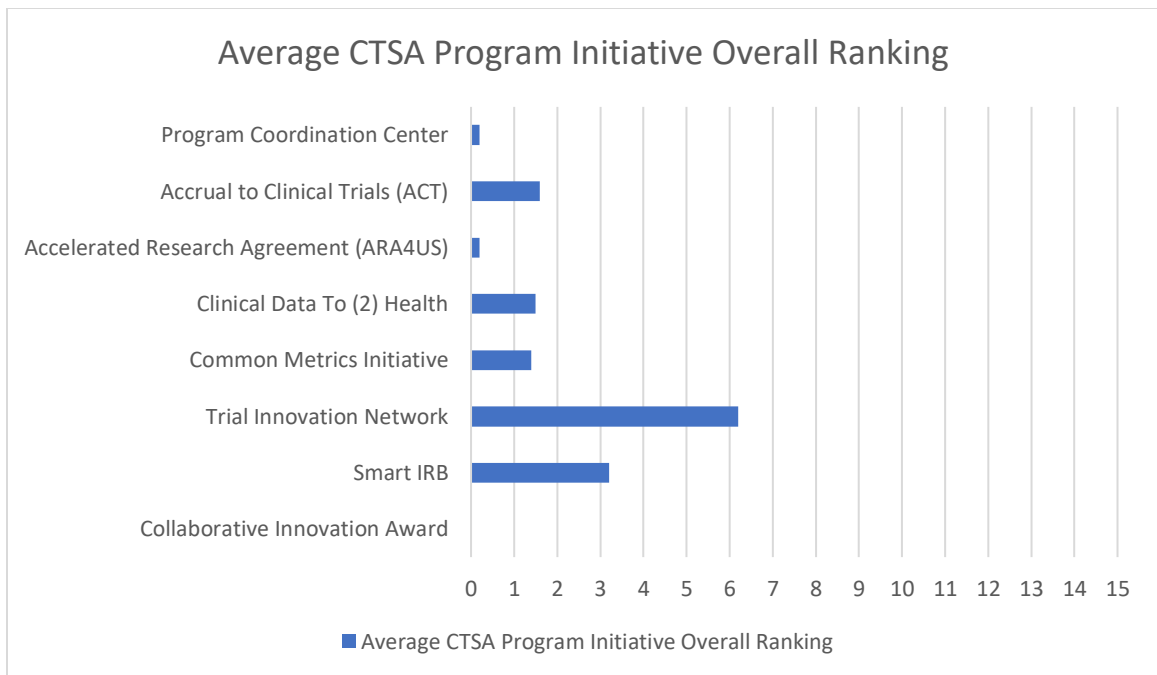


Figure 12. Average over CTSA program initiative ranking



CTSA Initiative #1 Program Coordination Center (CLIC)

The overall category score for the translational science program initiative the **Program Coordination Center (CLIC)** across the CTSA continuum ranked at a Level #3 with an average of 0.2 (SD = 1.2) out of a range of 0-15. The data diversity of this category was low with a score of 0.1 (SD = 0.4) out of a range of 0-3 data points. The navigation level was low, averaging 0.1 (SD = 0.6) out of a range of 0-5. (See **Table 13**)

Table 13. CTSA Initiative #1: Program Coordination Center

<i>CTSA Initiative #1: Program Coordination Center (CLIC)</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	0.1	0.1	0.2	Level #3
<i>Mode</i>	0	0	0	Level #3
<i>Median</i>	0	0	0	Level #3
<i>Standard Deviation</i>	0.4	0.6	1.2	

CTSA Initiative #2 Accrual to Clinical Trials (ACT Network)

The overall category score for the translational science program initiative the **Accrual to Clinical Trials (ACT Network)** across the CTSA continuum needed more representation with a Level #3 ranking and an average of 1.6 (SD = 3.6) out of a range of 0-15. The data diversity average was low as well with a score of 0.5 (SD = 1.0) out of a range of 0-3 data points. The navigation level was low, averaging 0.7 (SD = 1.4) out of a range of 0-5. (See **Table 14**)

Table 14. CTSA Initiative #2 Accrual to Clinical Trials

<i>CTSA Initiative #2 Accrual to Clinical Trials (ACT Network)</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	0.5	0.7	1.6	Level #3
<i>Mode</i>	0	0	0	Level #3
<i>Median</i>	0	0	0	Level #3
<i>Standard Deviation</i>	1.0	1.4	3.6	

CTSA Initiative #3 Accelerated Research Agreements (ARA4US.org)

The overall category score for the translational science program initiative **Accelerated Research Agreements (ARA4US.org)** across the CTSA continuum ranked at a Level #3 with an average of 0.2 (SD = 0.9) out of a range of 0-15. The data diversity of this category was low with a score of 0.1 (SD = 0.4) out of a range of 0-3 data points. The navigation level was low, averaging 0.1 (SD = 0.5) out of a range of 0-5.

Table 15. CTSA Initiative #3 ARA4US.org

<i>CTSA Initiative #3 ARA4US.org</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	0.1	0.1	0.2	Level #3
<i>Mode</i>	0	0	0	Level #3
<i>Median</i>	0	0	0	Level #3
<i>Standard Deviation</i>	0.4	0.5	0.9	

CTSA Initiative #4 Clinical Data to Health (CD2H)

The overall category score for the translational science program initiative **Clinical Data 2 Health (CD2H)** across the CTSA continuum ranked at a Level #3 with an average of 1.5 (SD = 3.5) out of a range of 0-15. The data diversity of this category was low with a score of 0.5 (SD = 1.0) out of a range of 0-3 data points. The navigation level was low, averaging 0.7 (SD = 1.3) out of a range of 0-5.

Table 16. CTSA Initiative #4 Clinical Data to Health

<i>CTSA Initiative #4 Clinical Data to Health (CD2H)</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	0.5	0.7	1.5	Level #3
<i>Mode</i>	0	0	0	Level #3
<i>Median</i>	0	0	0	Level #3
<i>Standard Deviation</i>	1.0	1.3	3.5	

CTSA Initiative #5 Common Metrics Initiative (CM)

The overall category score for the translational science program initiative the **Common Metrics Initiative (CM)** across the CTSA continuum ranked at a Level #3 with an average of 1.4 (SD = 3.1) out of a range of 0-15. The data diversity of this category was low with a score of 0.4 (SD = 0.9) out of a range of 0-3 data points. The navigation level was low, averaging 0.8 (SD = 1.5) out of a range of 0-5.

Table 17. CTSA Initiative #5 Common Metrics Initiative

<i>CTSA Initiative #5 Common Metrics Initiative (CM)</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	0.4	0.8	1.4	Level #3
<i>Mode</i>	0	0	0	Level #3
<i>Median</i>	0	0	0	Level #3
<i>Standard Deviation</i>	0.9	1.5	3.1	

CTSA Initiative #6 Trial Innovation Network (TIN)

The overall category score for the translational science program initiative the **Trial Innovation Network (TIN)** across the CTSA continuum was the highest of the program initiatives just reaching a Level #2 with an average of 6.2 (SD = 5.1) out of a range of 0-15. The data diversity of this category scored a 1.8 (SD = 1.3) out of a range of 0-3 data points. The navigation level averaged 2.5 (SD = 1.8) out of a range of 0-5.

Table 18. CTSA Initiative #6 Trial Innovation Network

<i>CTSA Initiative #6 Trial Innovation Network</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	1.8	2.5	6.2	Level #2
<i>Mode</i>	3.0	4.0	0	Level #3
<i>Median</i>	2.0	3.0	0	Level #3
<i>Standard Deviation</i>	1.3	1.8	5.1	

CTSA Initiative #7 Smart IRB

The overall category score for the translational science program initiative the **Smart IRB** across the CTSA continuum ranked at a Level #3 with an average of 3.2 (SD = 4.5) out of a range of 0-15. The data diversity of this category was low with a score of 1.0 (SD = 1.2) out of a range of 0-3 data points. The navigation level was low, averaging 1.5 (SD = 1.8) out of a range of 0-5. (See **Table 19**)

Table 19. CTSA Initiative Smart IRB

<i>CTSA Initiative #7 Smart IRB</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	1.0	1.5	3.2	Needs more
<i>Mode</i>	0	0	0	Needs more
<i>Median</i>	0	0	0	Needs more
<i>Standard Deviation</i>	1.2	1.8	4.5	

CTSA Initiative #8 Collaborative Innovation Award (CCIA)

The overall category score for the translational science program initiative the **Common Metrics Initiative (CM)** across the CTSA continuum ranked at a Level #3 with an average of 0.5 (SD = 2.2) out of a range of 0-15. The data diversity of this category was low with a score of 0.2 (SD = 0.6) out of a range of 0-3 data points. The navigation level was low, averaging 0.3 (SD = 0.9) out of a range of 0-5. (See **Table 20**)

Table 20. CTSA # 8 Collaborative Innovation Award

<i>CTSA Initiative #8 Collaborative Innovation Award (CCIA)</i>				
	Data Diversity	Navigation Level	Overall	Ranking
<i>Range</i>	0-3	0-5	0-15	See Table 7
<i>Average</i>	0.2	0.3	0.5	Needs more
<i>Mode</i>	0	0	0	Needs more
<i>Median</i>	0	0	0	Needs more
<i>Standard Deviation</i>	0.6	0.9	2.2	

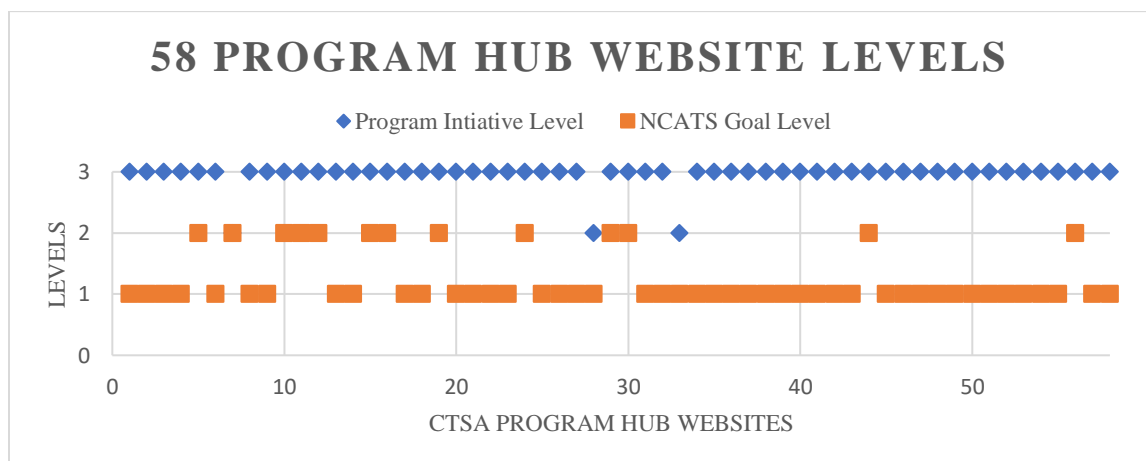
Results: From Big to Small

In big picture of the CTSA website development process, the 58 CTSA program hubs focused principally on NCATS goals rather than CTSA program initiatives. While four NCATS goals were represented well at Level #1, the **Special and Underserved Populations** category was not as well represented and barely reached Level #2. On the other hand, while seven CTSA program initiatives were not well represented by Level #3, the **Trial Innovation Network** was the only category that was able to at least reach Level #2. It is interesting that for the NCATS goals, a Level #2 was the lowest representation in its domain and for the CTSA program initiatives it was the highest representation in its domain. The **Trial Innovation Network** was able to get some type of representation on 72% of CTSA program hub websites while the **Special and Underserved Populations** Categories had representation on 64%. It presented a landscape that showed on a whole, the 58 program hubs seemed to represent the 13 categories along similar lines.

While the results revealed insight on the perceived importance of each of NCATS program goals and CTSA program initiatives in website content by the NCATS CTSA

funded institutions as whole, the comprehensive content evaluation was also able to evaluate the CTSA program from the perspective of each individual 58 program hubs. Granular level results were explored. The results presented detailed information regarding specific program hub website representation. First, they revealed the overall representational differences between the NCATS goals representation and CTSA program initiatives. **Figure 13** shows the disparity between goals and program initiative representation at each program hub by looking how close together the diamond and the square are in one column. In 14 of the 58 program hubs, the website representation between the NCATS goals and program initiatives were only one level apart. In only 2 of the 14 program hubs one level apart did the website represent both the program initiatives and the NCATS goals with at least a Level #2. (See **Figure 13**. 58 Program Hub Website Levels). In the remaining 44 program hubs, the gap between the representation of the 2 domains was greater.

Figure 13. 58 Program Hub Website Levels



Also, on the individual CTSA program hub level, the content evaluation presented a granular perspective of all its offerings relating to NCATS goals and CTSA initiatives. This content evaluation process identified specific gaps in content, data diversity, and navigation in either NCATS goals or CTSA program initiatives for every CTSA program hub website. Results from **Table 21** focused on what the evaluation protocol can reveal to one program hub about its website representation of CTSA initiatives. These specific results presented the *content score*, *diversity level*, and *navigation level* for the eight CTSA program initiatives. These results were recorded from one of the program hub scores. They identified a content gap in the Collaboration Innovation Awards Initiative, the Clinical Data to Health Initiative, the ARA4US website, the ACT Network, and the CTSA Center for Leading Innovation (CLIC). They identified a data diversity gap for the Common Metrics Initiative. They also showed navigation levels can be improved for the Smart IRB. (**Table 21. One CTSA Program Hub (CTSA Initiatives)**).

The results in **Table 22** focused on what the evaluation protocol can reveal to one program hub about its website representation of NCATS Goals. This example revealed there were no content gaps in NCATS goal representation. This CTSA website content evaluation shows only that NCATS Goal #3 Special and Underserved Populations could improve its navigation level through an access link on the website's home page. (See **Table 22. One CTSA Program Hub (NCATS Goals)**).

The overall scores for a single program hub presented in **Figure 14** provided a general understanding of domain representation. This program hub showed a

disparity between representation of the NCATS goals domain and CTSA program initiative domain. (See **Figure 14**. One CTSA Program Hub (Overall Ranking)).

Table 21. One CTSA Program Hub (CTSA Initiatives)

[illegible]

Table 22. One CTSA Program Hub (NCATS Goals)

One CTSA Program Hub (NCATS Goals)																														
Score	NCATS Goals																													
	NCATS #1 - DT	3	NCATS #1- NL	5	NCATS #1 Ranking	15	NCATS #2 - DT	3	NCATS #2 - NL	5	NCATS #2 Ranking	15	NCATS #3 - DT	3	NCATS #3- NL	4	NCATS #3 Ranking	12	NCATS #4 - DT	3	NCATS #4 - NL	5	NCATS #4 Ranking	15	NCATS #5 - DT	3	NCATS #5 - NL	5	NCATS #5 Ranking	15
	Level #3			Level #3			Level #3			Level #3			Level #3			Level #3														

Figure 14. One CTSA Program Hub (Overall Rankings)

One CTSA Program Hub (Overall Rankings)			
Level #1	Item NCATS Goals (Score 10-15)	CTSA Initiatives Ranking	NCATS Goals Ranking
	Overall NCATS Goal (Score 50-75)		
	Item CTSA Program Initiative (Score 10-15)		
	Overall CTSA Program Initiative (Score 80-120)		
Level #2	Item NCATS Goals (Score 5-9)	Level #3	Level #1
	Overall NCATS Goal (Score 25-49)		
	Item CTSA Program Initiative (Score 5-9)		
	Overall CTSA Program Initiative (Score 40-79)		
Level #3	Item NCATS (Score 1-4)	20	72
	Overall NCATS Goal (Score 1-24)		
	Item CTSA Program Initiative (Score 1-4)		
	Overall CTSA Program Initiative (Score 1-39)		

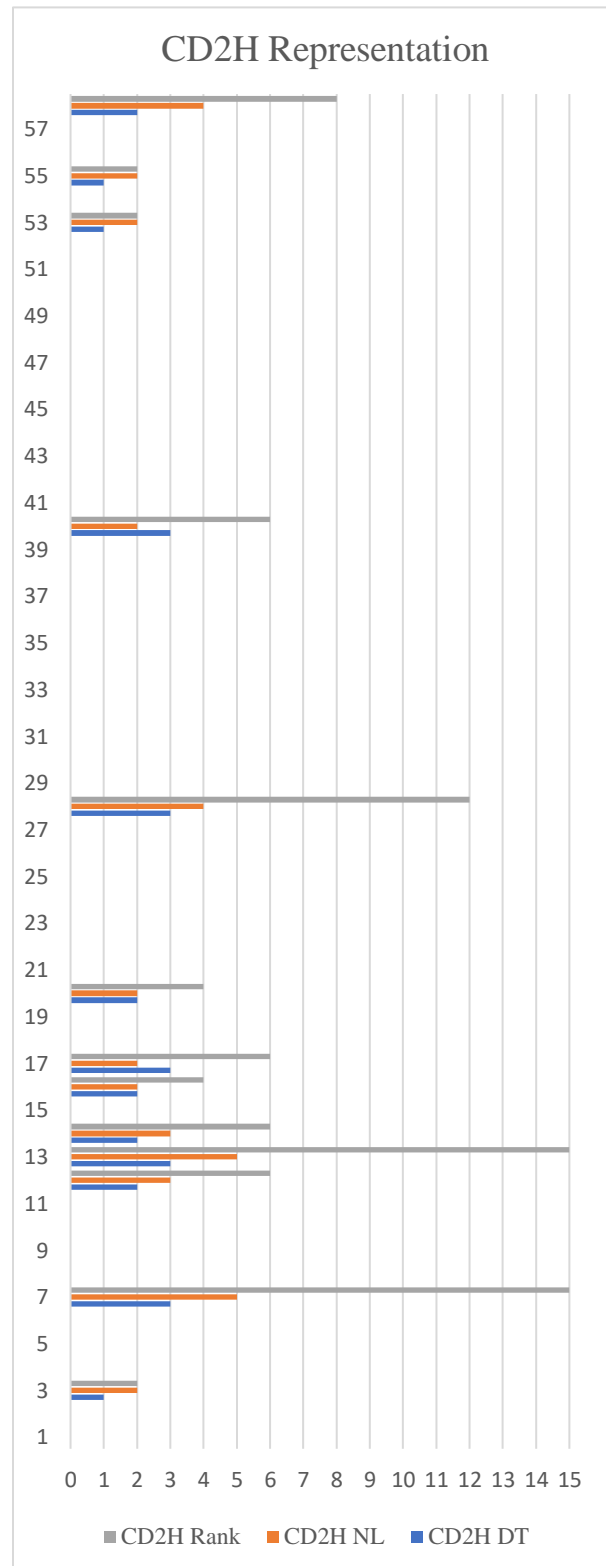
The results represented in **Tables 21**, **Table 22**, and **Figure 14** presented a granular breakdown of *content score*, *data diversity*, *navigation level*, and overall ranking for both evaluation domains (NCATS Goals and CTSA Initiatives). This information makes it possible for program hubs to evaluate their website content alignment with its funding source. This evaluation process if used by each CTSA institution can bring about better alignment across the continuum.

The results also presented granular view of the program goals and initiatives. The results in **Figure 15** provided a content breakdown across the continuum for the Clinical Data to Health (CD2H) program initiative. This information can provide specific details to the CD2H program representation. While Table 16 provided a summary of the results,

the information in **Figure 15** can provide the details. The results indicate which specific program hubs represent the program initiative. It identifies the 8 out of the 13 program hubs that represent the CD2H on their webpage represent it with at least a Level #2. It identifies the 3 program hubs that represent the CH2H with only one data type. It identifies the 7 program hubs where their data is more difficult to find.

These results provide an opportunity for the CD2H to more quickly investigate the different ways their content is presented by knowing which program hubs represent their initiative on their webpage. They also present more direct outreach opportunities for the CD2H to offer more content to the specific program hubs that fall short; or to reach out to introduce the value of their program

Figure 15. CD2H Representation



initiative to those program hubs that have neglected to represent the CD2H on their program hub website.

Supplemental Data Collection

Supplemental data collected related to this research identified additional CTSA program hub website content and functionalities that played a role in identifying or interpreting the content related to NCATS goals and CTSA initiatives. Functionalities included access point for different users and free text searching capabilities.

A small collection of the program hubs delineated the content by type of user. These few websites directed different users such as researchers, community partners, and the public to different access points of the website. (See **Figure 16**. CTSA program hub user directed content). The practice of including different users helps promote a strong community engagement network.

Free text searching capabilities play a role in content identification. Since some program hub websites presented content within text, but had no content sections directly related to it, it made free text searching the best method to locate this information. Many program hub websites provided content for CTSA program initiative websites through news feeds and newsletters. This method provided quality information about CTSA program initiatives, but as the news feed changed or the newsletter became outdated the content became difficult to locate. In this instance the content was also most commonly identified through free text searching.

The free text search functionality was a helpful navigation tool to identify domain and category content that was initially difficult to find. All CTSA program hub websites

offered a free text search option to identify needed content. Data was not collected on the free text searching capabilities for each webpage, but when a new free text search functionality was identified it was recorded. There were program hub websites offered expanded functionalities for their free text search option. One functionality identified included a free text search options that offered advanced search tools that enabled the user to customize the search process. Some program hub website free text search functionalities went outside the parameters of the CTSA program hub website to the entire university while others remained within the program hub website. One website's free text search option did not work.

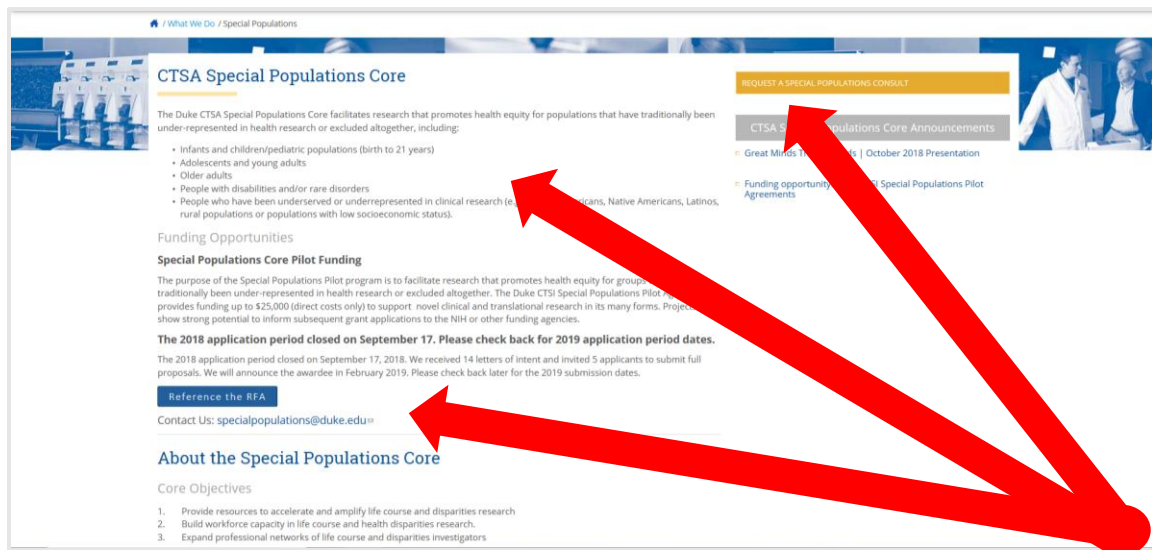
Figure 16. CTSA program hub user directed content.



Exemplar content for underrepresented NCATS Goals

Exemplar content was characterized by content that provided ample program or goal information that also provided interactive content through functionalities such as links and contact information that included either a phone number or email. Exemplar content was identified for each category in both the NCATS goal domain and the CTSA initiative domain. Most of the CTSA program hub websites offered exemplar content for the 4 NCATS goals but did not sufficiently represent the **Integration of Special and Underserved Populations** category. Exemplar content was identified and included in this evaluation to provide evidence of how generally underrepresented categories across the continuum have been thoroughly and consistently represented in a few exemplar CTSA program hub web pages. An example of the highest scoring representation (Level #1) of the NCATS goal for special and underserved populations focuses on the goal as a core and provides content related to funding opportunities, general announcements, and core objectives. It also provides interactive links that enable users to “Request a Special Populations Consult” or “Reference the RFA”. Finally, this exemplar web content provides a contact email for further information. (See **Figure 17**. CTSA program hub website content on Special and Underserved Populations.)

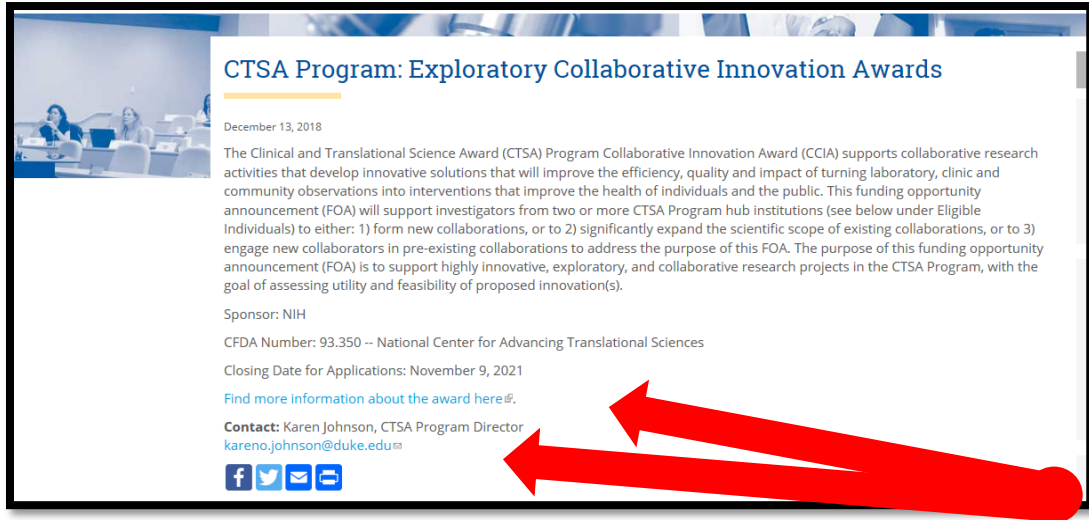
Figure 17. CTSA program hub website content on Special and Underserved Populations



Exemplar content for underrepresented CTSA Initiatives

Exemplar content aligned with the CTSA program initiatives, although available, was more difficult to identify. Exemplar content for the Collaborative Innovation Awards can be seen in Figure 19. This is an example of a consortium-wide underrepresented CTSA program initiative category that is well represented by one of the CTSA program hub websites. The example includes enough textual content to explain what the awards are about, and their value to interested researchers. It offers information on the closing date and provides an interactive link that directs users to: “Find more information about the award here”. It also provides the name and email contact for further information. (**Figure 18.** CTSA program hub website content on Collaborative Innovation Awards).

Figure 18. CTSA program hub website content on Collaborative Innovation Awards



Another CTSA program hub provided outstanding content for the Trial Innovation Network (See **Figure 19.** Exemplar CTSA program hub webpage on the Trial Innovation Network). This example (1) answers appropriate questions regarding the CTSA program initiative, (2) provides 3 different interactive links to the Trial Innovation Network webpage, the NCATS webpage, and “Detailed information on the [Trial Innovation Network] proposal form...”, and (3) offers a links for support and email contacts.

Figure 19. Exemplar CTSA program hub webpage on the Trial Innovation Network

The image is a screenshot of a webpage titled "Clinical Research Resources" under the "Trial Innovation Network" header. The page contains several sections with teal-colored headings: "WHAT IS TRIAL INNOVATION NETWORK?", "WHAT SERVICES ARE OFFERED THROUGH TRIAL INNOVATION NETWORK?", "WHO CAN SUBMIT A PROPOSAL TO TRIAL INNOVATION NETWORK?", and "HOW SHOULD PROPOSALS BE SUBMITTED?". The text describes the network's collaborative nature, the services provided (like budgeting, IRB, and recruitment), and the submission process for proposals. At the bottom, there are two buttons: an orange one for "REQUEST TRIAL INNOVATION NETWORK SUPPORT" and a blue one for "EMAIL TRIALINNOVATION@PENNSTATEHEALTH.PSU.EDU".

Clinical Research Resources

Trial Innovation Network

WHAT IS TRIAL INNOVATION NETWORK?

[Trial Innovation Network](#) is a collaborative initiative of [National Center for Advancing Translational Sciences \(NCATS\)](#) that seeks to address critical roadblocks in clinical trials and accelerate the translation of novel research into clinical practice.

Through its Clinical and Translational Science Award (CTSA) program grant, Penn State has become a member of the Trial Innovation Network, which provides study investigators with a broad range of services and consultations to optimize clinical trials and studies.

These services and consultations are designed to help investigators develop proposals into protocols, optimize study operations and enhance recruitment and enrollment. Trial Innovation Network is a rapidly developing and evolving collaborative initiative that leverages the expertise, skills and knowledge of the entire CTSA Consortium.

WHAT SERVICES ARE OFFERED THROUGH TRIAL INNOVATION NETWORK?

Individual services available include study budget, projected timelines, recruitment and retention plan and materials, initiating a central IRB, study feasibility assessment, standard agreements, community engagement, and electronic health record cohort assessment. A liaison team reviews multi-site project proposals and determines what projects should be submitted to the Trial Innovation Network for further review and consideration.

WHO CAN SUBMIT A PROPOSAL TO TRIAL INNOVATION NETWORK?

All full-time faculty at Penn State can submit.

HOW SHOULD PROPOSALS BE SUBMITTED?

Investigators must contact their local Trial Innovation Liaison Team to discuss their proposal and obtain a brief consultation prior to submission. A consultation with the local Trial Innovation Liaison Team is important because these teams will directly connect the local hubs to the national network and provide advice and input on proposals.

Proposals submitted to Trial Innovation Network should have a strong scientific hypothesis and should be responsive to each section of the Proposal Intake Form. [Detailed information on the proposal form can be found here.](#)

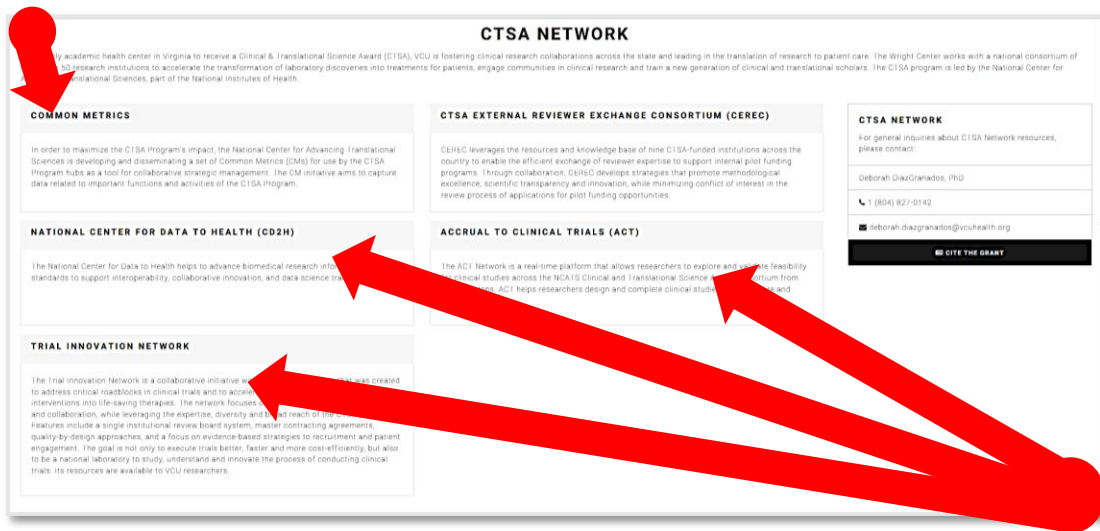
Full-time faculty with questions about the Trial Innovation Network, or who are interested in submitting a proposal, should complete the CTSI Service Request Form.

REQUEST TRIAL INNOVATION NETWORK SUPPORT

EMAIL TRIALINNOVATION@PENNSTATEHEALTH.PSU.EDU

One CTSA program hub webpage introduced and provided Level #3 content on 4 different CTSA program initiatives as a group. This information organization structure illustrated how these program categories could be organized under one topic creating a better understanding of the domain and its categories. Each title on this page is an interactive link to further details on the CTSA program initiative category. There is also a content link for the CTSA program as a network and a contact link for each program category identified. (See **Figure 20.** CTSA program hub website CTSA Network).

Figure 20. CTSA program hub website CTSA Network



Chapter IV

DISCUSSION

Integration of Special and Underserved Populations

Website representation of the integration of special and underserved populations fell short by nearly 40% of all the other NCATS goals. The disparity was the most evident discrepancy among the NCATS domain results. The difference between this NCATS category and the other four is: *who* versus *how*. Looking at the NCATS goal domain categories, the integration of underserved and special populations is the only category that is related to *who* the funding and governing body wants to be certain benefits from this investment. The other four NCATS goal categories (workforce training and education, quality and efficiency in research, community engagement and outreach, and cutting-edge informatics) relate more to *how* they want the funding recipients to go about doing this. Are the CTSA program hub websites inherently addressing the *how* more than the *who* despite genuine internal efforts (albeit private) to integrate special and underserved populations in their research? Are the CTSA program hub websites not reflective of their efforts to integrate the special and underserved populations into research? Should they be?

Translational science that includes special and underserved populations leads to an identification of differences in disease progression and treatment. It can help

geographically challenged communities as well. Including website content that puts a “public face” on *who* a CTSA program hub wants to serve as their special and underserved population can introduce their research audience members to consider research that benefits this population. It can also serve as a community outreach component for the general public audience. Finally, it can cast a light on the diverse special and underserved groups across the continuum for researchers to investigate.

It is interesting to note that of the hubs providing content in the category focused on different special and underserved populations represented different groups depending on the region. A program hub located in southern California focused on Latinos and teens for their special and underserved population. A program hub located in the northern Midwest focused on older adults. If the program hubs had consistently included this topic across the continuum it would be interesting to see if there was an association between the special or underserved populations chosen and the region the hub was in. This would have been an opportunity to show how the heterogeneity of the hubs combined with the common thread of web content can show how the hubs are responding to the particular needs in their community and yield interesting secondary research.

The fact that nearly 40 percent of the program hub websites are devoid of content that does this in a meaningful manner leaves one important website development opportunities for the individual program hubs that have omitted the category.

CTSA Program Initiatives

The results also show a clear disconnect of representation for CTSA program initiatives. More specific data was not available to pinpoint the likely reason, but several possibilities present themselves.

One reason for this overall disconnect may well be that the NCATS goals are seen as more crucial than the CTSA program initiatives. NCATS goals represent the basic institutional criteria needed for the CTSA awards. They are clearly outlined in the funding requirements. The program initiatives are the tools and programs offered and highlighted by the CTSA program to help the awarded institutions reach the NCATS goals. The contrast of website emphasis on the NCATS goal domain rather than the CTSA initiative domain may indicate that the CTSA program hubs see the program initiatives as options or guidelines rather than the concrete means by which they reach the NCATS goals.

Another reason the CTSA program initiatives are underrepresented may be that program hub websites have assessed the initiatives and decided to only highlight the programs or initiatives that are deemed useful to their users. If this were a reason for the underrepresentation, this could lead to actionable responses. First, the CTSA program initiative administrators could look to find pathways to impress upon the CTSA program hubs the value of their initiative to the community and offer tools and content for their program hub websites. Second, the CTSA program initiative administrators could use a survey to investigate the reasons their program initiatives are not better represented and look to either build improvements or find a new approach.

A third reason may be that the CTSA program hubs are unaware of these information gaps in their website design. Program hub websites are information rich. Determining what content to include can be a complex task. Web development task may be farmed out to different program experts. In this process, CTSA administrators may

just be unaware content that would help to align their organization with the funding and governing body was missing. An internal content evaluation along the standard this research presents would effectively resolve CTSA program hub website content gaps along this line.

What is interesting about the CTSA program initiative results is that even though they were not well represented among the program hub websites overall, the eight program initiatives were represented by at least one CTSA program hub website. This tells us that the consortium as a group believed that all the eight program initiatives were significant enough to include content on at least one of the program hub websites.

It should be noted that the NIH does call for a commitment to the national CTSA program initiatives in its CTSA funding. The research plan in the Funding Opportunity Announcement (FOA) for the U54 Clinical and Translational Science Award requires applicants to describe their commitment to innovation in processes and methods in the context of the national CTSA Program as well as requiring a specific commitment to the use of the Trial Innovation Network. [10] This commitment request suggests that CTSA program hub websites might benefit from improving the representation of CTSA program initiatives on their websites. One interesting point is that the Trial Innovation Network is the most referenced CTSA program initiative in the U54 FOA and it is also the most represented CTSA initiative category among the program hub websites with content representation at 72% of the CTSA program hub websites.

Summary of Novel Contributions

The results of the content evaluation generally reveal what is being highlighted by the CTSA program hub websites, and what isn't being highlighted by the CTSA program hub websites. Understanding these basic content questions, allows us to investigate the reason for inclusion and exclusion gaps. These questions can inform a variety of audiences including the CTSA funding and governing bodies, the CTSA program initiative administrators, the individual CTSA program hubs and independent researchers.

The results serve the National Institute of Health and the National Center for the Advancement of Translational Science as the funding and governing bodies respectively of the CTSA program awards. These institutions can use these results to evaluate the level of alignment of funded CTSA program hubs with the NIH and NCATS goals and initiatives for the CTSA. They can also use the results to re-evaluate the purpose and usefulness of the poorly represented CTSA program initiatives and determine if these program initiatives should be better promoted by the consortium or should be reconsidered. Since the content for the 4 NCATS goals were represented in 100% of the program hub website, data rich internal assessments can be done into content presentation practices among the different program hubs. Administrative surveys can be developed to help better understand the integration of special and underserved populations gap.

The results also provide detailed information for each of the CTSA program initiatives. This provides an opportunity for administrators of these program initiatives to re-assess their presentation and outreach through the development and delivery of content or interactive contact links to CTSA program hubs. This strategy provides a roadmap to improve each program initiative's presence across the CTSA continuum.

The results also serve as a guide to website development for each CTSA program hub on an individual level. CTSA program hub web development teams can review their existing content along the lines of this evaluation protocol to be able to understand which goals and initiatives should be included in their website presentation and how they could be represented. The robust content in 4 of the NCATS goals (education and training, patient and community engagement, quality and efficiency in research, and informatics) across the continuum can serve as an opportunity for individual academic medical center departments (such as Informatics or Research) to conduct a thorough review of their counterparts' website representation to understand what their own department's contribution to the program hub and the consortium as a group should be. In this vein, CTSA website development that serves the individual program hub community for a specific department should be partially based on the inclusion of universal tools and information related to the field whether it be cutting edge informatics or quality and efficiency in research. Since these results show all CTSA program hubs represent these areas thoroughly, a review of their content development practice will produce authoritative results. Because the websites are being built under the umbrella of the CTSA consortium a common thread should exist among them, but each program hub should also look to develop website content that contributes unique information and tools as well. A systematic review of the category can identify information and tool gaps within the consortium as a whole, providing pathway opportunities for website content to contribute to the CTSA continuum.

The final audience that can benefit from these results are the independent researchers. To understand the utility of this information we can look back at the

literature reviewed in this field of research. The results inform researchers on which categories have a thorough and content representation among the program hubs. Knowing that 100% CTSA program hubs represent their strategies for at least 4 NCATS goals presents new opportunities for research to begin in these areas using an evaluation of CTSA online program offerings and strategies.

The Bottom Line

CTSA Website Hubs are the informatics tool that distributes research tools and information on approaches to the translation of science. This consortium of program hubs is united by a common funding source with common explicit goals, program initiatives and evaluation metrics. By the nature of their funding directive, they are expected to train their workforce, engage patients and communities for collaboration, improve research methods, integrate special and underserved populations, and introduce cutting-edge informatics. Each program hub website present itself as the virtual opportunity to facilitate these directives. They are not only the public face of the CTSA consortium, but the portal for many to effective and efficient clinical and translational research.

Looking at the components of program hub websites through the lens of this content evaluation ranking system provides valuable insight to the aspirations of the NCATS / CTSA program. It identifies CTSA program hub website's information gaps, content diversity deficiencies, and navigation concerns that relate to their funding source goals and initiatives content.

The outcomes of this research should lead to research, programs, goals or initiatives that (1) help CTSA program hubs unify NCATS translational science messaging, (2) empower users (researchers, community, patients) to leverage a CTSA

program hub website for their unique needs, (3) showcase the many components of translating science, (4) connect users with translational research tools and strategies encouraged by NCATS, (5) deliver comprehensive translational science information and tools to a diverse population.

Data Limitations

One limitation of the data for this research is that it is only representative of the content that each individual CTSA program hub decided to include in their website at one point in time. It cannot be translated to a comprehensive understanding of the program hubs in their entirety. A program hub may have a highly developed initiative for integrating special and underserved populations that is not included on the website. The data culled from that program hub would reflect that there was an information gap in the integration of special and underserved populations when in fact it had a comprehensive program attending to this NCATS goal. So, the reader is strongly cautioned to not assume that because a particular NCATS goal or program initiative is not represented on the website, that it is not being addressed by the local hub.

Another limitation of the data from this research is the website's currency. Website content can evolve and change at any given time. In the duration of the evaluation process of this research, 2 websites redesigned their websites completely. Other websites simply updated their content. An example is that CTSA program initiatives that were highlighted on the home page were no longer found a week later. What can be understood from this research keeping this limitation in mind is that it is a snapshot in time. While subjective redesigning or editing content of 58 different websites

is a limitation in validating the accuracy of the results, the evaluation process can be leveraged to be able to look at changes over time.

Potential Sources for Error

One potential source of error in the data is terminology. Different websites titled different NCATS program goals in different terms and phrases. “Training”, “Education”, “Training Academy”, “Career Development”, and “Workforce Development” were among different terms used for NCATS goal #1. NCATS goal #2, quality and efficiency in research, was represented under many different titles including but not limited to: “Clinical and Translational Resources”, “Research Commons”, “Do Research”, “Investigator Resources”, “Foundations for Discovery”, “Research Tools”, “Support”, “I want to...”, and “CR Assist”. Because representation for each of these goals was identified in 100% of the websites the reason for the mention here is not because there was an actual error, but because these terminologies were an issue in the validation process and are a potential source of error for replicating the process.

Another source of error was the casual placement of NCAT goal or program initiative related information within a website but not directly attributing to the NCAT goal or program initiative. For example, KL2 and TL1 scholar awards are identified as one of the 3 common metric components in the common metric initiative. [54] If a website included content about KL2 or TL1 scholar awards, it was not included as content for the common metric initiative unless the content was either titled under “common metrics “ or “common metrics initiative”, or at least it was aimed at providing tools and information that worked towards explaining, promoting, or achieving the goals within the CTSA consortium’s common metrics initiative.

Future Research

Future research should begin with a pilot project that captures the use of the evaluation tool in a website redesign project. Input from the website design stakeholders should be captured to determine the changes implemented as a result, along with usage metrics to determine the change in website traffic flow before and after the improved content, content diversity and navigation levels for NCATS goals and CTSA program initiative categories.

Additional research should include a study of the impact any web design changes made in the capacity of NCATS goal and CTSA program initiative alignment and improved content diversity and navigation had on website usage metrics among different clinical and translational science users (students, researchers, public, administrators, clinical investigators).

Ideally, future research should lead to evidence that informs the CTSA continuum on recommendations related to the effect of the inclusion of all NCATS goals and CTSA program initiatives in CTSA program hub website design. The theoretical implementation of the evaluation protocols in this research as a CTSA website development checklist would lead to future research that could precisely and more efficiently inform on clinical and translational best practices, tool identification, and information gaps in the areas of integrating special and underserved populations in clinical research, the use of cutting-edge informatics, community engagement, patient recruitment, research collaboration, training and education, quality and efficiency.

Chapter VI

SUMMARY AND CONCLUSION

A content analysis of CTSA websites demonstrates that there are information gaps among award recipient websites that diminish alignment with the NIH and NCATS. The outcome of this research should lead to the eventual adoption and implementation of CTSA website content development along the parameters of this scoring system.

The use of this evaluation process by individual CTSA program hubs can empower website leveraging opportunities for diverse users. Implementing these leveraging opportunities consortium-wide should not only lead to the establishment of a common set of data that aligns (or should align) the consortium among members and with NCATS / CTSA goals and program initiatives, but also should strengthen the CTSA network's capacity.

This research can open the door to a new approach to research into clinical and translational science best practices through the investigation of consortium websites' content, functions, and services. The common set of aligned data arising out of this research should also provide a new data set that enables researchers to better understand the landscape of CTSA institutions' differing programs and approaches to implementing

clinical and translational science in training and education, patient and community engagement, the integration of special and underserved populations, new innovations of methods and processes, and the advancement of cutting-edge informatics.

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