Clinical and Translational Science Awards Program
Coordination, Communication, & Operations Support

CTSA Program Webinar

September 27, 2023

National Center for Advancing Translational Sciences

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UNIVERSITY of ROCHESTER

Agenda

TIME	TOPIC	PRESENTERS
2:00 PM ET	Welcome	Beck Lazelle, PhD *CCOS*
2:01– 2:15 PM	NCATS/CTSA Updates	Mike Kurilla, MD, PhD Director, Division of Clinical Innovation NCATS
2:15 – 2:20 PM	Call for Publications JCTS	Cynthia Vinson, PhD, MPA *Senior Advisor for Implementation Science, NCI*
2:20 – 2:35 PM	Clinical Research Workload and Complexity WG Report out	Allison Norful PhD, RN, ANP-BC, FAAN *Assistant Professor, Columbia University* Bernadette Capili PhD, NP-c *Director, Heilbrunn Family Center for Research Nursing at The Rockefeller University*
2:35 – 2:55 PM	SPARCRequest	Royce Sampson MSN, RN, CRA *Director, Office of Clinical Research at Medical University of South Carolina* Jillian Harvey PhD, MPH *Evaluation Director, Medical University of South Carolina*
2:55-3:00 PM	CCOS Updates	Kerry James, MPH PMP *CCOS*
3:00 PM ET	Adjourn	

NCATS

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NCATS/CTSA Program Updates

Michael Kurilla, MD, PhD

Director, Division of Clinical Innovation

NCATS

September 28, 2023

NIH National Center for Advancing Translational Sciences

NIH Director Nomination

- President Biden Announced Nomination of **Dr. Monica Bertagnolli** in May

- Senate HELP Committee to hold a confirmation hearing on the nomination

- Next steps following confirmation hearing:
  - Senate HELP Committee Vote
  - Full Senate Confirmation Floor Vote

NCATS Advisory Council – September 28

- **Agenda:**
  - 1:00 Director's Report
  - 2:00 Renee Wegrzyn: ARPA-H The Mission
  - 2:30 Break
  - 2:45 Clearance of Concepts: Presentation and Discussion
  - 3:10 Program Update: Division of Clinical Innovation
  - 3:45 Program Update: Office of Drug Development Partnership Program
  - 4:45 Clearance of Concepts: Presentation and Discussion
  - 5:40 Adjourn
- **NIH Videocast Link:** https://videocast.nih.gov/watch=52212

List of CTSA Partners Updated with FY23 UM1s September 2023

- For the purposes of **PAR-21-293**, NIH funding to the **Partner/Partnering Institution is used for determination of maximum direct cost budget requests**. NOT-TR-22-032
- Partner/Partnering Institution(s) must be effectively integrated into the proposed activities of the CTSA UM1 hub and are necessary for attaining its strategic goals and research priorities.
- An organization named as Partner/Partnering Institution in a CTSA UM1 application (and subsequent UM1 award), or a CTSA UL1 award funded previously under **PAR-18-940**, **PAR-18-464** or **PAR-15-304** may be listed as a Partner with only one UM1 or UL1 unless the UM1 and UL1 are from the same organization.
- The list of Institutions that are partners of CTSA Program hubs in FY22 are the following:

- **CTSA Partner List - FY22 (updated 9.1.2022)** (PDF - 135KB) TO BE REPLACED with FY23 list upon NCATS website update. FY23 partner list emailed to all CTSA PIs and Administrators on 9.25.2023

Any updates/changes must be requested by the institution's AOR to the NCATS Grants Specialist

https://ncats.nih.gov/ctsa/funding/CPUBRT

National Center for Advancing Translational Sciences

Seeking New CTSA Program Steering Committee Members!

- NCATS is seeking **5 UL1/UM1 PIs** to serve on the committee for the next 2-3 years (2024-2027).
- If you would like to self-nominate or suggest a fellow PI, please submit the PI name, institution, and brief explanation by **Wednesday, October 18th** here

The eligibility criteria for SC appointments:

- A PI must be officially named in the Notice of Grant Award of an active CTSA.
- The PI's hub award must have at least 3 years remaining during the project period.
- The PI has not served on the SC since December 2017

National Center for Advancing Translational Sciences

Notice of Special Interest: NOT-TR-23-026
Advancing Recruitment through the Trial Innovation Network (AR-TIN)

- **Purpose:** To design, develop, demonstrate, implement, and evaluate digital and non-digital innovative tools and resources to improve participant recruitment in clinical trials
- **NOSI/NOFO:** NOT-TR-23-026 / PAR-22-167 UG3/UH3
- **Budget:** may not exceed $650K direct costs per year for up to 5 years
- **Receipt Dates:** October 17, 2023; February 15, 2024; June 18, 2024; October 17, 2024
- **Tools and resources of interest include, but are not limited to:**
  - methods to improve disease progression modeling to advance the use of participant-based information that will inform safety and efficacy,
  - tools and resources that advance the digitalization of clinical trials activities,
  - innovative ways to incorporate clinical and demographic characteristics of intended populations in the absence of self-identification,
  - improving rural inclusion in centralized and decentralized clinical trials,
  - user-friendly dynamic model on the inclusion/exclusion criteria and its impact on participant recruitment in clinical trials
  - proposals that explore the utilization of artificial intelligence (AI) and other digital-based technologies to increase and improve participant recruitment in clinical trials.
- Awardees will be members of the Trial Innovation Network
- **NCATS POC:** Ken Wiley, Jr., Ph.D., Email: ar-tin@nih.gov

2024 Supporting Instructions for CTSA RPPRs

CTSA Specific Instructions for UL1, KL2, and TL1:

- Minor changes compared to the prior year (see page 5 in PDF)
- Download the PDF and open on your computer (NOT in your browser) to access the attached appendices
- Access here: https://ctsa.ncats.nih.gov/governance-guidelines/guidelines/rppr-instructions/

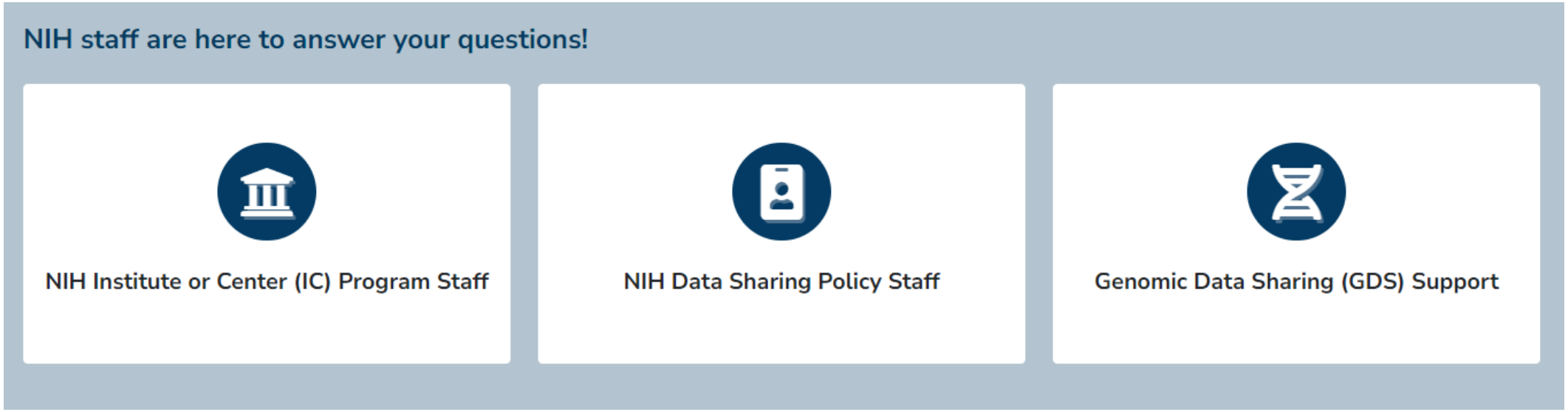
CTSA Specific Instructions for UM1: (in progress)

- Guidance on reporting for Element E research projects
- Section G reporting of EAB/EAC, Pilots, Collaborators will be retained

Other new CTSA mechanisms K12/T32s/R25/RC2: (in progress)

- K12 / T32s: Use NIH RPPR instructions **WITH** Appendix 3: Training Individual Progress Report (formatted table)

NIH Data Management and Sharing Policy Reminder



NIH Data Sharing Policy Staff

- Contact our central mailbox for questions about NIH Sharing Policies including the new Data Management and Sharing Policy sharing@nih.gov

NEW NIH Application Instruction Updates – DMS Costs (NOT-OD-23-161)

- DMS costs may be requested in many cost categories; no longer required to have a single DMS cost line item

National Center for Advancing Translational Sciences

2023 National Diversity in STEM Conference

- **Dates:** October 26-28, 2023 in Portland, Oregon
- **Conference:** Society for Advancement of Chicanos/Hispanics & Native Americans in Science (SACNAS) National Diversity in STEM Conference.
- **CTSA Program Staff Attendees:** If you or someone in your program—such as scholars, trainees, and/or R25 participants—would be interested in meeting with CTSA Program staff, please contact:
  - Jamie Doyle (jamie.doyle@nih.gov)
  - Andrew Louden (andrew.louden@nih.gov)

National Center for Advancing Translational Sciences

CTSA Community of Practice (CoP) to Advance Mentorship Inaugural Event

- Provide individuals in the CTSA and wider community with access to information and research about evidence-based mentorship education, mentorship policies and practices, and assessment strategies.

- **WEBINAR:** Barriers and Supports to Advancing a Culture of Mentorship
  - Tuesday, October 17th, 2023; 10:00 - 11:15 AM PT / 12:00 - 1:15 PM CT / 1:00 - 2:15 PM E
  - https://uwmadison.zoom.us/j/99079257721?pwd=dWdTN0xlY3RxVGkyM2xXUHJ2TFhFUT09&from=addon
  - Meeting ID: 990 7925 7721; Passcode: 721064

- **AGENDA:** (75 min)
  - Overview of the CTSA-led Community of Practice to Advance a Culture of Mentorship Presentation: Barriers and
  - Supports to Advancing a Culture of Mentorship
  - Small Group Discussions and Report Outs
  - Sharing CoP Resources and Ways to Engage
  - Q&A

- **CONTACT:** Dr. Melissa McDaniels, CoP Lead, mmcdaniels@wisc.edu

National Center for Advancing Translational Sciences

Request for Information: NOT-OD-23-180

- **Request for Information (RFI):**
  - Inviting Comments and Suggestions on Opportunities and Challenges for the Collection, Use, and Sharing of Real-World Data (RWD) including Electronic Health Records, for NIH Supported Biomedical and Behavioral Research NOT-OD-23-180
- **Issued by:** NIH Office of Data Science Strategy (ODSS)
- **Purpose:**
  - To solicit public comments on the use of Real-World Data (RWD), including Electronic Health Records, for Biomedical and Behavioral Research.
- **Suggested Topics:**
  - Scientific value and quality considerations for collection, use, and sharing of RWD in biomedical and behavioral research.
  - Using RWD as part of the scientific paradigm, including open science, scientific rigor and reproducibility, and team science.
  - Administrative and logistical considerations for collecting, using, and sharing RWD for biomedical research.
  - Ethical considerations for using RWD for biomedical and behavioral research.
- **Response due:** December 14, 2023: submission website: datascience.nih.gov/rfi-rwd
- **Inquiries:** NIH Office of Data Science Strategy RWD-rfi@od.nih.gov

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NCATS 2024 Strategic Plan

Current NCATS Strategic Plan (Fall 2016): https://ncats.nih.gov/strategicplan

If you have feedback for the NCATS 2024 strategic plan, please send comments to:

NCATS2024StrategicPlan@nih.gov

NEW! Request for Information (RFI): Inviting Input on NCATS' Strategic Plan for 2024-2029 (NOT-TR-23-027)
Responses accepted through November 1, 2023

National Center for Advancing Translational Sciences

Notice of Award (NoA) Delays

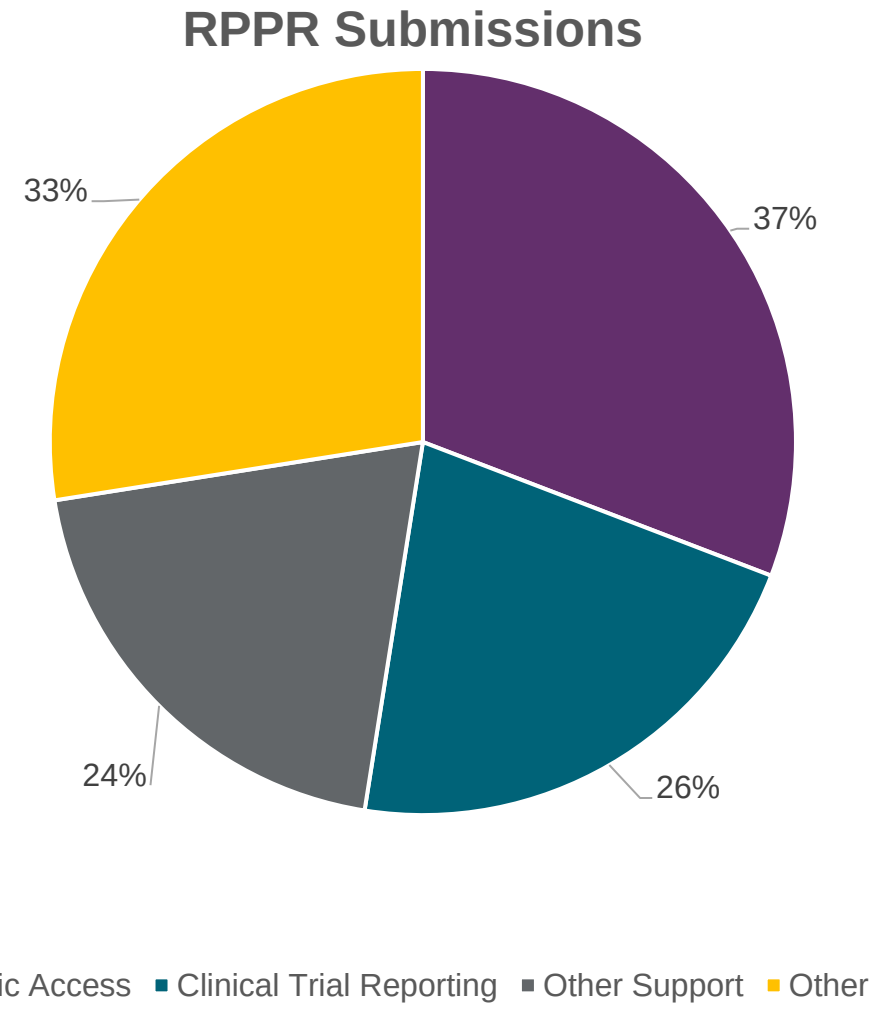
- Non-competing grant applications are considered awarded on time if the NoA is issued prior to or on the budget period start date.
- NIH cannot issue a NoA until all compliance issues are resolved and/or NIH provides the option to the NIH Institute/Center/Offices to issue restricted awards.
  - If a recipient fails to comply with the terms and conditions of award, NIH may take enforcement action including disallowing costs, withholding of further awards, or wholly or partly suspending the grant, pending corrective action.
  - Compliance concerns resulting in special award actions are required to be reported to the NIH Office of Policy for Extramural Research Administration (OPERA).
  - Compliance resolution requires substantial staff time from all parties involved.

Research Performance Progress Report (RPPR) Reviews

- All FY23 non-competing UL1 RPPR application submissions were analyzed.
- 28% of the RPPRs reviewed did not include any non-compliance concerns.
- Most RPPRs without non-compliance concerns resulted in NoAs issued prior to the budget period start date. (Note – two were issued within 4 days of the budget period start date to accommodate for new prior approval request submissions.)

Non-Compliance Delays

- There is a direct correlation between non-compliant RPPR submissions and late NoAs.
- 72% of UL1 RPPR applications were submitted with a non-compliance concern requiring resolution prior to award.
- 48% included more than one non-compliance concern.
- NoA delays stemmed from 1 – 112 days late.
- Three major areas of non-compliance – public access, clinical trial reporting, and other support.



Moving Forward…Working Together

- UL1/KL2/TL1 are linked applications meaning the review must be conducted simultaneously which also means that non-compliance or concerns on one component application impacts the others causing additional delays.
- The new suite of Notice of Funding Opportunities (NOFOs) will be subject to independent reviews and award actions.

NCATS Support:

- Additional guidance will be provided over the next few months for the three primary areas of compliance concern.
- Orientation discussions will be held with all new UM1 recipients to better understand and assist with individual Hub challenges.
- More proactive communication will be provided directly with individual Hubs on compliance concerns, resolutions, and enforcement.

Upcoming Dates to Remember

Next CTSA Program Webinar

October 25, 2023; 2-3 PM ET. Register here.

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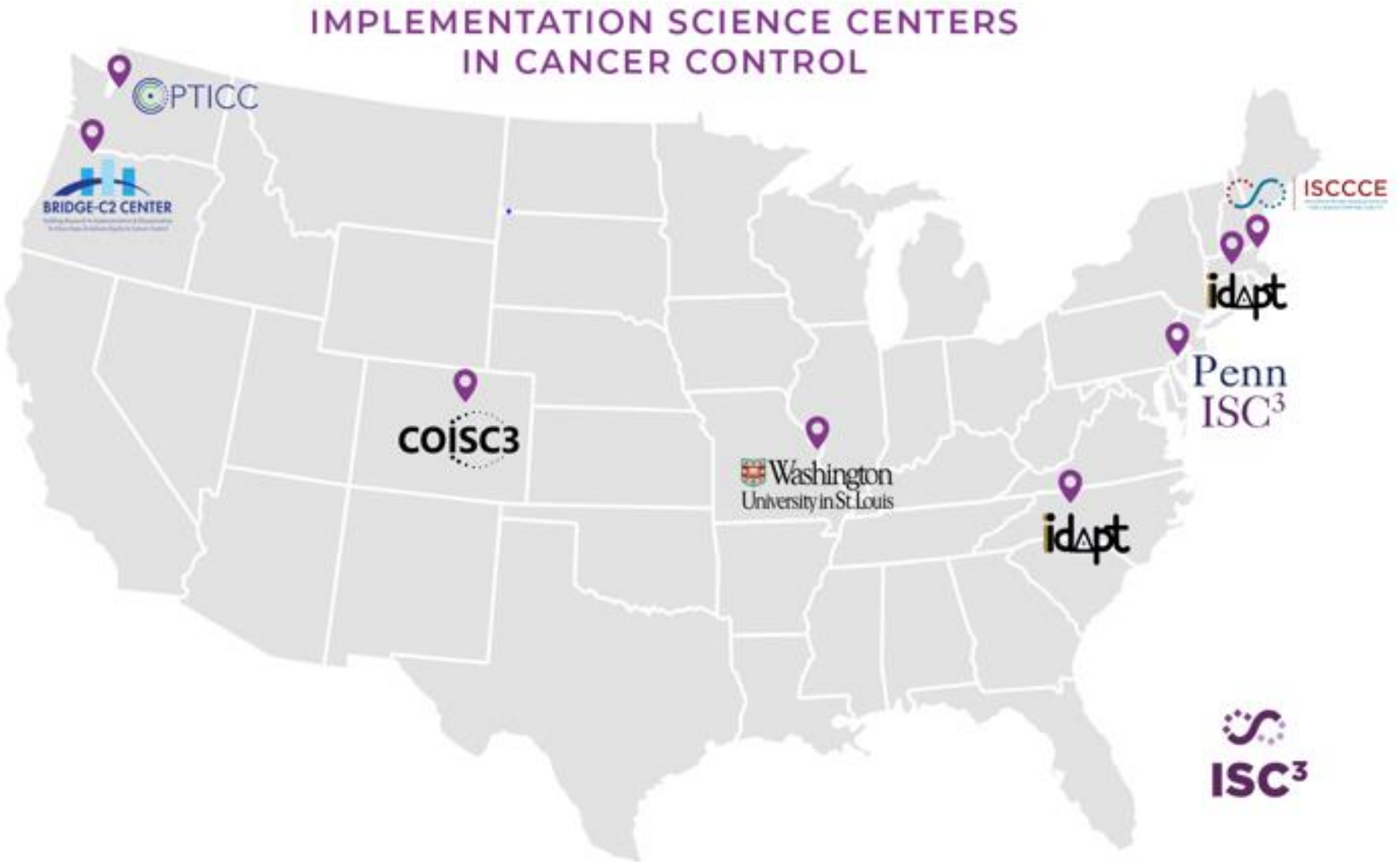
National Center for Advancing Translational Sciences

Journal of Clinical and Translational Sciences Themed Issue on Impact Measures in Implementation Science

Cynthia A. Vinson, PhD, MPA
Senior Advisor for Implementation Science

NIH NATIONAL CANCER INSTITUTE

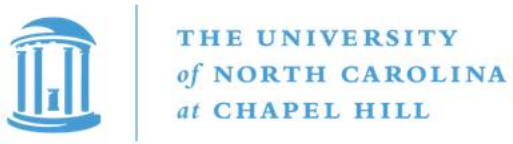
Origin of the Themed Issue



PI/MPI	Institution(s)	Themes	Implementation Labs (iLabs)
Karen Emmons Elsie Taveras	Harvard	Health equity Cancer screening	Federally Qualified Health Centers
Jennifer DeVoe Nathalie Huguet	Oregon Health & Science University	Underserved populations Cancer prevention	Primary care Safety net clinics
Russell E. Glasgow	University of Colorado	Pragmatic research Cancer prevention	Rural primary care practices
Rinad Beidas Justin Bekelman Robert Schnoll	University of Pennsylvania	Behavioral economics Equitable implementation Cancer care delivery	Hospitals Community-based practices
Bryan J. Weiner Margaret Hannon	University of Washington	Methods, measures Cancer treatment and care	Primary care clinics, health systems, cancer centers, local/state health departments
Kristie Long Foley Thomas Houston Sarah Cutrona	Wake Forest University of Massachusetts	Technology-assisted implementation Intervention adaptations Cancer control	Primary care practices Cancer centers Community-oncology practices
Ross C. Brownson Graham A. Colditz	Washington University in St. Louis	Sustainability Systems science Cancer control	FQHCs, primary care, health departments, community organizations

Journal of Clinical and Translational Science Themed Issue

- Focus: Advancing Understanding and Use of Impact Measures in Implementation Science
- Areas of interest:
  - Descriptive studies on the application of impact measures (e.g., TSBM) in clinical, community, economic or policy to document impacts of implementation science;
  - Case studies of how impact measures have been used to measure outcomes in implementation science projects across a wide range of health conditions (e.g., cancer, diabetes, heart disease, mental health, infectious diseases) and contexts (e.g., policy, community evaluation, healthcare delivery, etc.);
  - Papers that focus on extensions or modifications to existing impact measures (e.g., TSBM) to account for additional categories of impact that are not as clearly delineated in the base model;
  - Identifying measures of implementation science impact beyond academic metrics; and
  - Developing approaches that will further build a focus on health equity into assessment of implementation science impact.
- Submissions due: February 15, 2024



CTSA Working Group:
Clinical Research Study Complexity Assessment

Goals of the Presentation

- Provide an overview of the *Study Complexity Workgroup* project
- Discuss data obtained from
  - Phase 1 – Content, Face, and Cognitive Validity
  - Phase 2 – Inter-rater Reliability Testing
- Summarize the next steps and dissemination plans

Background of the Project

- Barriers and challenges to developing and implementing clinical research.
  - Complex regulatory requirements
  - Restrictive eligibility criteria
  - Specific study timelines
  - Limiting funding
  - Appropriate staffing

Goals of the Project

- Identify the dimensions and attributes of clinical research complexity.
- Develop a scoring rubric to scale clinical research study complexity.
- Establish the initial psychometric properties of an instrument that aims to measure clinical research study complexity.

Available Tools for Study Complexity

- Methods of evaluate clinical research study complexity are scant.
- Available tools are specific to oncology research
  - Ontario Protocol Assessment Level
  - Wichita Community Clinical-Trial Oncology Protocol Acuity
  - NCI Trial Complexity Elements and Scoring Model

Processes Used in Clinical Research Studies

- Logistics/feasibility of protocol
- Protocol approvals
- Work with multiple departments (i.e., radiology, pharmacy, laboratory)
- Participant recruitment, screening, study visits, follow-ups
- Communication with sponsors, team members, study participants

Dimensions of Scaling Study Complexity

Structure			Process		Outcomes
Environment	Personnel	Resources	Procedures	Team-based processes	Study Outcomes
• Ample physical space in primary institution to conduct study procedures • Institutional and Stakeholder Support • Access to external environments required to conduct study procedures (if applicable)	• Research team size/composition • Research team experience level • Proposed investigator effort/allocation of time to complete study • Access to support staff to carry out study procedures	• Required equipment & supplies to carry out procedures • Sufficient funding	• Study procedures (*core elements) • Feasibility of recruitment and enrollment, the sample size • Number of study arms - registration or randomization steps - complexity of the intervention - length of study (number of study visits) - data collection complexity - follow-up requirements - personnel impact (number of staff to coordinate study) • Feasibility of timeline for study completion	• Delineated roles and responsibilities for each study team member • Measures of accountability for task completion • Conflict resolution	• Novel evidence produced that warrants investigation and future research • Plan for feedback and evaluation of methodologic success needed for subsequent study planning

* Adapted from NCI Trial Complexity Elements; Model adapted from Donabedian's Quality Model

Original NCI Trial Complexity Elements and Scoring Model

Element Number	Study Element
1	Study Arms
2	Informed Consent Process
3	Registration or Randomization Steps
4	Complexity of Investigational Treatment (Tx)
5	Length of Investigational Tx
6	Feasibility & Personnel Impact
7	Data Collection Complexity
8	Follow-up Requirements
9	Ancillary Studies (includes correlative studies, imaging)
10	Participant Feasibility & Enrollment

Heilbrunn Research Complexity Index

Element Number	Study Element
0	Pre-Study Prep
1	Study Design
2	Recruitment
3	Informed Consent
4	Randomization
5	Intervention/Dosing
6	Research Team
7	Data Collection
8	Follow-up Requirement
9	Data Analysis
10	Dissemination

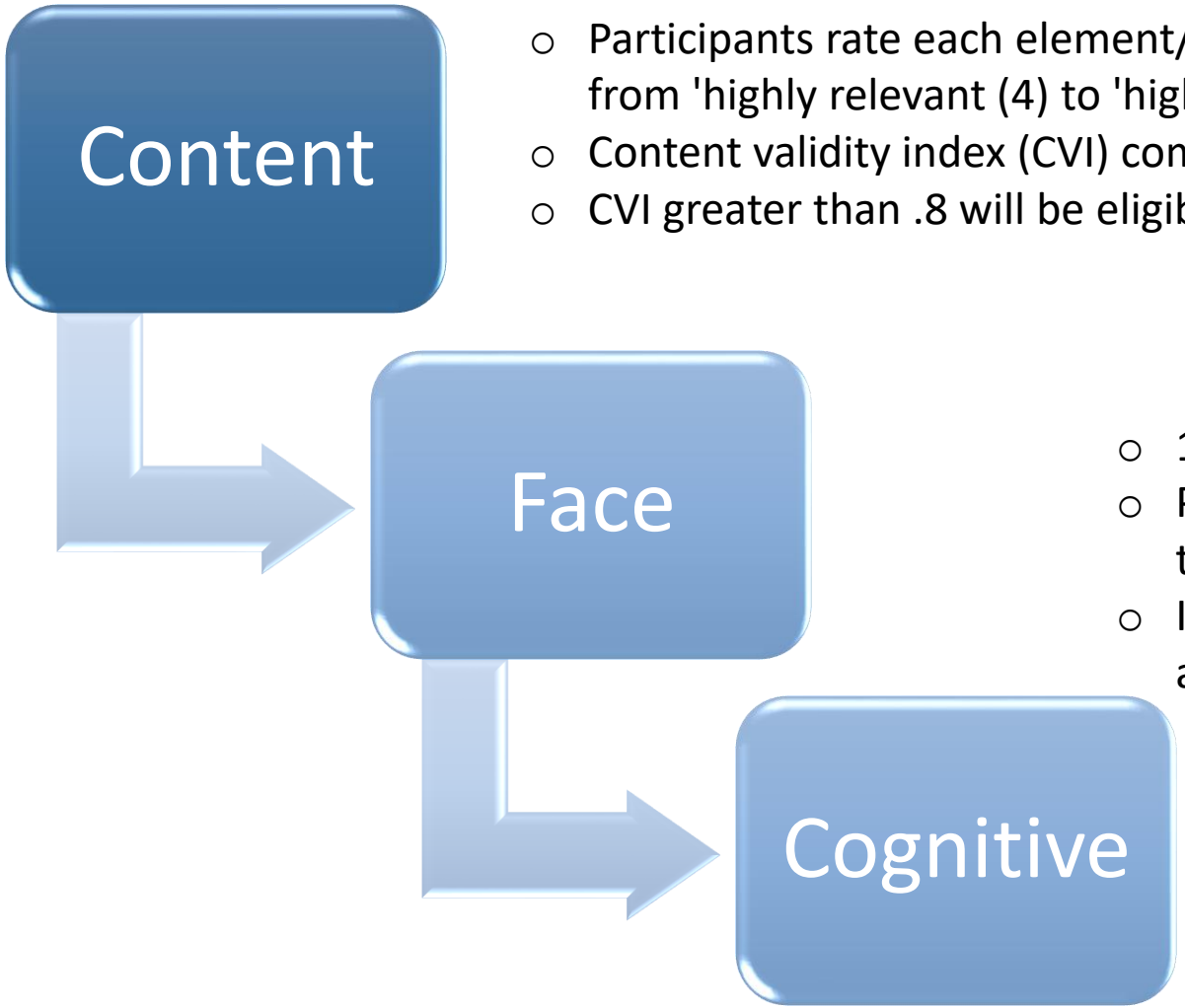
Content, Face & Cognitive Validity

Phase 1

- Content, Face, and Cognitive validity testing
- N = 6 Targeted

Eligibility Criteria

- Engaged in clinical research for five years or more
- Experience in preparing, directing, or coordinating clinical studies sponsored by industry, foundation, and/or government
- Certified in Good Clinical Practice
- Completed training in research, ethics, and compliance



- Participants rate each element/response tier 4 point Likert-type scale ranging from 'highly relevant (4) to 'highly irrelevant' (1).
- Content validity index (CVI) computed.
- CVI greater than .8 will be eligible for inclusion and further psychometric testing

- 1:1 interviews
- Participants asked to read each item aloud and interpret the intended element and response options
- Iterative revisions with each subsequent interview until agreement reached

CTSA Clinical & Translational Science Awards Program

CLIC Center for Leading Innovation & Collaboration
clic-ctsa.org

Resize font:

Clinical Research Workload and Study Complexity Assessment

Section A: Pre-Study Preparation

On a scale from 1-4, how **relevant** is the *Selection of Measures* item? (1= extremely irrelevant, consider removal; 2= somewhat irrelevant, major revision recommended; 3=slightly irrelevant, minor revisions recommended; 4= extremely relevant, no revisions recommended).

	1	2	3	4	
1. Selection of Measures (e.g. validated measures to the target population, translated, number of measures needed)	○	○	○	○	reset
Tier 1 (1 point): -1 measure -Validated in population	○	○	○	○	reset
Tier 2 (2 points): -2 to 3 measures -Not validated in population	○	○	○	○	reset
Tier 3 (3 points): -4 or more measures -Unknown validity of measures	○	○	○	○	reset

On a scale from 1-4, how **clear** is your understanding of what *Selection of Measures* is measuring? (1= extremely unclear, consider removal; 2= somewhat unclear, major revision recommended; 3=slightly unclear, minor revisions recommended; 4= extremely clear, no revisions recommended).

Phase 1 Results

- Content Validity (n=7)
  - CVI .42-1.0
  - 34 elements/tiers fell below 0.8 threshold
  - New Instrument development justification
- Face & Cognitive Interviews (n=8)
  - Iterative revisions of elements and tiers
  - Goal: Inclusive of all study design and elements of research

25 Elements

- Selection of Study Instruments
- Physical equipment
- Budget Preparation
- Consultant Agreements
- Facilities or vendor agreement
- Multiple PI agreements
- Hiring and Job Descriptions
- Study Arms
- Access to Target Population
- Vulnerable Populations
- Participant Eligibility
- Incentives
- Informed Consent
- Randomization
- Type of Intervention
- Intervention Administration
- Research team
- Data Collection (Procedures)
- Data Collection (Frequency)
- IRB Prep
- Compliance Reporting
- Expected AE/Safety
- Follow up
- Statistical Analysis
- Dissemination

HEILBRUNN RESEARCH COMPLEXITY INSTRUMENT:
The purpose of this instrument is to scale the complexity of a research protocol.
For each of the following elements, circle which level best fits the protocol.

Study Element	1 point	2 points	3 points
Selection of Study Instruments (e.g., surveys, tools)	1 instrument ***and*** Instruments validated in population	2 to 3 instruments ***or*** Instruments valid but not validated in targeted population ***or*** At least 1 case report form; simple; 1-page form	4 or more instruments ***or*** Unknown validity ***or*** 2 or more case report forms that require multiple categorization; multiple pages
Physical Equipment	Not applicable ***or*** Usual or standard care equipment (e.g. thermometer, ECG)	New to study team ***or*** Some learning required	Complex equipment in learning ***or*** Calibration needed
Budget Preparation/ Approvals	2 or fewer authorizers	3-4 authorizers	5 or greater authorizers
Consultant Agreements	Consultant Agreements (0)	Consultant Agreements that include different roles for each person (1-3)	Consultant Agreements that include different roles for each person (4 or more)

Phase 2

- Pilot testing to establish initial reliability
- Instrument built into REDCap
- Participants score 2 independent clinical research protocols
- N = 30 (Target)

Eligibility Criteria

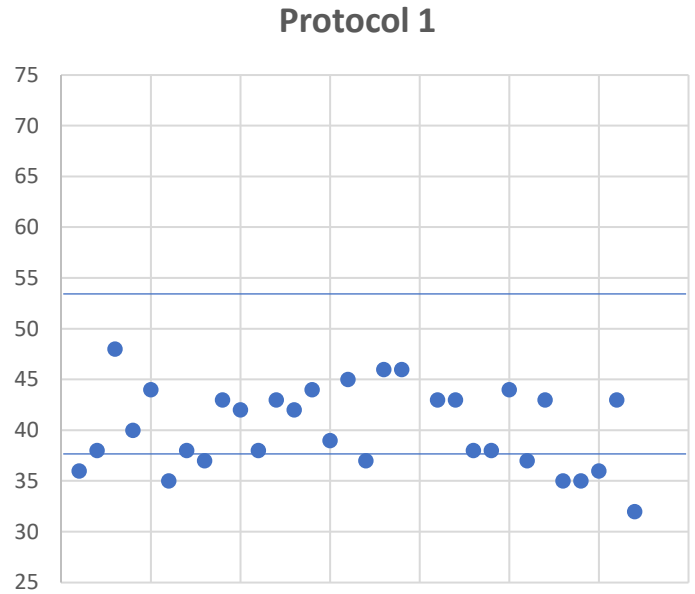
- engaged in clinical research for five years or more
- experience in preparing, directing, or coordinating clinical studies sponsored by industry, foundation, and/or government
- certified in Good Clinical Practice
- completed training in research, ethics, and compliance

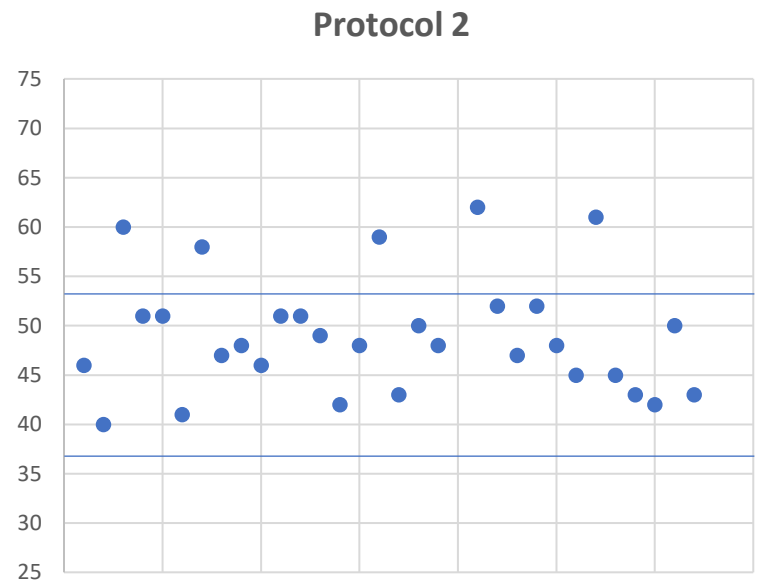
Data analysis: Descriptives (item mean/SD), % agreement; Fleiss Kappa statistic for inter-rater reliability

Phase 2: Pilot Testing

Phase 2 results

- **N=31 participants**
- **Potential Range 25-75 points**
- **Protocol 1 composite score range 32-48**
- **Protocol 2 composite score range 40-60**





Agreement on Individual Categories[a]

Rating Category	Conditional Probability	Kappa	Asymptotic Standard Error	z	Sig.	95% Confidence Interval Lower Bound	95% Confidence Interval Upper Bound
1.00	.502	.216	.010	20.873	.000	.196	.237
2.00	.503	.122	.010	11.792	.000	.102	.143
3.00	.427	.282	.010	27.184	.000	.262	.302

a. Sample data contains 31 raters.

	Protocol 1			Protocol 2		
Element	1	2	3	1	2	3
Selection of Study Instruments	0.00%	22.58%	77.42%	0.00%	22.58%	64.52%
Physical equipment	51.61%	48.39%	0.00%	45.16%	41.94%	0.00%
Budget Preparation	83.87%	12.90%	0.00%	70.97%	12.90%	0.00%
Consultant Agreements	67.74%	29.03%	3.23%	58.06%	29.03%	0.00%
Facilities or vendor agreement	25.81%	70.97%	3.23%	19.35%	64.52%	3.23%
Multiple PI agreements	74.19%	12.90%	12.90%	67.74%	12.90%	6.45%
Hiring and Job Descriptions	64.52%	32.26%	3.23%	58.06%	25.81%	3.23%
Study Arms	77.42%	6.45%	16.13%	67.74%	6.45%	12.90%
Access to Target Population	41.94%	38.71%	19.35%	35.48%	32.26%	19.35%
Vulnerable Populations	29.03%	64.52%	6.45%	25.81%	54.84%	6.45%
Participant Eligibility	0.00%	74.19%	22.58%	0.00%	61.29%	22.58%
Incentives	6.45%	16.13%	77.42%	6.45%	12.90%	67.74%
Informed Consent	19.35%	77.42%	3.23%	16.13%	67.74%	3.23%
Randomization	100.00%	0.00%	0.00%	90.32%	0.00%	0.00%
Type of Intervention	93.55%	6.45%	0.00%	80.65%	6.45%	0.00%
Intervention Administration	90.32%	9.68%	0.00%	77.42%	9.68%	0.00%
Research team	58.06%	32.26%	9.68%	51.61%	25.81%	9.68%
Data Collection (Procedures)	19.35%	58.06%	22.58%	16.13%	51.61%	19.35%
Data Collection (Frequency)	25.81%	64.52%	9.68%	22.58%	54.84%	9.68%
IRB Prep	0.00%	83.87%	16.13%	0.00%	70.97%	16.13%
Compliance Reporting	38.71%	58.06%	0.00%	38.71%	45.16%	0.00%
Expected AE/Safety	90.32%	9.68%	0.00%	77.42%	9.68%	0.00%
Follow up	87.10%	12.90%	0.00%	74.19%	12.90%	0.00%
Statistical Analysis	54.84%	35.48%	9.68%	51.61%	25.81%	9.68%
Dissemination	70.97%	16.13%	9.68%	61.29%	12.90%	9.68%

Summary

- Develop and establish initial psychometric properties of a novel instrument to scale study complexity
- Pilot testing demonstrates high cognitive validity and fair inter-rater reliability
- 4 elements potentially warrant further investigation including revision and/or removal
- Future research should include construct validity testing with a greater sample size
- Potential Future Use
  - Grant/Budget Planning
  - Resource allocation
  - % effort delineation
- Dissemination Plans
  - Manuscript
  - Professional Association Presentations
    - International Association for Clinical Research Nurses
    - Memorial Sloan Kettering Research Round Table
    - Society of Clinical Research Associates
    - Sigma Theta Tau International
    - Academy Health

Next Steps

Dissemination Plans

- Manuscript
- Professional Association Presentations
  - International Association for Clinical Research Nurses
  - Memorial Sloan Kettering Research Round Table
  - Society of Clinical Research Associates
  - Sigma Theta Tau International
  - Academy Health
- Construct Validity Testing

Contact Information:

Bernadette ‘Candy’ Capili, PhD, NP-C : Bcapili@Rockefeller.edu

Allison Norful, PhD, RN, FAAN: aan2139@cumc.columbia.edu

Clinical Research Study Complexity Assessment Workgroup Members:

Margaret Barton-Burke PhD, RN, FAAN (Memorial Sloan Kettering Cancer Center)

Bernadette ‘Candy’ Capili PhD, NP-C (Rockefeller University) - CHAIR

Christine Kovner PhD, RN, FAAN (New York University)

Allison Norful, PhD, RN, ANP-BC, FAAN (Columbia University)- STUDY LEAD

Olga Jarrín Montaner, PhD, RN, FAAN (Rutgers University)

Laura Viera MS, CCRP (University of North Carolina-Chapel Hill)

Bridget Adams, MS (Oregon Health & Science University)

Ashley Arrington (University of North Carolina-Chapel Hill)

Jackie Attia (University of Rochester – CCOS)

Maria Chiodo, MPH (University of Rochester)

Gallya Gannot, PhD (NIH, NCATS)

Susanne Heininger (University of Rochester)

Scott McIntosh, PhD (University of Rochester – CCOS)

Kitt Swartz, MPH (Oregon Health & Science University

Abby Spike (University of Rochester – CCOS)

CLIC Center for Leading Innovation & Collaboration

Thank you

A Collaborative Approach to CTSA Program Evaluation Data: SPARCRequest© (SPARC)

MUSC
Medical University of South Carolina

Changing What's Possible | MUSC.edu

Jillian Harvey, PhD, MPH, SCTR Program Evaluation Director

Royce Sampson, MSN, RN, CRA, Primary Administrator, SPARC Product Owner

Leila Forney, DNP, CCRP, CHRC, SPARC Project Director

South Carolina Clinical & Translational Research Institute Medical University of South Carolina

This project was supported by the National Center For Advancing Translational Sciences of the National Institutes of Health under Award Number UL1TR001450

Presentation Goals & Outcomes

Goals: Present an innovative solution to address CTSA evaluation challenges, support the field of translational science, and promote impactful partnerships and collaborations.

Expected Outcomes: Dissemination of a best practice to address evaluation challenges, support CTSA programs, and build CTSA consortium collaborations to advance clinical and translational science.

Agenda

- SPARC and RINS Update
- CTSA Program Evaluation Challenges
- The Future of Evaluation
- Evaluation Utilization
- CTSA Collaborations and Dissemination

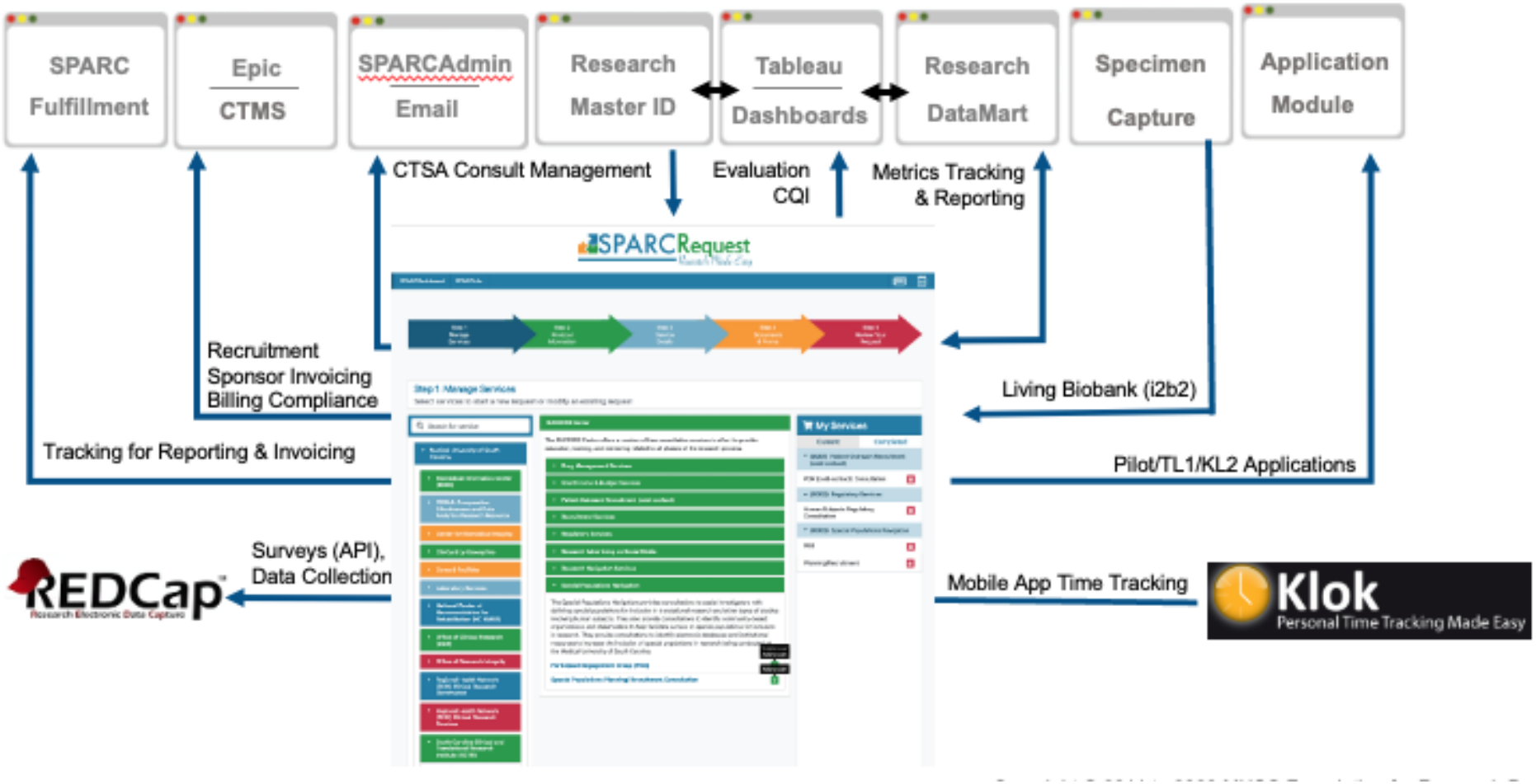
MUSC
Medical University of South Carolina

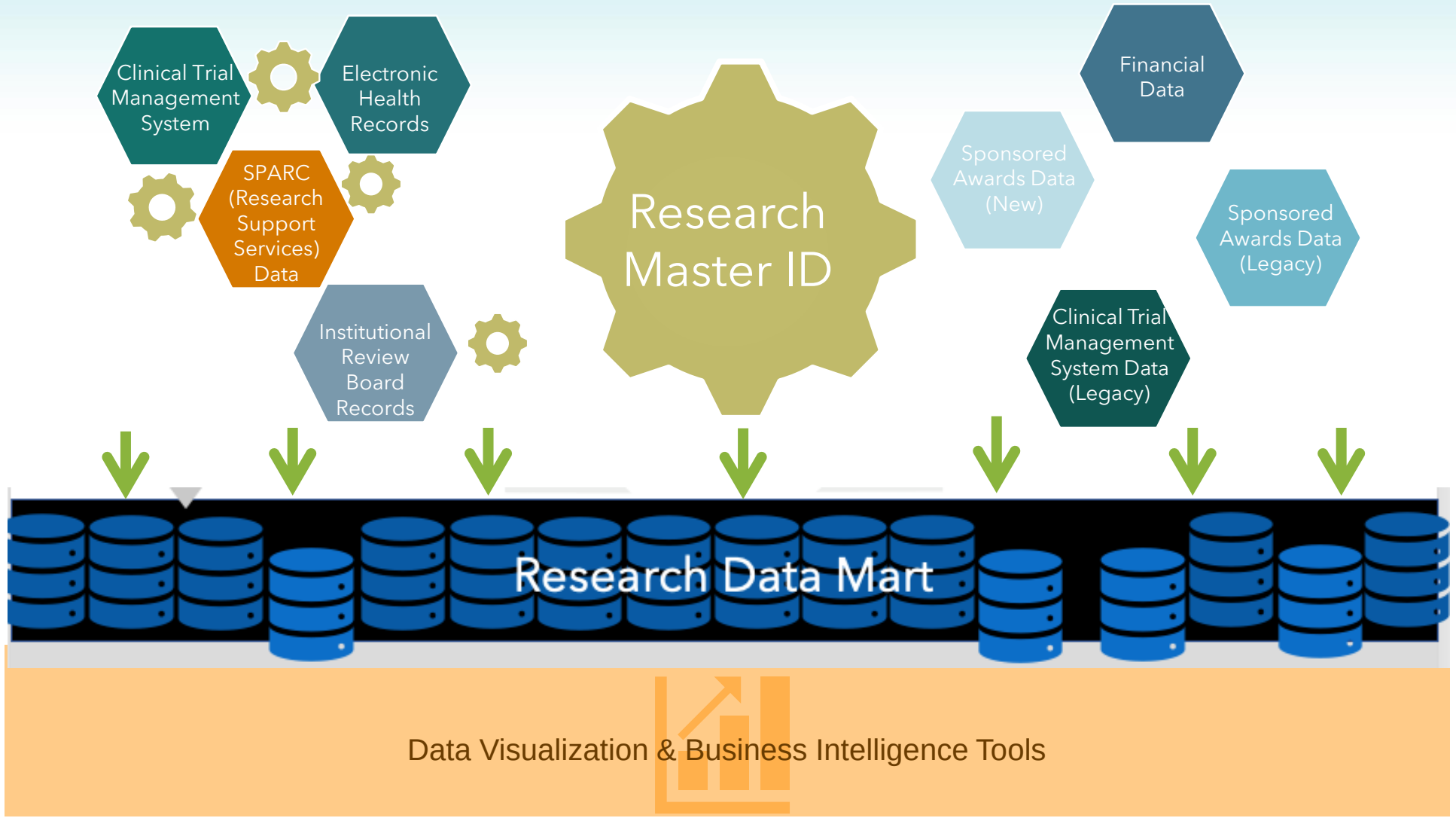
South Carolina Clinical & Translational Research Institute

Updates:

What is SPARCRequest© and the Research Integrated Network of Systems (RINS)

SPARCRequest© CTSA eStorefront: *"A Research Transaction Manager"*




Clinical Trial Management System
Electronic Health Records
SPARC (Research Support Services) Data
Institutional Review Board Records
Research Master ID
Financial Data
Sponsored Awards Data (New)
Sponsored Awards Data (Legacy)
Clinical Trial Management System Data (Legacy)
Research Data Mart
Data Visualization & Business Intelligence Tools

Program Evaluation Challenges

Service Utilization and Evaluation Challenges

1. Unclear of all available services
2. Confusion navigating “external” services
3. Lack of awareness of when CTSA services were used
4. Difficulty knowing and tracking each service that has been recommended for a study

Source: Elworth JT, Vaught M, Harvey J, Paranal R, Zell A, El Bcheraoui C, Elworth JT, Vaught M, Harvey J, Paranal R, Zell A, El Bcheraoui C. Exploratory study of the underutilization of CTSA module services. J Clin Transl Sci. 2022; 6(1):e114. PMID: 36285017; PMCID: PMC9549576.

Evaluation & Service Managers have limited bandwidth

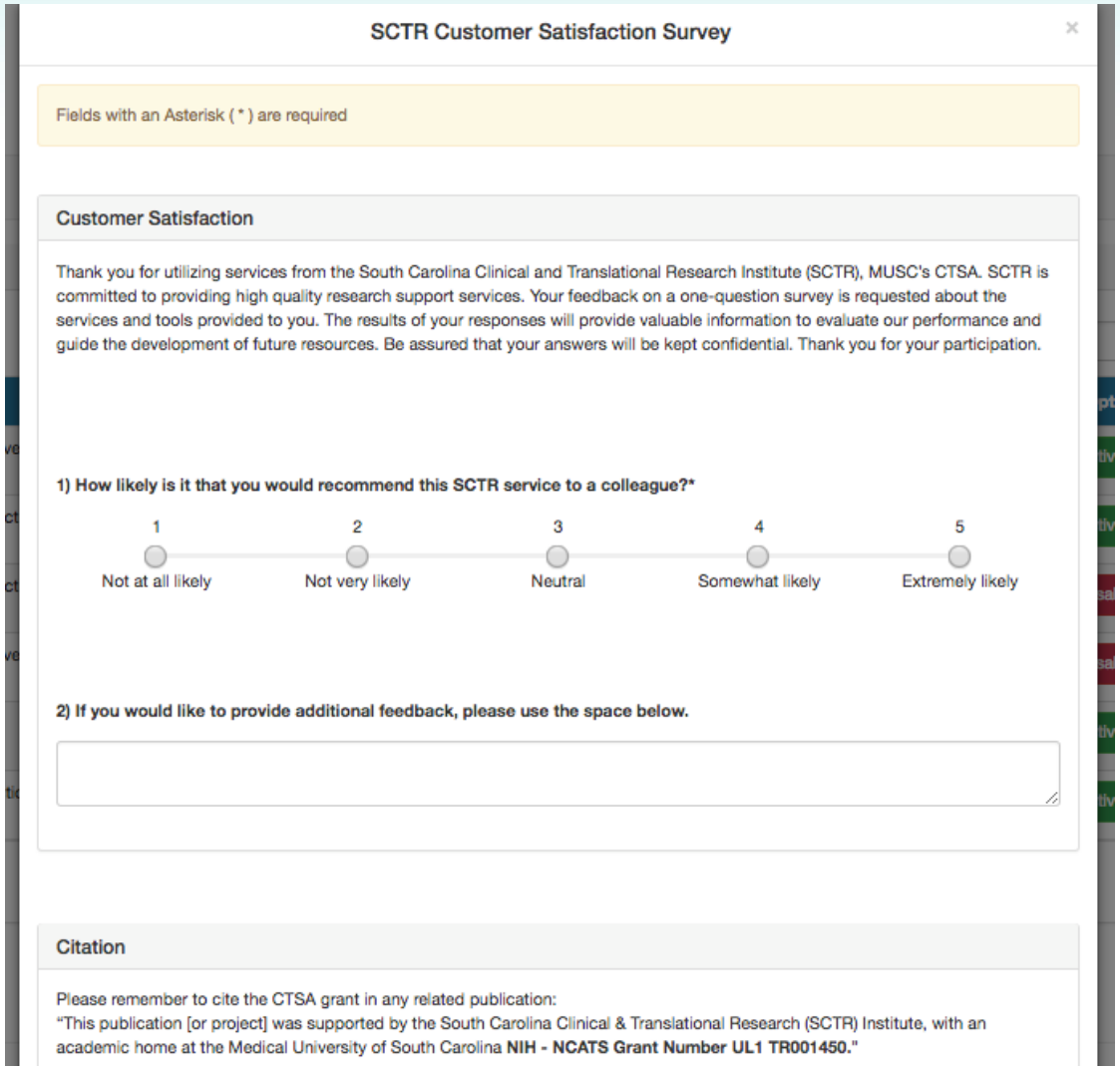
There is a growing demand for data

Item	Feasibility	Importance
1. Number and type of **patents or trademarks** filed and/or received (e.g. IP data, implementation science etc.)		
2. Number and type of **trainings offered by Hub** (e.g. courses, certificates, workshops, seminars, tracks, etc.)		
3. **Institutional collaboration and commitment to clinical and translational science research** (e.g. number of projects and protocols, in-kind support, $ and personnel)		
4. Number of **pilot grants advancing to clinical trial proposals and/or awards**		
5. Median **time to complete CTSA Hub-supported consultation and/or services** (duration in days)		
6. Number and type of measurable **plans, policies or changes related to diversity, equity, and inclusion**		
7. Number and types of CTSA **Hub interactions with state, local and public health entities**		
8. Qualitative data regarding how **gender and racial diversity in clinical translational research** can be achieved and/or what is needed		
9. Number and types of **new or ongoing collaborations with multiple CTSA Hubs and/or national consortium**		
10. Number and percent of **pilot awardees** overall and by relevant demographics (e.g. women and underrepresented populations)		
11. For newly-emerging health crises requiring a rapid response: Number of CTSA-affiliated **investigators publishing relevant results within X period of time** (in months or years)		
12. Relative **familiarity with the term "translational science"** among key indicator groups (healthcare providers, leaders of relevant community organizations and academic faculty in relevant fields)		
13. Number and type of **underrepresented populations in clinical trials**		
14. Number and type of CTSA Hub supported **services with subsequent grants and/or publications cited**		
15. Number of different **CTSA initiatives with a specific focus on greater than one of the following: quality, safety, efficiency and effectiveness of clinical research**		
16. Number, type, duration, and quality of Hub-supported **community engagement services and tools**		
17. Number of **datasets made discoverable** as a result of Hub-supported Informatics resources		
18. The collection of high-level **success stories** (e.g. novel approaches or collaborations, mitigating translational science roadblocks...)		
19. Number and type of **changes in promotion and tenure policy as the result of Hub activities**		
20. Number of Hub supported **opportunities created for novel care approaches for clinical research participants** relative to other regional providers		
21. **Cost per participant enrolled** in NIH-supported clinical trials		
22. **Scientific interdisciplinarity** as measured by number and type of Doctoral/MBA/MPH degree types, scientific areas, and/or collaborations between and support of various departments, in Hub-supported work		

Evaluation Utilization

Evaluation Utilization

SPARCRequest©: Evaluation Data Collection



SCTR Customer Satisfaction Survey

Fields with an Asterisk (*) are required

Customer Satisfaction

Thank you for utilizing services from the South Carolina Clinical and Translational Research Institute (SCTR), MUSC's CTSA. SCTR is committed to providing high quality research support services. Your feedback on a one-question survey is requested about the services and tools provided to you. The results of your responses will provide valuable information to evaluate our performance and guide the development of future resources. Be assured that your answers will be kept confidential. Thank you for your participation.

1) How likely is it that you would recommend this SCTR service to a colleague?*

1	2	3	4	5
Not at all likely	Not very likely	Neutral	Somewhat likely	Extremely likely

2) If you would like to provide additional feedback, please use the space below.

Citation

Please remember to cite the CTSA grant in any related publication:
"This publication [or project] was supported by the South Carolina Clinical & Translational Research (SCTR) Institute, with an academic home at the Medical University of South Carolina **NIH - NCATS Grant Number UL1 TR001450.**"

SCTR Impact: Helping Research Happen at MUSC

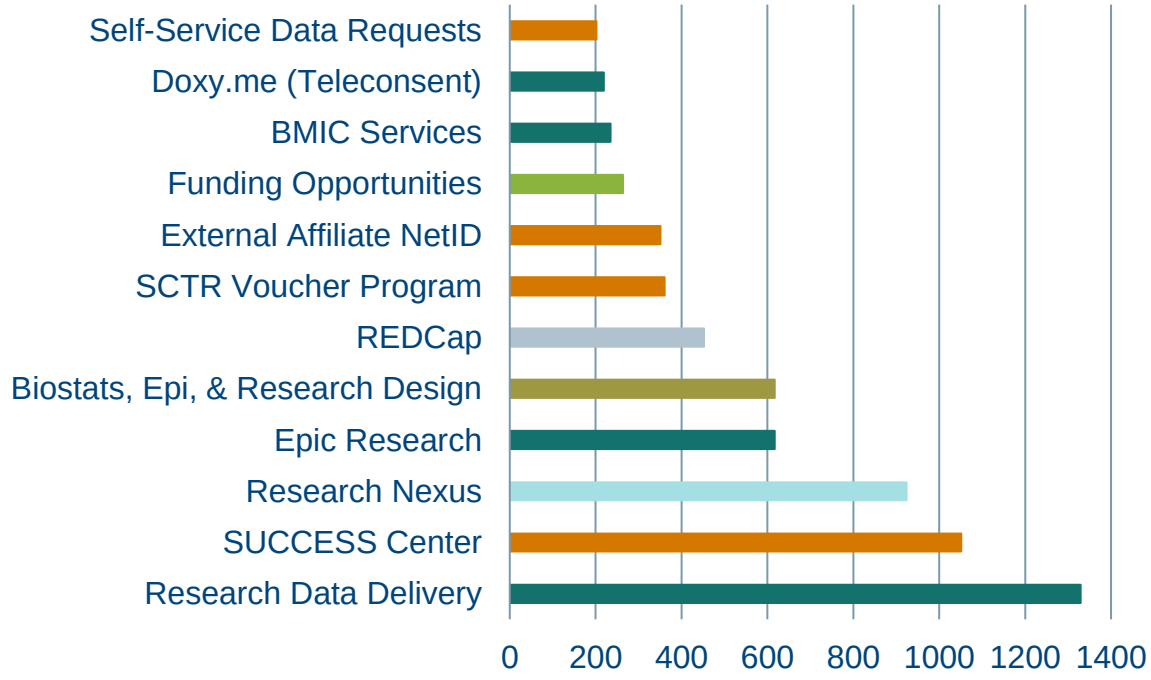
SPARCRequest
Request Services

July 2018 - June 2023

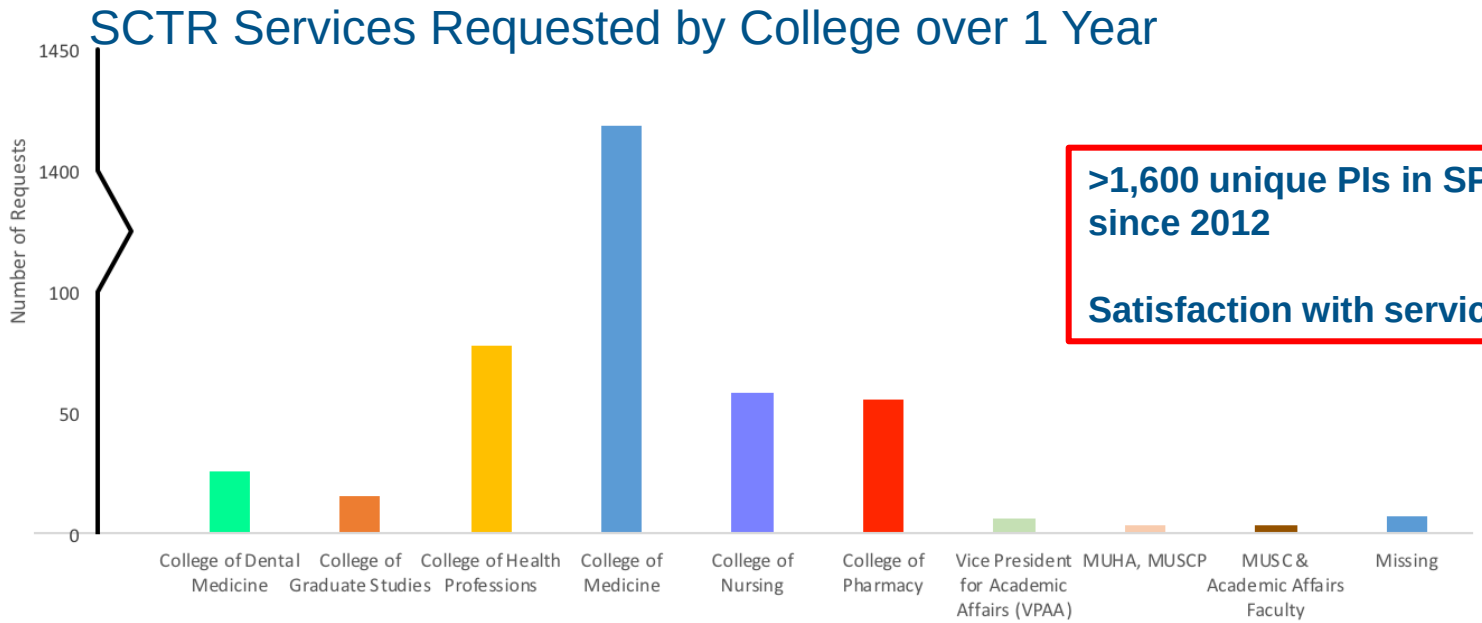
SCTR	**4,823**	**9,872**	**3,235**
BMIC	**2,467**	**2,896**	**1,845**
	Requests	Services	Protocols

97%
Satisfaction

SCTR & BMIC Program Requests, 2018-2023



High Institutional Visibility and Utilization

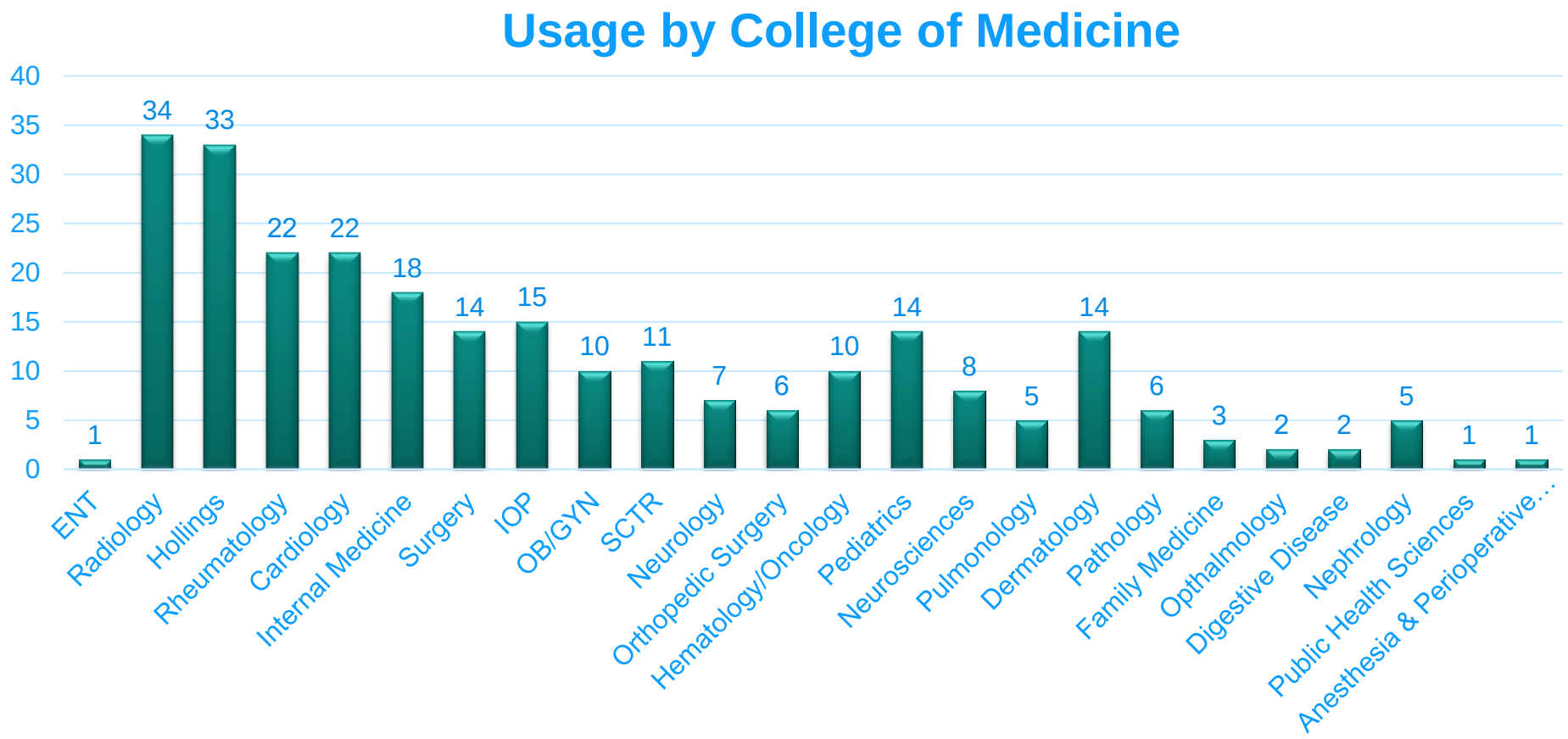


>1,600 unique PIs in SPARC since 2012

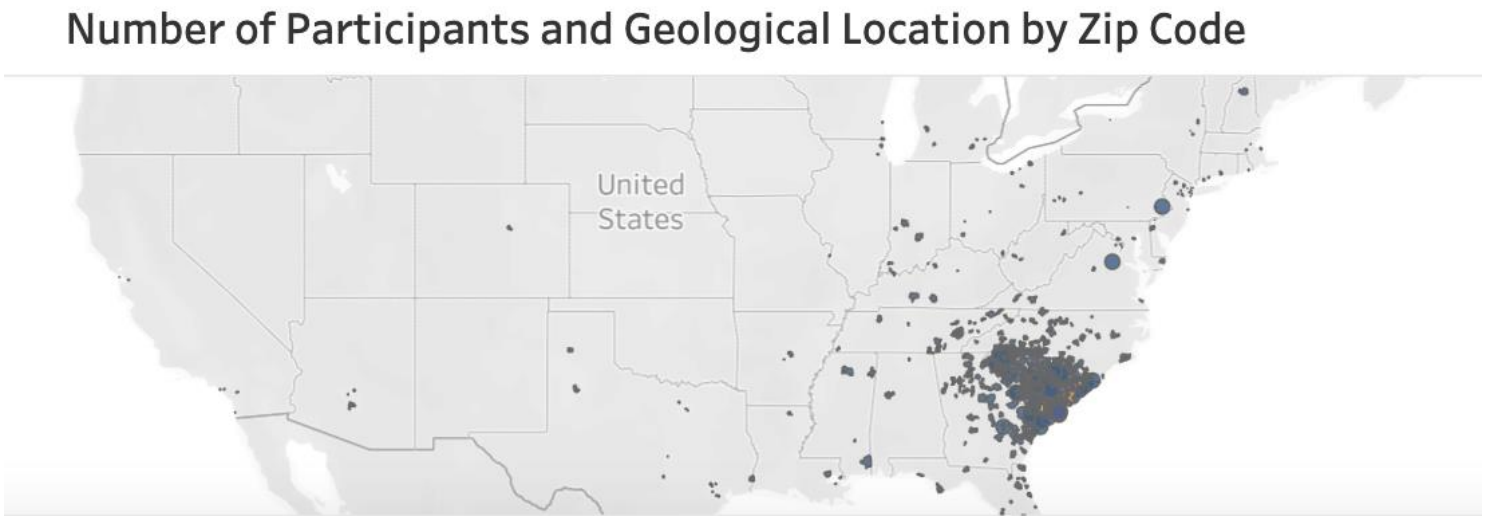
Satisfaction with services >97%

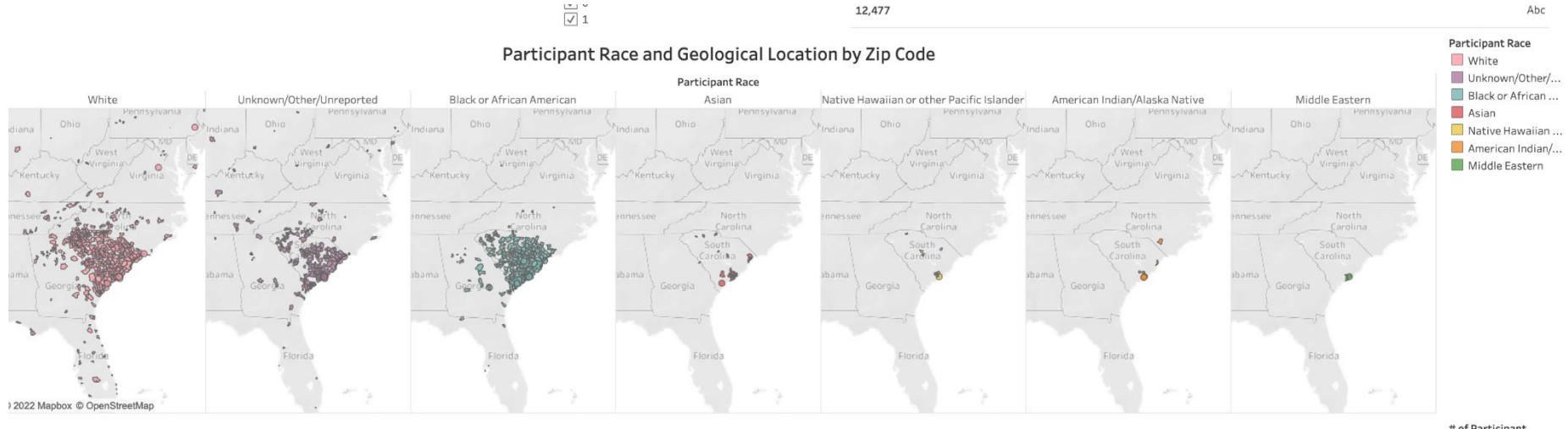
Services	Number	Services	Number
Biomedical Informatics Services	24	Recruitment & Special Populations	15
Biostatistics, Design, & Epidemiology	302	REDCap	142
Clinical Data Warehouse	40	Regulatory Services	236
Clinical Research Ethics Program	4	Research Coordination & Management	134
Clinical Trials Design Center & TIN	7	Research Data Requests	208
Community Engagement & Research	3	Research Navigation Services	9
Drug Management Services	5	Research Nexus	1331
Epic Research	2	Science Consultation	3
External Affiliate NetID	61	Self-Service Research Data & Feasibility	43
Grant Forms & Budget Services	45	Telehealth Research Services	2
Nexus Biorepository	3	Voucher Program	68

Stakeholder Metric Tracking & Reporting



SPARC: SCTR Research Nexus Clinical Research Unit: Research Participants (location, race, age, gender)

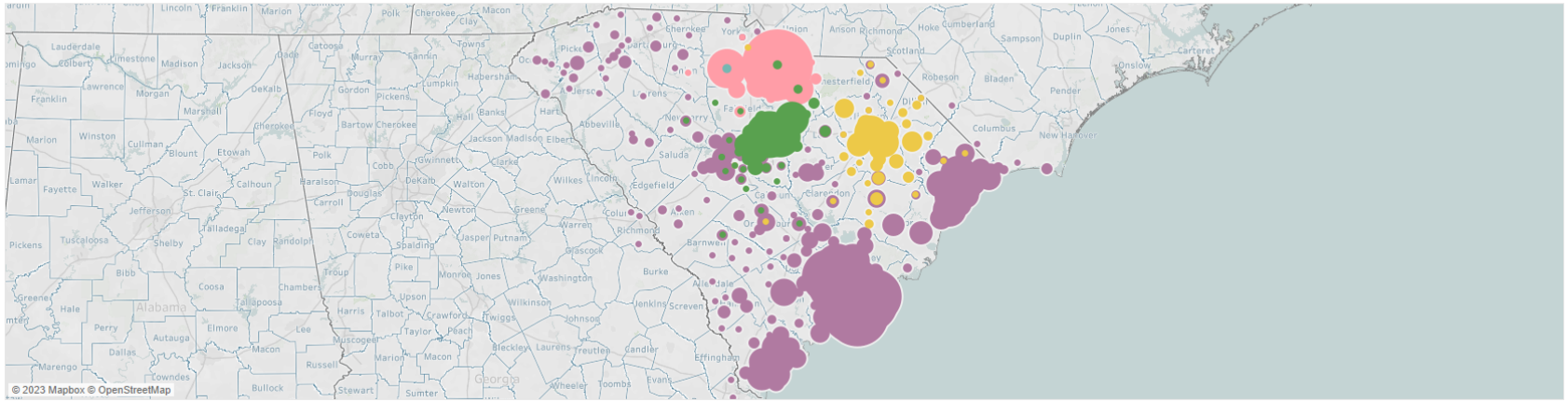




USC.edu

RINS: MUSC Main Campus and Regional Health Network (RHN) Research Participants

Study Site Density Map



Study Site
- MUSC - Chester
- MUSC - Columbia
- MUSC - Florence
- MUSC - Lancaster
- MUSC - Main Campus

Pi Names
All

Protocol No.
All

Study Site
Multiple values

Subject Status
Multiple values

Month of Date
Multiple values

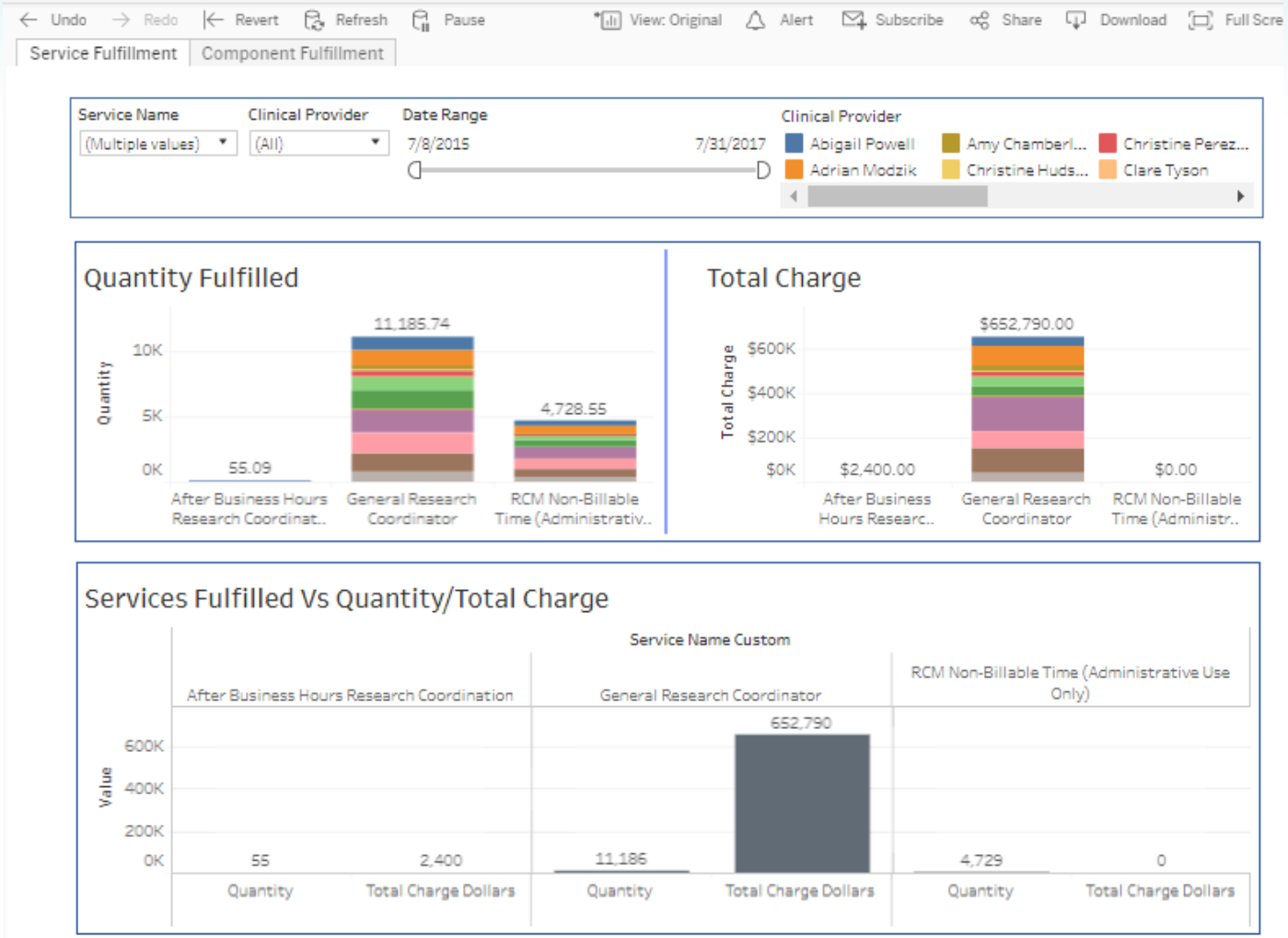
Year of Date
Multiple values

Date

Study Site	January 2022	February 2022	March 2022	April 2022	May 2022	June 2022	July 2022	August 2022	September 2022	October 2022	November 2022	December 2022	January 2023	February 2023	March 2023	April 2023	May 2023	June 2023	Grand Total
MUSC - Chester								1	3										4
MUSC - Columbia					1	2		3	4	30	33	16	33	31	43	26	11		233
MUSC - Florence		8	18	11	9	5	7	22	21	11	8	7	17	12	12	9	7	1	185
MUSC - Lancaster				2		2	3	9	20	11	24	45	37	40	29	38	26		286
MUSC - Main Campus	106	123	175	118	153	131	126	165	152	168	144	114	150	143	190	138	165	11	2,472
Grand Total	106	131	193	131	163	140	136	200	200	220	209	182	237	226	274	211	209	12	3,180

SPARCRequest© Supports:

Program & Service Center Management



Continuous Quality Improvement– Challenges & SPARC Opportunities

Service Utilization and Evaluation Challenges

1. Unclear of all available services

2. Confusion navigating “external” services

3. Lack of awareness when CTSA services are used

4. Difficulty knowing and tracking each service that has been recommended for a study

SPARCRequest Opportunities

- SPARC Catalog of Services
- SPARCRequest can add services & track referrals
- Dashboards for Study Teams and Service Managers
- Document repository for study teams and service providers
- Access to study protocol documents

Cross CTSA Functionality

Current Open Source Partners

Join Our SPARC Open-Source Governance Community

Next steps & How to Get Involved

Contact us at:

SPARCRequest@musc.edu

Action Items:

Explore CTSA Consortium options for SPARCRequest©

- Cloud Instance
- Shared Marketplace
- Shared Evaluation Opportunities

SPARCRequest©: https://research.musc.edu/resources/sctr/research-resources/tools/sparcrequest

SPARCRequest© (SPARC) Confluence Wiki
https://sparcrequest.atlassian.net/wiki/spaces/RD/overview

SPARCRequest
Videos: https://sparcrequest.atlassian.net/wiki/spaces/AG/pages/37093447/Training+Videos

Questions and Discussion

2023 Fall CTSA Program Annual Meeting

Leveraging Real World Data and AI to Advance Translation

Registration is (still) open! Be sure to register before close date on Oct 16th

October 16th
Registration for Fall Program Meeting closes

November 6 - 8th
Fall Program Meeting

Nov 6	Nov 7	Nov 8
CTSA Administrators *Morning* Steering Committee Meeting *Afternoon*	CTSA Program Meeting *Full day* Poster and Networking Session *Evening*	CTSA Program Meeting *Morning only*

Check CCOS website for detailed agenda, speaker bios, session descriptions

LOGISTICS

2023 Fall CTSA Program Annual Meeting Poster Session on Nov 7 (6-8pm ET)

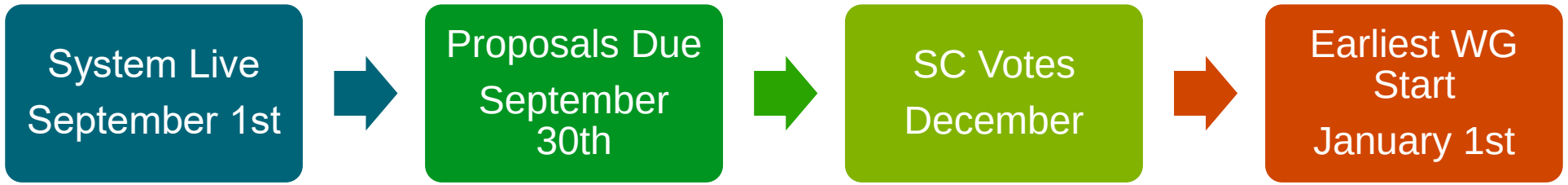
Poster Submission Form is now available on CCOS website

- Poster session is designed to spotlight **CTSA trainees and scholars**
- Each hub may submit a **single** poster from a TL1/T32 trainee or KL2/K12 scholar related to the overarching theme of the meeting
  - If your Hub does not have a current TL1/T32 trainee or KL2/K12 scholar working in an area related to the meeting theme, we would encourage you to identify an early career candidate that is in line with the spirit of this poster session and request approval via FallPlanningCmt@ccos.ctsa.io
- Hub Administrators (or designee) may submit the abstract and digital poster representing their hub to the CCOS website
- ***The submission portal will close on October 23rd***
- A poster gallery will be viewable on the CCOS website on Oct 27th
- Awardees to be recognized during session on Nov 8th

Working Group Proposal Submission Period

Closes on September 30th, 2023

All proposals should be submitted no later than **September 30th.**



LOGISTICS

Working Group Proposals – Helpful Links

- General Information and application link:
  - https://ccos-cc.ctsa.io/groups/working-groups/proposal-cycle-information
- Proposal Application Questions:
  - https://uploads.ccos-cc.ctsa.io/CCOS_WG_Proposal_Submission_Form_v1_2023_Sept1_1d500510ff.pdf
- CTSA Program Groups Guidance FAQs
  - https://uploads.ccos-cc.ctsa.io/CTSA_Program_Group_Guidance_FA_Qs_305ff833dd.pdf

CCOS Website Updates

Released

- CTSA Program Group pages
- Hub Directory
- CTSA Program Calendar (w/filter)
- Help – Landing page
- News articles
- User registration
- Working Group Proposal form
- Poster Submission Form
- Meeting archive (April-June)

Next up

- Meeting archive (Jan to Present)
- Poster Gallery
- Steering Committee Review Form for Working Group proposals
- Cycle X Working Group pages
- Webinar page plus archive
- Pod Submission Form
- CTSA Guidance documents
- Spring 2024 In Person Meeting
- Spring 2024 Collaborative Workshop

Thank you!

Reminders

Next CTSA Webinar is Wednesday, October 25 at 2pm ET

Webinar Registration Link:

https://zoom.us/webinar/register/WN_qy2vYoxnSdGzbhABVjQFzQ