A Mixed Methods Evaluation of Georgia CTSA Support of the Technology Transfer Process

Georgia Clinical & Translational Science Alliance

(Georgia CTSA)

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Executive Summary

The purpose of this evaluation report is to assess the factors associated with success along the **technology transfer process (TTP)** and to provide an analysis of the social and scientific impact of support from the Georgia Clinical & Translational Science Alliance (**Georgia CTSA**; formerly known as the Atlanta Clinical & Translational Science Institute; ACTSI). Since 2007, the Georgia CTSA has focused on accelerating clinical and translational research resulting in health-related technology disclosures, patents, and licensures. This evaluation is intended to provide an overview of the impact of Georgia CTSA-supported invention disclosures and patents from 2007-2020 and to analyze the value of Georgia CTSA-supported research leading to market ready medical advancements.

Method

A mixed methods approach was used to assess innovation impact during the TTP from Georgia CTSA-supported applications submitted between 2007-2020. Data was gathered on disclosures supported by the Georgia CTSA, including inventors' names, filing dates, type of program support, and the number of invention disclosures. Multiple data sources were used to collect the full details on each disclosure (i.e., United States Patent & Trademark Office (USPTO), each university Office of Technology Transfer (OTT), Google Patent, Request and Process Information Database (RAPID), and Dimensions). The progress of each of these invention disclosures was assessed throughout the TTP including those that were abandoned, failed, and granted patents. Disclosures that were granted patents were descriptively analyzed across the commercialization process, and Georgia CTSA support was identified.

Results

The first step in the commercialization process is the formal disclosure of an invention. Data gathered from 2007-2020 indicate that a total of 42 invention disclosures, 11 patents, and 3 licenses were supported by the Georgia CTSA. Approximately 27% of the invention disclosures supported by the Georgia CTSA resulted in a patent.

On average, it took approximately three years (38 months) for a Georgia CTSA-supported research patent to move from application status to patent granted status. In addition, 91% of the patents started the process post-2012, indicating a shifting institutional priority toward patent protected research.

These disclosures were supported by three different Georgia CTSA programs, with the majority of them receiving pilot grant funding. Also, 91% of the patents granted were categorized as a scientific method utility patent (also called a "process") and 9% were categorized as a medical device utility patent (also called a "machine").

Conclusion

Georgia CTSA-supported research is yielding a robust body of patent-protected research. The Georgia CTSA Pilot Grants program plays a key role in providing investigators with the opportunity to conduct the preliminary research needed to apply for additional follow-on funding to further their research studies. Translating research into a commercialized innovation is a key factor in improving health in Georgia. While the Georgia CTSA has made great strides in translating science into market ready products using the TTP, some suggested recommendations for improvement include:

Challenges	Recommendations
• Citation of Georgia CTSA grant in disclosure and patent applications • Lack of investigator and research project support details recorded in Georgia CTSA internal tracking database	• Strengthen internal Georgia CTSA invention disclosure and patent reporting requirements • Yearly reports to monitor the progress of Georgia CTSA invention disclosures and patents
• Follow-up with investigators during the patent application process	• Emphasize greater intentional efforts to support investigators throughout the TTP and toward pursuing invention disclosures • Facilitate stronger connections on the TTP between principal investigators (PIs) and their respective OTTs • Increase monitoring of patent applications by communicating with PIs and OTTs to reduce administrative issues and delays
• Patent reporting between Georgia CTSA and alliance universities' OTTs	• Build stronger reporting connections between the Georgia CTSA and OTTs for reporting disclosure and patent data

Introduction

The **Georgia Clinical and Translational Science Alliance (Georgia CTSA)**, formerly the Atlanta Clinical & Translational Science Institute (ACTSI) is an inter-institutional alliance that supports dynamic clinical and translational research projects by fostering collaborations between research investigators, community clinicians, professional societies, and industry collaborators. Emory University (Emory) engaged three of its close academic partners - Morehouse School of Medicine (MSM), Georgia Institute of Technology (Georgia Tech), and the University of Georgia (UGA) - to form the Georgia CTSA. This strategic alliance offers compelling, unique, and synergistic advantages to researchers and patients statewide and improves the way biomedical research is conducted across the country. The consortium, funded through the National Center for Advancing Translational Sciences (NCATS), part of the National Institutes of Health's Clinical and Translational Science Awards, shares a common vision to translate laboratory discoveries into treatments for patients, engage communities in clinical research efforts, and train the next generation of clinical investigators.

The purpose of this evaluation report is to provide an overview of the impact of Georgia CTSA-supported invention disclosures and patents from 2007-2020 and to analyze the value of Georgia CTSA-supported research leading to market ready medical advancements. There is an important link between public research investments and commercial applications, however, their connection can be difficult to track due to this research being freely accessible to multiple different parties.[1] It is possible that publicly funded research can have multiple useful applications that may have deviated from the original research topic area over a long time period. These initial research investments can lay the foundation for several future inventions, and it is important to accurately credit this support and its contribution to a particular innovation.[1] As part of the NCATS consortium, the Georgia CTSA is one of many publicly funded research science hubs that serve to provide support toward the latest scientific discoveries and inventions. Measuring the impact of Georgia CTSA-supported patents offers insight into the value of publicly funded research and demonstrates the essential role that translational science has in improving the health of the public.

This report defines support as: (1) investigators funded by the Georgia CTSA; (2) research receiving direct funding from Georgia CTSA; and/or (3) research using Georgia CTSA resources such as core laboratory services and clinical data, expert consultation from Georgia CTSA staff, and educational and training support such as courses and workshops.

To obtain a valid patent, a patent application must contain a full and clear disclosure of the invention in the manner prescribed by 35 U.S.C. 112(a).[1] There are three types of patents: (1) utility patents; (2) design patents; and (3) plant patents. Only utility patents were reported as being linked to Georgia CTSA support, therefore, only this type will be further defined and discussed. A utility patent is granted to "any new and useful process, machine, article of manufacture, or composition of matter, or any new and useful improvement thereof."[2] Invention disclosures and patents included in this report are classified as either a scientific method (or process) utility patent or a medical device (or machine) utility patent. A method refers to a series of steps performing a function or accomplishing a result.[2] The requirement for an adequate disclosure ensures that the public receives something in return for the exclusionary rights that are granted to the inventor by a patent. The first step in determining intellectual property rights is an invention disclosure. The invention disclosures for Georgia CTSA-supported inventions are disclosed to the university or institution. Important dates in the technology transfer process (TTP) include priority dates, filing dates, and publication dates. The priority date is the date a patent application in relation to your invention is first filed. In the case of Georgia CTSA supported applications, this is normally the

[1] Li, D., Azoulay, P., and Sampat, B. (2017). The applied value of public investments in biomedical research. *Science*. 356, 78-81.
[2] United States Patent and Trademark Office - An Agency of the Department of Commerce. (n.d) Patent basics. Retrieved from https://www.uspto.gov/patents/basics

provisional filing date. The publication date is the date a patent application is published and no longer considered confidential. Publication generally occurs eighteen months after the earliest priority date of the application.

Different types of applications for a patent include provisional or non-provisional. A provisional application is a patent application filed in the US Patent and Trademark Office (USPTO) for the purposes of establishing a priority date. It normally includes less information than a standard non-provisional application and is far less expensive. Provisional applications expire after one year and can provide more time and opportunity for an inventor to conduct additional research or complete the invention before filing for a non-provisional patent, but it does not allow for full patent issuance. Provisional applications are not examined by the patent office, and it must include enough data that supports the claim for filing a non-provisional application. For an invention to be fully patented, the inventor must file for a non-provisional application. An inventor can convert a provisional application to a non-provisional application within 12 months of the initial filing date. Non-provisional patents are also filed in the USPTO and examined by a patent examiner to determine if all requirements have been met for full patentability.

With regard to translational technological research, the stages of development from innovation to patient care, or from 'bench to bedside', is known as the **technology transfer process (TTP) and** can take approximately 17 years in its entirety.[3] **Figure 1** represents the traditional pathway of the TTP. Previously, several metrics have been operationalized to serve as proxy-measures of innovation impact.[4] Specifically, the scientific community utilized the amount of research expenditures, journal impact factors, and citation metrics to measure productivity.[3] However, these metrics by themselves neither capture the totality of the TTP, nor do they provide evaluative insight into the transfer time between innovation and care.[3] It is important to note that not all disclosed inventions must follow the path in Figure 1. For example, some inventions can receive a trademark, bypass the patent process, and still be commercialized.

Figure 1. Traditional Pathway of Technology Transfer Process (TTP)

As of December 2021, the USPTO estimates that the duration of traditional total patency (the time from filing a patent application to issuance) to be approximately two years (22.8 months).[5] A time series analysis of Georgia CTSA's patent applications is intended to illuminate any barriers associated with the patenting process in relation to the USPTO. This evaluation is intended to provide an overview of the impact of Georgia CTSA-supported invention disclosures and patents from 2007-2020 and to analyze the value of Georgia CTSA-supported research leading to market ready medical advancements.

Methodology

A mixed methods approach was used to assess and measure innovation impact during the TTP from Georgia CTSA-supported patent applications. Between fall 2019 and spring 2020, the Office of Technology Transfer (OTT) for each of the four Georgia CTSA institutions were contacted and sent a request for all invention disclosure and patent records received that cite any of the nine Georgia CTSA grant numbers. Disclosure details

[3] Balas, E.A., & Boren, S.A. (2000). Managing clinical knowledge for health care and improvement. *Yearbook of medical informatics 2000: Patient-centered systems*, 65-70.
[4] Balas, E.A., & Elikin, P.L. (2013). Technology Transfer from Biomedical Research to Clinical Practice: Measuring Innovation Performance. *Evaluation & the Health Professions*, 36(4) 505-517.
[5] States Patent and Trademark Office - An Agency of the Department of Commerce. (1994). Patents Data, at a Glance May 2021. Retrieved from https://www.uspto.gov/dashboard/patents/

were provided from all four OTTs. To ensure there was a comprehensive collection of patent data, invention disclosures, and patent records, details were also collected from four additional sources:

1) *United States Patent & Trademark Office (USPTO) Public Patent Application Information Retrieval (PAIR) system*[6] – A public database managed by the federal government that provides the status of patents and patent application data
2) *Request and Progress Information Database (RAPID)*[7] – An internal database that aggregates research data including patent application numbers, inventors, and assignees
3) *Google Patent*[8] – A search engine that provides details on patent numbers, priority dates, and patent citations
4) *Dimensions*[9] – A comprehensive online data infrastructure that explores connections between a wide range of research data

Inclusion criteria for disclosure and patent data in this report meet one of the following:

1) Acknowledgement of a Georgia CTSA grant project number (UL1 TR002378, UL1 TR000454, UL1 RR025008, KL2 TR002381, KL2 TR000455, KL2 RR025009, TL1 TR002382, TL1 TR000456, TL1 RR025010)
2) An investigator(s) that has acknowledged receiving Georgia CTSA program support on an invention

Using each of these data sources, the following categories of information were collected for each patent:

1) Filing date of application, date the patent was issued, university assignee, patent number, patent title, patent description, patent research topic area, government support clause (grant number cited)
2) Number of times the patent was cited in a separate patent application(s), Georgia CTSA-supported investigator(s), and the Georgia CTSA program associated with support provided to the application

The RAPID internal database was used to determine Georgia CTSA program impact and support for patented cases. In addition, the database tracks important research project details, such as project title and description, funding information, research team names, and associated research publications and patents. Investigator names were searched in RAPID to identify Georgia CTSA-specific program support provided and then matched to each corresponding disclosure application. There are some limitations in the data listed in the RAPID database. In some instances, there was not complete information for the Principal Investigators (PIs) involved, the partner institutions involved, and/or which project supported the invention. There are also some reporting concerns, such as data entry duplication and lack of reporting support follow-up. Additional details about the invention disclosures were found via searches on Google Patent, Dimensions, and through the USPTO Public PAIR system. The USPTO Public PAIR was used to collect the filing date and the date of patent issuance for each of the Georgia CTSA-supported patents. The duration in months between the filing date and the date of patent issuance was calculated for each Georgia CTSA-supported patent.

[6] United States Patent and Trademark Office - An Agency of the Department of Commerce. (n.d.) *Portal Applications.* Retrieved from https://www.uspto.gov/learning-and-resources/portal-applications
[7] RAPID Authentication. (n.d.). Retrieved from https://rapid.app.emory.edu/
[8] Google. (n.d.). Google Patents. Retrieved from https://patents.google.com/
[9] Dimensions. (n.d.). Retrieved from https://www.dimensions.ai/

Results

Data gathered from 2007-2020 showed a total of 42 invention disclosures, 11 patents, and 3 licenses supported by Georgia CTSA. Approximately 27% of invention disclosures supported by Georgia CTSA resulted in a patent.

The technology transfer process begins with reporting to the technology transfer office at the housing institution. For example, the 42 invention disclosures were reported at Emory, MSM, Georgia Tech, and UGA. **Figure 2** represents the percentage of research disclosures per institution.

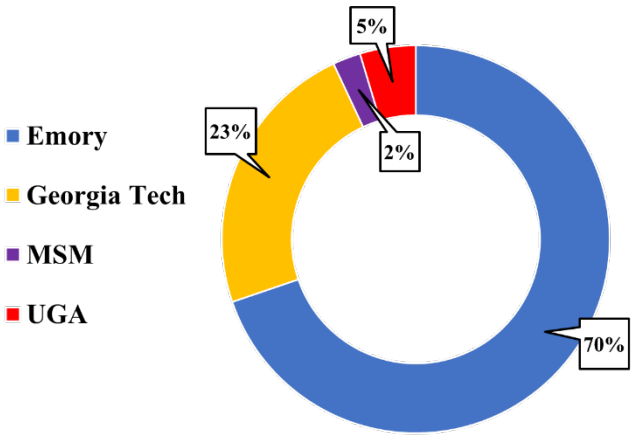

Figure 2. Georgia CTSA-supported Invention Disclosures by Institution

A total of 29 (70%) disclosures applications were filed through Emory, 10 (23%) were filed through Georgia Tech, one (2%) filed through MSM, and two (5%) filed through UGA. Once an invention is disclosed, it may begin the patent application process through the USPTO. **Table 1** includes summary details of the status of all 42 Georgia CTSA-supported invention disclosures since 2007, by institution.

Table 1. Invention Disclosure TTP Progression: Georgia CTSA-supported Applications

Institution	Invention Disclosure Application Status								
	Patent Granted	Pending Application	Application Abandoned	Application Expired	Waived to NIH	Released/ Elect Title	To Be Evaluated	No Patent Filed	**Total**
Emory	9*	2	1	2	6	2	3	6	**31***
Georgia Tech	1	2	--	4	--	--	--	2	**9**
Morehouse School of Medicine	1	--	--	--	--	--	--	--	**1**
University of Georgia	--	2	--	--	--	--	--	--	**2**
Total	**11**	**6**	**1**	**6**	**6**	**2**	**3**	**8**	**43***

**Difference in total number is due to a single disclosure application resulting in two separate patents.*

Six of Georgia CTSA's supported disclosure applications failed to be granted patents due to lack of response to a USPTO office action request or failure to pay the patent issuance fee. Six disclosure applications resulted in waiving the rights over to the NIH for reasons such as having "low commercial potential" or "too many patentability challenges." In other instances, one disclosure application was granted "elect title" by the housing institution to retain ownership of the invention, whereas another application was fully released from the housing institution and assigned over to a third-party owner. At the time of data collection, six disclosure applications were pending review and three applications were still awaiting initial evaluation. Of the 42 disclosure applications, 11 were fully granted patents, which are listed below in **Table 2**. **Table 2** lists the patent title, its housing institution, the type of program support provided, the patent number, and additional details such as the

utility patent classification. Nine patents were granted under Emory, one under Georgia Tech, and one under MSM. Ten patents are classified as methods, and only one as a medical device. Two of these patents were also issued a license. A third Georgia CTSA-supported disclosure application was issued a license as an active research tool; however, it was never fully patented (see **Appendix A** for more details).

Three Georgia CTSA programs were identified and link to providing support to the patents and research tool listed below: **Pilot Grants** (7 patents), **Georgia CTSA Clinical Research Centers (GCRCs**; 4 patents), **Community Engagement (CE**, 1 patent), **Informatics** (1 patent), and **Biostatistics, Epidemiology, and Research Design (BERD**; 1 patent). Additional information on how these programs provided support is detailed under *Patent Descriptions and Georgia CTSA Impact* and in **Appendix A**. The patent details and information listed in that section were obtained using the USPTO Public Pair System.[6]

Table 2. Georgia CTSA Supported Active U.S. Patents

Patent Title	Institution	Program Support Provided	Patent Number	Additional Info
Antibodies Directed Against Influenza #1	Emory	GCRCs	U.S. 9,469,685	Method
Antibodies Directed Against Influenza #2	Emory	GCRCs	U.S. 9,321,829	Method
Antibodies Directed Against Influenza #3	Emory	GCRCs	U.S. 10,208,107	Method
Generation of Endothelial-like Cells from Human Fibroblasts with Single Transcription Factor	Emory	Pilot Grants	U.S. 10,023,842	Method
Generation of Transgene-Free Induced Pluripotent Stem Cells from Somatic Cells by Small-Molecule Chemicals	Emory	Pilot Grants	U.S. 9,458,131	Method
iCHOOSE Kidney	Emory	BERD	No Patent – Research Tool	License Issued
Method to Localize Medical Device Leads to Optimize Patient Response	Emory	Pilot Grants	U.S. 9,858,687	Method
Monoclonal Antibodies that Specifically Inhibit Ectodomain Shedding of Platelet Glycoprotein lb-alpha	Emory	Pilot Grants	U.S. 10,081,678	Method License Issued
Respiratory Syncytial Virus Antigenomic Plasmid for Reverse Genetics	Emory	Pilot Grants	U.S. 10,227,569	Method License Issued
Serum Chymase ELISA Predicts Vascular Disease in Patients with Chronic Kidney Disease	Emory	Pilot Grants	U.S. 9,724,412	Method
System and Method for Chronic Illness Care	MSM	GCRCs, CE, Informatics	U.S. 8,234,131	Method
Wireless Head Angular Motion Monitoring and Feedback System	Georgia Tech	Pilot Grants	U.S. 9,355,309	Medical Device

When performing a time series evaluation of these patents, the span of invention disclosure application initiation to final patent issuance ranged from approximately two to seven years. **Table 3** lists order of issuance (based on patent granted date), patent title and number, the invention disclosure application filing date, the patent granted date, and approximate duration of time taken to receive official patent status (measured in months). The average duration for a Georgia CTSA-supported patent to reach issuance is approximately three years (38 months). In comparison to the USPTO Traditional Total Patency average, it takes Georgia CTSA-supported research one year longer to be granted patent status. In some cases, specifically for life sciences, average processing time from filing an application to receiving a first USPTO action can take up to two years. This extended processing time can increase patent issuance to over three years.[10] Applications may also file for a Request for Continued Examination (RCE), which increases total patency issuance time to approximately three years and eight months (46.2 months).[5]

[10] Dykeman, D., & Abramson, D. (2011). Patent strategies for life sciences companies to navigate the changing patent landscape. *J Commer Biotechnol* 17, 358–364.

Table 3. Time Series Evaluation of Georgia CTSA-supported U.S. Patents

Order #	Georgia CTSA Patent Title	US Patent Number	Filing Date	Patent Granted Date	Approx. Duration (Months)
1	System and Method for Chronic Illness Care	U.S. 8,234,131	7/14/2009	7/31/2012	36
2	Respiratory Syncytial Virus Antigenomic Plasmid for Reverse Genetics	U.S. 10,227,569	4/11/2012	3/12/2019	83
3	Wireless Head Angular Motion Monitoring and Feedback System	U.S. 9,355,309	1/8/2013	5/31/2016	40
4	Method to Localize Medical Device Leads to Optimize Patient Response	U.S. 9,858,687	1/16/2013	1/2/2018	60
5	Antibodies Directed Against Influenza #1	U.S. 9,469,685	7/8/2013	10/18/2016	39
6	Antibodies Directed Against Influenza #2	U.S. 9,321,829	4/9/2014	4/26/2016	24
7	Serum Chymase ELISA Predicts Vascular Disease in Patients with Chronic Kidney Disease	U.S. 9,724,412	4/9/2014	8/8/2017	40
8	Generation of Transgene-Free Induced Pluripotent Stem Cells from Somatic Cells by Small-Molecule Chemicals	U.S. 9,458,131	5/2/2014	10/4/2016	29
9	Generation of Endothelial-like Cells from Human Fibroblasts with Single Transcription Factor	U.S. 10,023,842	4/29/2015	7/17/2018	39
10	Monoclonal Antibodies that Specifically Inhibit Ectodomain Shedding of Platelet Glycoprotein lb-alpha	U.S. 10,081,678	7/29/2015	9/25/2018	38
11	Antibodies Directed Against Influenza #3	U.S. 10,208,107	3/29/2016	2/19/2019	35

Figure 3 is a visual timeline representation of the time series data listed in **Table 3** for the Georgia CTSA-supported patents. The timeline spans from the inception of the Georgia CTSA in 2007 to 2020. The first Georgia CTSA-supported patent was issued in 2012, and the most recent patent was granted in 2019. As shown, there is a range in review and approval process time among the 11 patents. The majority of these patenting processes fall between 2013 and 2016.

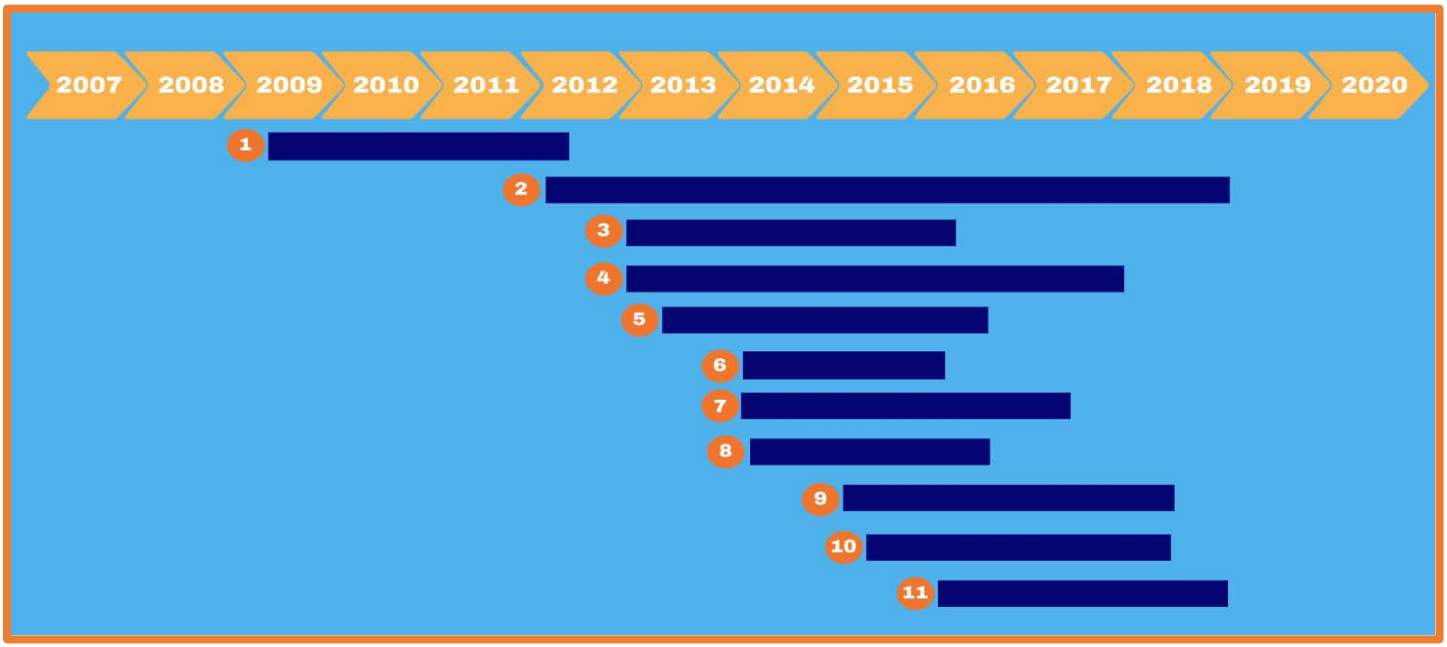

Figure 3. Timeline of Patenting Process Duration for Georgia CTSA-supported Patents

Patent Descriptions and Georgia CTSA Support Impact

Antibodies Directed Against Influenza (U.S. 9,469,685) presents antibodies, antibody fragments, and peptides that bind to an HA domain of influenza (H1N1, H5N1, or both). Influenza is a leading cause of death in the United States. The H1N1 influenza pandemic proposed unique challenges within the young adult population and very little knowledge on pre-existing antibody solutions was present at that time. This patent is related to better understanding the B cell responses and antibody mechanisms produced by influenza infection to prevent future atypical infection patterns and provides methods for using these antibodies for diagnosis and treatment. The patents U.S. 9,321,829 and U.S. 10,208,107 provide additional improvements to this invention. Georgia CTSA provided nursing staff support for the research project *Characterization of the Immune Response to Influenza Vaccination in Healthy Volunteers,* from 2007 – 2014 through the GCRCs program.

Endothelial and Endothelial like Cells Produced from Fibroblasts and Uses (U.S. 10,023,842) explores the use of endothelial cells (ECs) for cell therapy. ECs are essential for repairing injured or ischemic tissues. Other forms of cell development have been found to provide minimal endothelial trans-differentiation potential. This patent relates to identifying methods to improve compositions and techniques for EC generation. Georgia CTSA provided initial Pilot Grants (Funded by ACTSI/Georgia Tech Regenerative Medicine and Engineering Center) toward the research project *Direct reprogramming of somatic cells into endothelial cells and their therapeutic application* through a $50,000 award.

Compounds and Compositions Used to Epigenetically Transform Cells and Methods (U.S. 9,458,131) explores the natural phenomenon of pluripotency, a process that occurs naturally in early embryos and may be maintained in vitro in cultured embryonic stem cells. This patent relates to methods of nuclear reprogramming, a process used to make induced pluripotent stem (IPS) cells, in order to mimic innate genetic processes that occur during embryonic development. Georgia CTSA provided initial Pilot Grants (Funded by ACTSI/Georgia Tech Regenerative Medicine and Engineering Center) toward the research project *Patient-derived Induced Pluripotent Stem Cells, Endothelial Differentiation and Vascular Regeneration-1* through a $100,000 award. The awarded investigator mentioned that this grant helped them develop a collaborative research project, specifically in starting projects in collaboration with experts in other areas of regenerative medicine such as biomedical engineering and biochemistry. This collaboration ultimately helped to support the acquisition of a Pre-clinical Research Core (RC1) grant.

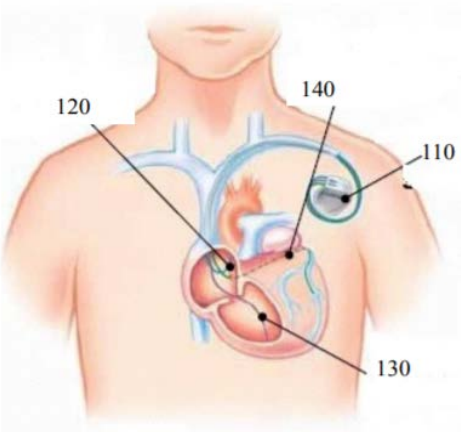

Figure 4. Example of a CRT Device Implanted in a Heart of a Patient

Systems, Methods, and Computer Readable Storage Media Storing Instructions for Generating an Image Integrating Functional, Physiological and Anatomical Images (U.S. 9,858,687) explores the challenges of providing successful cardiac resynchronization therapy (CRT) treatment for patients with symptomatic heart failure. In order to achieve maximum efficiency with CRT, ideal placement of a pacing device is essential, as shown in **Figure 4**. This patent relates to methods of using imaging to indicate optimal locations for performing CRT in patients. Georgia CTSA provided initial Pilot Grants (Funded by Research Technologies Coulter) toward the research project *An Imaging-Based Method to Plan Cardiac Pacemaker Lead Placement* through a $100,000 award.

Specific Binding Antibodies of Glycoprotein IB Alpha as Selective Ectodomain Shedding Inhibitors (U.S. 10,081,678) explores methods of preventing platelet ectodomain shedding and maintaining platelet blood serum levels for in vitro or in vivo applications. Administering donated platelets is an essential strategy for medical care of patients with thrombocytopenia, a condition caused by bone marrow dysfunctions or chemotherapy treatment. However, platelet effectiveness decreases over time if not optimally stored. This patent

relates to methods for improving platelet storage. Georgia CTSA provided initial Pilot Grants (Funded by ACTSI/University Research Committee (URC)) toward the research project *Improving platelet storage by specific inhibition of GPIb-alpha shedding* through a $30,000 award.

Respiratory Syncytial Virus Expression Vectors (U.S. 10,227,569) explores methods of generating human respiratory syncytial virus (RSV), a leading cause of hospital visits during infancy and childhood. This patent relates to better understanding plasmid stability when generating RSV particles from cloned DNA in efforts to progress vaccination development. Georgia CTSA provided initial Pilot Grants toward the research project *Respiratory Syncytial Virus Strains: Impact on Disease and Immunity* through a $30,000 award. The awarded investigator mentioned that this funding allowed the research team to generate preliminary data that later supported acquisition of an R01 grant, U19 grant, and a publication.

Serum Chymase Elisa Predicts Vascular Disease in Patients with Chronic Kidney Disease (also known as *Chymase compositions, antibodies, diagnostics, and therapeutic methods related thereto*, U.S. 9,724,412) explores challenges in artificial replacement for lost kidney function in patients with kidney failure. Hemodialysis, a popular form of treatment, requires repeated reliable access to the bloodstream known as arteriovenous fistula (AVF). Consequently, 60% of AVF procedures fail to mature properly to sustain proper hemodialysis. The patent relates to identifying ways to predict if patients are at greater risk of AVF nonmaturation in efforts to provide the most effective treatment options. Georgia CTSA provided initial Pilot Grants support toward the research project *Impact of Vitamin D on Arteriovenous Fistula Maturation in End-Stage Renal Disease (ESRD) Patients* through a $30,000 award. The awarded investigator mentioned that this pilot program provided the necessary funding needed to get their research project started. As a result, they were able to receive follow-on grant funding to extend their research for an additional year.

The *System and Method for Chronic Illness Care* (U.S. 8,234,131) explores computerized systems for providing care for chronic illnesses. Healthcare disparities in chronic illness care are most likely present among high-risk patients with multiple co-morbidities and increased use of pay-for-performance healthcare models make it more difficult for clinicians to accurately manage and provide care for these patients. This patent relates to a computerized system that includes medical professional modules programmed for receiving, storing, and providing data for patients with chronic illness to address these inadequacies in care. The awarded investigators are Georgia CTSA personnel from the GCRCs, CE, and Informatics programs. This patent was funded as part of a grant supplement, *ACT NOW, EHealthyStrides at Big Bethel AME Supplement to ACTSI Grant*, for the implementation of Health 360x in collaboration with Big Bethel African Methodist Episcopal (AME) Church. This project used principles of community-engaged research and biomedical informatics tools to assist consented diabetic congregants (participants) of the Big Bethel AME Church in Atlanta under the guidance of a trained coach to improve diabetes self-management skills.

The Wireless Head Angular Motion Monitoring and Feedback System (also known as *Generation of Medical Image Series Including a Patient Photograph* (U.S. 9,355,309) explores methods to reducing and preventing mislabeling of medical imaging studies and risk of wrong treatment due to incorrect documentation (**Figure 5**). Medical imaging studies are prone to associating the wrong demographic information to a patient's imaging examination. This patent relates to systems, methods, and computer-readable storage media that details how to generate an integrated image series that includes both a patient image and a medical image at the point of care.

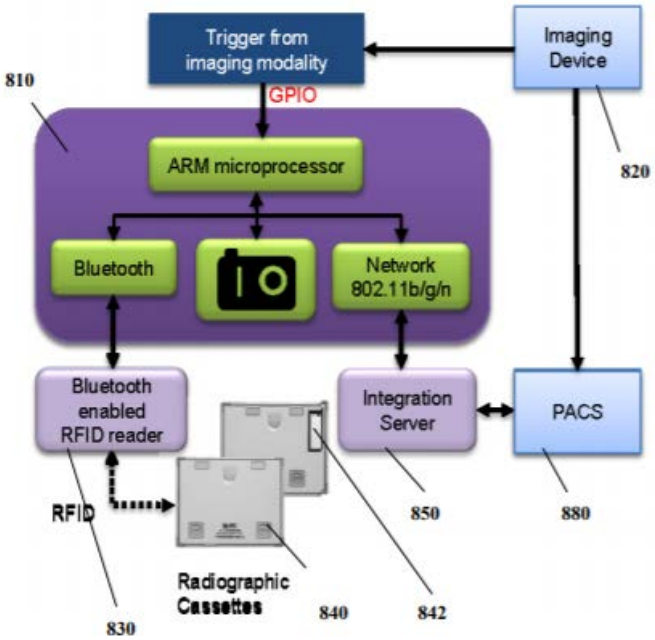

Figure 5. Example of a Medical Image System

Georgia CTSA provided initial Pilot Grants support toward the research project *Tagging Medical Data Streams with Patient Photographs to Decrease Patient Misidentification Errors* through a $25,000 award. The objective of this study was to implement and test a novel technique of incorporating point-of-care digital photography with medical imaging studies to decrease patient misidentification errors and improve radiologists' efficiency. This pilot award provided the resources needed to conduct the preliminary prototype and evaluation of the proposed research project. The results of this proposed work formed the basis for additional grant applications to Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs for further development of the system architecture and with Patient-Centered Outcomes Research Institute (PCORI) for clinical performance evaluation of the technique. Ultimately, investigators sought assistance from Emory OTT to submit their final patent application on this proposed technique.

Discussion & Conclusion

The TTP is critical to translating innovative research into protected intellectual property including medical devices as well as methods for diagnosis, treatment, and prevention. Since 2007, the Georgia CTSA has supported clinical and translational research resulting in health-related innovation disclosures, patents, and licensures.

The objective of this report was to evaluate indicators associated with success along the TTP and to assess the impact of Georgia CTSA support. There are several limitations to this evaluation including a lack of publicly available data and incomplete data in both the USPTO and Georgia CTSA databases. Regardless, this mixed methods evaluation of Georgia CTSA's technology transfer process revealed the following:

1. Georgia CTSA-supported research is yielding a robust body of patent-protected research.
2. The Georgia CTSA Pilot Grants program plays a key role in providing investigators with the opportunity to conduct the preliminary research needed to apply for additional follow-on funding to further their studies.
3. Pilot grants open the door for investigators to conduct research that leads to translational discovery, patentable inventions, and new research methods.

Georgia CTSA support has resulted in great strides in translating science into market ready products. Recommendations for future directions include:

Table 4. Challenges Faced by Georgia CTSA in the TTP and Recommendations for Future Improvement

Challenges	**Recommendations**
• Citation of Georgia CTSA grant in disclosure and patent applications • Lack of investigator and research project support details recorded in Georgia CTSA internal tracking database	• Strengthen internal Georgia CTSA invention disclosure and patent reporting requirements • Yearly reports to monitor the progress of Georgia CTSA invention disclosures and patents
• Follow-up with investigators during the patent application process	• Emphasize greater intentional efforts to support investigators throughout the TTP and toward pursuing invention disclosures • Facilitate stronger connections on the TTP between principal investigators (PIs) and their respective OTTs • Increase monitoring of patent applications by communicating with PIs and OTTs to reduce administrative issues and delays
• Patent reporting between Georgia CTSA and alliance universities' OTTs	• Build stronger reporting connections between the Georgia CTSA and OTTs for reporting disclosure and patent data

Commercialized innovation is a key factor in improving the health and wellbeing of communities. By strengthening the role of the Georgia CTSA in the TTP, it may be possible to not only produce more patent protected research but also expand the breadth of Georgia CTSA's economic, scientific, and societal impact.

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Acknowledgements

We would like to thank J. Cale Lennon, III, Director, Licensing for Emory University Office of Technology Transfer; Kimberly Dunn, Compliance Associate, Licensing for Emory University of Technology Transfer; Mark Coburn, Senior Associate Director, Technology Licensing for Georgia Tech Office of Industry Engagement; Emily Daniels, Administrative Manager, Innovation Gateway for University of Georgia Office of Research; and James Lillard, Director, Morehouse School of Medicine Office of Translational Technologies; for their invaluable assistance in gathering and assisting in analyzing invention disclosures and patents resulting from Georgia CTSA support.

In addition, we would like to thank Marie Manguerra, MPP; Joseph Caldwell, MPH; and Morgan Greenleaf, for their contributions and feedback on this report.

Research reported in this evaluation was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health under award number UL1TR002378. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Appendix

A. Full Descriptive Details for Georgia CTSA-supported Patents

U.S. Patent Number	Patent Title	Research-related Topic Area	Institution	Supported Investigators	RAPID Project Title	Associated Program Support	Grant Number Reported	Patent Citations
U.S. 9,469,685	Antibodies Directed Against Influenza #1	Medical and Health Sciences Public Health and Health Services	Emory	Rafi Ahmed Ken Kokko George Lyon Aneesh Mehta	Characterization of the Immune Response to Influenza Vaccination in Healthy Volunteers	GCRCs - Nursing Support from 2007-2014	NIH-RR025008	US10208107B2 CA2850720C US9969794B2 EP3037533A4 EP3157950A4 EP3374390A1 EP3445783A2 US20180244784A1 WO2019169231A1
U.S. 9,321,829	Antibodies Directed Against Influenza #2							US10208107B2 EP2486054A4 US9969794B2 CN103513032B EP3037533A4 AU2015231164B2 BR112018002824A2 EP3374390A1 CN106928350A US20200040081A1
U.S. 10,208,107	Antibodies Directed Against Influenza #3							
U.S. 10,023,842	Generation of Endothelial-like Cells from Human Fibroblasts with Single Transcription Factor	Engineering Biomedical Engineering	Emory	Young-Sup Yoon	Direct reprogramming of somatic cells into endothelial cells and their therapeutic application	Pilot Grants (ACTSI/GTEC Pilot Award) - $50,000	NIH-TR000454	US10503258B2 EP3333645A1
U.S. 9,458,131	Generation of Transgene-Free Induced Pluripotent Stem Cells from Somatic Cells by	Biological Sciences Biochemistry and Cell Biology	Emory	Young-Sup Yoon Xiaodong Cheng	Patient-derived Induced Pluripotent Stem Cells, Endothelial Differentiation	Pilot Grants (GTEC funded from EVPHA and	NIH-RR025008	US20150057263A1 CA2900652A1 US9890173B2 US9688688B2 AU2014219024B2 NZ719185A SG11201606934SA

	Small-Molecule Chemicals				and Vascular Regeneration-1	WHSC; ACTSI/GTEC Pilot Award) - $100,000		US10023879B2 CN104830754B SG11201808799SA MX2019002629A EP3509422A4 CA3036340A1
U.S. 9,858,687	Method to Localize Medical Device Leads to Optimize Patient Response	Information and Computing Sciences Artificial Intelligence and Image Processing	Emory	John Oshinski Michael Lloyd	An Imaging-Based Method to Plan Cardiac Pacemaker Lead Placement	Pilot Grants (Research Technologies Coulter) - $100,000	NIH-RR025008	WO2019012066A1
U.S. 10,081,678	Monoclonal Antibodies that Specifically Inhibit Ectodomain Shedding of Platelet Glycoprotein lb-alpha	Medical and Health Sciences Immunology	Emory	Renhao Li	Improving platelet storage by specific inhibition of GPIb-alpha shedding	Pilot Grants (ACTSI/URC Pilot Award) - $30,000	NIH-TR000454	US10503258B2 EP3333645A1
U.S. 10,227,569	Respiratory Syncytial Virus Antigenomic Plasmid for Reverse Genetics	Biological Sciences Genetics Microbiology	Emory	Martin Moore	Respiratory Syncytial Virus Strains: Impact on Disease and Immunity	Pilot Grants - $30,000	NIH-RR025008	US10626378B2 US9957486B2 CN105189756A US10100372B2 AU2017363180A1 WO2019162532A1
U.S. 9,724,412	Serum Chymase ELISA Predicts Vascular Disease in Patients with Chronic Kidney Disease	Medical Sciences Clinical Sciences	Emory	Haimanot Wasse	Impact of Vitamin D on Arteriovenous Fistula Maturation in End-Stage Renal Disease (ESRD) Patients	Pilot Grants - $30,000	NIH-RR025008	N/A

U.S. 8,234,131	System and Method for Chronic Illness Care	Medical and Health Sciences Public Health and Health Services	MSM	Elizabeth Ofili Priscilla Pemu Alexander Quarshie Priscilla Johnson	ACT NOW, EHealthyStrides at Big Bethel AME	GCRCs, CE, Informatics – Awardees are Georgia CTSA Personnel	NIH-RR025008	CN104184567B US10140674B2 US20150187226A1
U.S. 9,355,309	Wireless Head Angular Motion Monitoring and Feedback System	Information and Computing Sciences Artificial Intelligence and Image Processing	Georgia Tech	Srini Tridandapani James Provenzale Pamela Bhatti Kimberly Applegate	Tagging Medical Data Streams with patient Photographs to Decrease Patient Misidentification Errors	Pilot Grants - $25,000	NIH-RR025009	KR20150042871A US9517184B2 US9198835B2 USD717340S1 USD716841S1 USD735343S1 WO2015022430A1 JP6224561B2 US20170000462A1 JP6506683B2 US20180189368A1