

2019 Strategic Planning Activities Annual Summary and Report

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Justification Statement

The central leadership of the Georgia Clinical and Translational Science Alliance (Georgia CTSA), along with the Evaluation & Continuous Improvement (ECI) program, identified the need for annual discussion and reporting on the status of each program to consistently track and assess the aims and milestones of the programmatic infrastructure that supports clinical and translational research in Georgia. This is necessary to determine when programs need to adjust their plans and milestones in support of their individual specific aims and the overarching aims of the alliance. To serve this goal, the ECI team conducts annual Strategic Planning Activities used to characterize Program activities, inform development and monitoring of processes and milestones, and initiate mid-course amendments. Annual Strategic Planning Reports also provide summary evidence of effectiveness and impact in reaching each Program's specific aims and objectives year to year.

The Strategic Planning process consists of ECI developing and approach for strategic evaluation, directors meeting within their programs and then individually with ECI to evaluate and set goals. ECI collects information on key accomplishments in the previous year, as well as objectives for the next year, in order to evaluate indicators and monitor progress toward accomplishing milestones over the course of a program year. The timeline for the process is predetermined by ECI and communicated to each program to document the program progress and provide feedback. This includes completing written strategic planning worksheets and conducting interviews with program directors and team members to discuss the objectives detailed in these documents as well as methods for measuring outcomes. Results of the milestones, achievements, and overall impact are shared with the Executive Council for approval, and then included in the annual report to the External Advisory Committee at the end of each year. These efforts will contribute to more efficient progress toward the aims and goals of all program groups, which will, in turn, aid in the aggregate impact of the Georgia CTSA each year.

Acronym/Abbreviations List

BERD Biostatistics, Epidemiology & Research Design

CC Coordinating Center
CE Community Engagement

CMDTS Collaboration & Multi-Disciplinary Team Science

ECI Evaluation & Continuous Improvement

OGCC Organization, Governance, Collaboration & Communication

GCRCs Georgia CTSA Clinical Research Centers

ICa Innovation Catalyst

Infor Informatics

ISP Integrating Special Populations

Peds Pediatrics

Pilots Pilot Translational and Clinical Studies

QE/LTICs Quality & Efficiency/Liaison to Trial Innovation Centers

RC Recruitment Center
Res Ed Research Education

RKS Regulatory Knowledge & Support
TWD Translational Workforce Development

Overall Summative Evaluation of 2019 Strategic Planning Activities

An overarching goal for this year's strategic planning activities was to emphasize cross-institutional collaboration, impact among people and communities, sharable innovations, and common goals. The following summative evaluation describes the process and findings of the 2019 strategic planning process, providing a bird's eye view of the structure, accomplishments, and strategic plans of the Georgia CTSA.

Steps and Timeline

The Strategic Planning process was initiated in July 2019 when ECI gathered updated strategic planning worksheets from each program and conducted meetings attended by program leadership, ECI, and OGCC. Each program detailed current objectives and activities serving their specific aims, and answered questions regarding this year's strategic planning theme of *Making a Difference*, including how programs worked across institutions and communities, created innovative initiatives and made impact across common goals. OGCC discussed updates to communication plans and issues related to organizational governance and impact. ECI drafted brief reports summarizing the findings of the proceedings, including: (1) an elevator summary of aims and services; (2) progress against milestones over the past year; and (3) challenges and goals for the next year. Reports were submitted to each program for edits and approval and were included in this report once finalized.

Grant Year 2: How Have We Made a Difference?

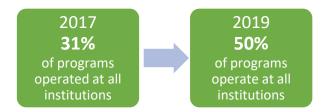
As part of the strategic planning process, programs were asked to identify notable ways that they have made a difference to specific people, communities, or projects in the past year. Answers frequently involved continuing successful ongoing activities, launching new initiatives, or expanding scope of work. Some programs are making a difference through the collective impact of long running services such as decades of clinical trial support through the GCRCs and training through the KL2 and TL1 programs, and over 12 years of pilot grants and specialized expert consultations. In the past year, stand-out accomplishments included a number of high profile events (e.g. 2nd annual State-wide Conference; CE's Biannual Community Research Forum), innovative products (ICa's RegCheck launch; QE/LTIC's Investigator Dashboard; RC's manuscript on research consent), and extensions of services (Peds' move to a larger & more productive clinical space; CE, ISP & ECI collaborating on the Grant Writing Crash Course in rural Georgia). Progress has been made through collaborative efforts across the multiple Georgia CTSA institutions, across programs, and across statewide and nationwide networks. Key accomplishments for every program are detailed in their respective individual summary reports.

Working Cohesively Across a Unified Alliance

Teamwork and Communication across Institutions

The Georgia CTSA has placed particular emphasis on operating as a unified team that leverages the complementary and unique strengths and resources of our four distinct institutions, Emory University, Morehouse School of Medicine (MSM), Georgia Institute of Technology (GA Tech) and the University of Georgia (UGA). In order to create an alliance that makes more of these institutions than the sum of their parts, program leaders work deliberately to cultivate ties with representatives at each relevant institution. **Table 1** summarizes staff representation at the four partner institutions for each program in the alliance. Representation is defined as having leadership or at least one staff member with a defined position/percent effort,

| Table 1. Staff representation at each partner institution | | | | | |
|---|--------------|--------------|----------------|--------------|--|
| | Emory | MSM | GA Tech | UGA | |
| OGCC | \checkmark | \checkmark | \checkmark | \checkmark | |
| CMDTS | \checkmark | \checkmark | \checkmark | \checkmark | |
| Res Ed | \checkmark | \checkmark | \checkmark | \checkmark | |
| Pilots | \checkmark | \checkmark | \checkmark | \checkmark | |
| ICa | \checkmark | \checkmark | \checkmark | \checkmark | |
| RKS | \checkmark | \checkmark | \checkmark | \checkmark | |
| BERD | \checkmark | ✓. | ✓. | \checkmark | |
| CE | \checkmark | \checkmark | \checkmark | \checkmark | |
| ECI | \checkmark | \checkmark | | \checkmark | |
| RC | \checkmark | \checkmark | | \checkmark | |
| ISP | \checkmark | ✓. | | \checkmark | |
| QE/LTICs | \checkmark | ✓. | | \checkmark | |
| GCRCs | \checkmark | ✓. | | \checkmark | |
| Infor | \checkmark | ✓. | \checkmark | | |
| Peds | \checkmark | \checkmark | | | |
| TWD | ✓ | | | ✓ | |



indicating that the program has formal operations and financial stake at that institution. This may include managerial or administrative staff, directors, co-directors, or steering board members.

Although programs do not necessarily have staff at all institutions, there has been a sincere effort to create new

or strengthen existing connections across institutions such that programs have team members with complementary strengths situated at the institutions that are relevant to their operations. This effort has been evidenced by an increase in staff representation from 31% of programs having personnel at all 4 institutions in 2017, to 50% of programs having personnel at all institutions in 2019. Further, this year we have recruited two new program directors with cross-institutional appointments, including Wilbur Lam, MD, PhD for Innovation Catalyst who is affiliated with the Emory Department of Pediatrics, Winship Cancer Institute, and the

Department of Biomedical Engineering at GA Tech, and Gari Clifford, DPhil for Informatics who is affiliated with the Emory department of Biomedical Informatics, the GA Tech department of Biomedical Engineering, and MSM. All programs have teams that collaborate across at least two institutions, including programs that focus directly on clinical trials (e.g. GCRCs, RC, LTICs, ISP) and operate at Emory, MSM, and UGA. Although GA Tech does not have a clinical trials unit, GA Tech investigators utilize relevant programs to conduct and collaborate on clinical trials focused on biomedical engineering and innovative health technologies.



The RKS and Peds programs streamlined data sharing processes by establishing IRB Reciprocity and Data Use Agreements and facilitating research data transfers across all four institutions.

Cross-institutional collaboration appears in other ways beyond operational presence at each institution. Importantly, all Georgia CTSA programs offer their resources (including events, services, consultations, grants) to investigators from all four partner institutions and their collaborators. For some resources, such as pilot grants, competitive advantages may be given to projects that involve more than one institution. Cross-institutional collaboration also occurs regularly with other institutions affiliated with the Georgia CTSA. For example, many programs have staff with joint appointments and operations at Children's Healthcare of Atlanta, Grady Hospital, and the Atlanta VA hospital.

Teamwork and Communication across Programs

In addition to cross-institutional communication and collaboration, the Georgia CTSA has emphasized crossprogram collaboration as a means of drawing together diverse skills and interests toward the common mission of the alliance. During the strategic planning process, ECI catalogued instances of cross-program collaborations that serve to enhance the impact of program support. Figure 1 depicts collaborative ties among programs as of 2019. These collaborations include explicitly shared activities that produce a shared product or achievement, claimed by and serving the aims of both programs. For example, in the past year the Pilots program leveraged their skills and knowledge in pre- and post-award processes for others by administering grants for the BERD, CE, Infor, and ICa programs.

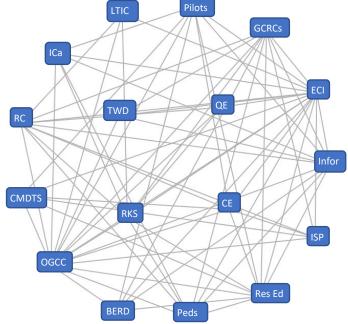


Figure 1. 2019 Collaboration Network among all Programs

The collaboration network reveals that, on average, programs worked with approximately **8 other programs**, with considerable variability. Programs such as OGCC and ECI touch all programs through their overarching role in the administrative home, and programs like Infor are also broadly-reaching through infrastructural offerings such as data platforms and technology. Conversely, some programs have focused activities that function more

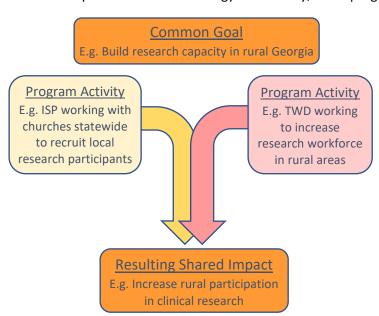


Figure 2. Model for Maximizing Shared Impact via Parallel Activities toward Common Goals

independently from other groups. TWD, for example, focuses very autonomously on developing their workforce development application, STELLAR. In 2017, the network density was 65%, indicating that 65% of all possible cross-program ties (88 out of 136) were represented; in 2019, the network density is 52% (70 out of 136 possible ties). Although some new connections were made, there was an overall net decline in collaborations. At the outset of Grant Year 1, several programs expressed intentions to work with other groups on certain objectives, but since then, plans and goals for some of these programs have become more sharply focused and defined. Overall, this shift underscores the clarity of focus that has been achieved with regard to strategic plans.

In addition to cross-program collaborations,

programs work toward ambitious common goals in parallel, even when not working in tandem (see **Figure 2**). It may not be necessary or advantageous for programs to work on specific projects together, but the Georgia CTSA may still play an anchoring role in maximizing such efforts via cross-promotion, shared resources and central coordination, preventing duplication of efforts and encouraging cooperation wherever relevant.

Finally, in addition to collaboration among Georgia CTSA programs, many programs cooperate extensively with external entities across the state, including Peds work with the Georgia Kids and Families Impacting Disease through Science (KIDS) Advisory Board and ICa with Atlanta's Women in Technology organization. Some are national projects in which the Georgia CTSA is participating, such as the national CTSA Evaluators' workgroups, the All of Us Research Program and an NIH Collaborative Influenza Vaccine Innovation Center grant, with a team led by UGA, with Emory and GA Tech partners, to develop a new, more advanced influenza vaccine.



Over half of all Georgia CTSA programs are working collaboratively and independently on outreach initiatives targeted towards understanding the needs of researchers and patients in rural health settings.

Innovations Outside Atlanta

The addition of UGA as a new partner institution in 2016 brought with it an increased emphasis on operations and impact beyond Atlanta. Many existing programs have made conscious efforts to reach beyond their previous scope, while new programs commenced their operations with an eye toward impact across Georgia and beyond. Programs have worked toward achieving this goal by incorporating new partners and new services that address issues of statewide or even nationwide concern.

A notable way in which the Georgia CTSA reaches beyond Atlanta city limits is through the **Annual Georgia CTSA Statewide Conference**, a collaborative and inclusive venture involving all programs and all institutions in the alliance, as well as being open to participants throughout Georgia. This successful, two-day event featured Dr. Michael Kurilla from NCATS as the keynote speaker, and made a clear contribution to clinical and translational science in Georgia by creating a forum for the exchange of ideas and opportunities to create and strengthen professional networks. The conference hosted **236 attendees from at least 18 institutions and organizations across**



The CMDTS program cooperated with ISP and CE to hold a collaborative Blue Sky Group at UGA to discuss critical health issues among rural health populations throughout Georgia.

Georgia, and was given a rating of **4.6 stars** (out of 5) by post-event survey respondents. In Grant Year 3, the conference will grow to a regional conference, including representatives from other CTSA hubs and institutions from neighboring states (University of Florida, University of Miami, University of Alabama at Birmingham and Medical University of South Carolina). This expansion will allow for even farther-reaching impact and opportunities for regional communication and collaboration.



Many other Georgia CTSA programs are engaging in activities with regional and even national scope. For example, the Pediatrics program sponsored the Southeastern Pediatric Research Conference with attendance from across the U.S. and the hub received a

supplemental grant to improve online education infrastructure. Several **cross-hub collaborations** have been undertaken this year, including co-authored manuscripts and grant applications, sharing of tools and applications developed here, presentations at national meetings, and inter-state consultations and communications. For example, ECI collaborated with 2 other CTSA hubs to publish an evaluation of the nation CTSA consortium's publication record, RC worked with the University of Washington to research patients' perspectives on electronic recruitment methods, Infor participated in DRIVe Solving ICU Sepsis project across Emory, Harvard, and UCSD, and the CC worked with Emory and UGA faculty to submit a multi-CSA hub U01 grant. These activities ensure that the reach of the Georgia CTSA does not stop at the state border and that opportunities for productive collaborations are embraced whenever possible.

Next Steps: Strategic Plans for Grant Year 3

At this time, the initiatives of the Georgia CTSA are well-established and program activities are in full swing. The focus is currently shifting to enhancing awareness of these operations among relevant investigators, community members, and potential collaborators. Many established researchers, especially in Atlanta, are well aware of and utilize services, however, there are new faculty to reach (e.g. those at UGA or newly hired faculty), and past users to be updated on new and expanded opportunities. Effective communication and promotion of both resources and successful efforts is vital. Plans to address this need include dissemination of the 2019 Georgia CTSA Impact Report, an overhaul of the hub website, GeorgiaCTSA.org, and enhancement of the role of the Georgia CTSA Coordinating Center (CC; see Figure 3), a recent innovation at this hub, in connecting investigators, especially new investigators, with support from relevant programs.

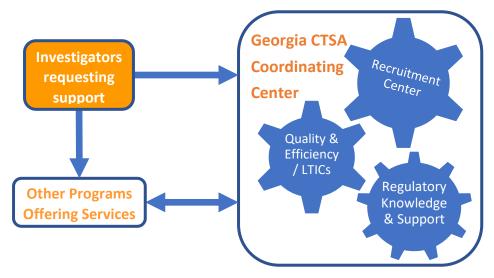


Figure 3. The Georgia CTSA Coordinating Center is operated jointly by the RKS, QE/LTICs, and RC programs, with the support and guidance of the Admin Home. The Coordinating Center serves as an efficient and centralized front door for customers seeking Georgia CTSA support, including:

- (1) navigation of available services
- (2) direct referrals to programs for support
- (3) customized studio consultations

In the next year, it will be especially important for programs to cooperate with other programs to most optimally support their initiatives and health research activities, ensuring that investigators are accessing all potentially useful resources. In light of the evolving needs of the hub, the CC will work to address several current challenges:

| Challenge | Action Plan |
|---|---|
| Customers have difficulty identifying relevant resources among the breadth of services described on the hub website | → Improve the hub website to be more user-focused and include a mechanism for guiding investigators to the services that meet their needs |
| Investigators frequently seek assistance at later stages of their research project, when assistance could have been of more useful at earlier stages | → The CC and OGCC will retool and enhance the current studio consultation format and work to raise awareness of this resource and others for use during the planning stages of research projects |
| Customers first engage the Georgia CTSA at numerous entry points along the research pipeline, and most programs specialize in only a narrow segment of the research process. Customers who utilize specific services are often unaware of other resources that could carry their work further | → Further emphasis will be placed on bi-directional coordination between the CC and all other programs in the alliance. The CC will keep abreast of current and upcoming initiatives in order to refer investigators, and programs will promote use of the CC as a follow-on step after their program's support |

These planned actions will serve to bolster the successful activities of the Georgia CTSA's programs by improving knowledge, utilization, and efficient delivery of the many available resources. Customers will have support in locating relevant services, at the most advantageous times and in the most efficient ways, and Georgia CTSA programs will have a method for **passing the baton** from one program to another, effectively moving translational research forward. Awareness will be raised such that investigators will understand to use resources such as a BERD consultation when formulating a data plan, not after analyses are carried out, and to consult GCRC on cost



structure during the budget planning phase of a study, rather than after a grant is awarded. After investigators use one resource, an effort will be made to usher them to other useful resources via the CC. For instance, when investigators attend CMDTS collaboration events, they will learn about opportunities to be passed on to another resource, such as a studio consultation or pilot grant, in order to advance potential collaborations to the next step along the research pipeline.

In the coming year, the leadership of the Georgia CTSA will utilize this document, along with the External Advisory Committee report, to inform priorities for the December 5th leadership retreat. In early 2020, ECI will conduct a Year 3 Needs Assessment in order to understand individual and program priorities and continue to drive forward motion toward the upcoming grant renewal. With a strategic planning process that allows programs to optimally serve their specific aims and the overarching goals of the alliance, the Georgia CTSA is now well-positioned to pursue peak productivity toward common goals.

Individual Program Summary Reports (ECI Example)

(presented in order of meeting date)

The following reports condense the main findings of each individual strategic planning meetings in terms of:

- (1) an elevator speech summary of aims and services
- (2) explanation of progress against milestones over the past year
- (3) description of challenges and goals for the next year



| Program: | Evaluation & Continuous Improvement (ECI) | Meeting Date: | 08/16/2019 | Institutional representation: | |
|--|---|--|--|---|--|
| Attendees: | Eric Nehl, Nikki Llewellyn, Amber Weber (Emory), Dorothy Carter (UGA), Latrice Rollins (MSM) | | | | |
| Elevator Summary of aims: | | | | | |
| Progress against milestones in the /past year: | Supported the Georgia CTSA by conducting strategic planning for each program, track outputs/outcomes, completing RPPR, and coordinating the common metrics initiative Aided intra-alliance and external communication by disseminating a manuscript and program results to the Georgia CTSA website, serving on national committees, and he community members across the state Contributed to 2 Georgia CTSA related grants (ACME POCT and Georgia CTSA Education Georgia CTSA programs and partners Served on the dissertation committee for a GA Tech Public Policy Doctoral student who the CTSA consortium Inter-institutional collaboration: As a program that overarches the consortium, ECI's so programs and the entire state of Georgia. E.g. Collaborated across Georgia CTSA institutions by publishing a manuscript (with authors from Emory, UGA, MSM and 2 additional disseminated widely among NCATS and CTSA hubs with several more in progress, and evaluators workgroup on bibliometrics and 2) American Evaluation Association Transla Topical Interest Group. | oster presentation olding evaluation nal Supplement) in wrote on publications and across al CTSA hubs) that chairing 1) nation | ns, publishing a training for a support of ation output of a stitutions, national CTSA t was al CTSA | ✓ BERD ✓ CE ✓ CMDTS ✓ GCRCs ✓ ICa ✓ Infor ✓ ISP ✓ OGCC ✓ Peds ✓ Pilots ✓ QE/LTICs ✓ RC ✓ Res Ed ✓ RKS ✓ TWD | |
| Challenges and Goals for the next year: | Continue to develop manuscripts using innovative methods with both internal data so with evaluators across the CTSA hubs (e.g. patent data, bibliometric inter-disciplinarity). Work with Informatics program and LITS to improve RAPID to a system that is interoped CRAssist, ensure all programs are tracking activities, and create metric dashboards to and achievements. Develop innovative ways to measure/track and understand best practices for successful alliance. Implement alliance-wide Year 3 needs assessment in preparation for the competitive Examine bibliometrics at later stages of translation such as publications that have beel late stage clinical trials. | y & pilot ROI). erable with Emory showcase produc ful collaboration a renewal. | y eIRB and tivity, progress across the | Initials & Date of Approval: EJN 9/13/19 | |