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- CTSA site services, training, and pilot grant funding can benefit researchers at any stage of their career, from trainees to faculty.
- While all CTSA-funded programs offer support for research and training, the focus and services offered vary by institution.

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Clinical and Translational Science Awards

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Topic Relevance by Time

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Introduction

Academic medical centers offer a multitude of opportunities for research. However, it can be difficult to bridge the gaps between the bench, the bedside, and the marketplace. The National Institutes of Health (NIH) have identified this challenge, and offer Clinical and Translational Science Awards (CTSAs) to research institutions to help spur innovations. This chapter will explore the CTSA concept and how an academic entrepreneur can best tap into the services offered by a CTSA, discussing Columbia's Irving Institute as an example.

History of Clinical and Translational Science Awards

The twenty-first century brought a new dawn in the convergence of technology and scientific medical discoveries. However, few of these discoveries are translated into improved clinical care,

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undermining achievement of one of the key goals of the NIH: “foster[ing] fundamental creative discoveries, innovative research strategies, and their applications as a basis for ultimately protecting and improving health” (“Mission and Goals”).

In 2002, Dr. Elias Zerhouni was appointed as director of the NIH during a dynamic time: the institute’s budget had been doubled between 1998 and 2003 (E. Zerhouni), yet only 36% of the NIH budget was spent on clinical research and training activities (E. A. Zerhouni). Prior to joining the NIH, Zerhouni had developed clinically relevant cancer and cardiovascular disease diagnostics. Once at the NIH, he sought to capitalize on the growth in NIH funding to address “critical scientific gaps.” He set up discussions between legislators, administration officials, institute directors, patient advocates, and scientific leaders to develop “the NIH roadmap,” explaining the reorganization as follows:

The NIH earned its reputation for success because of the vitality of its institutes, centers, and offices and because of the diverse ways in which it funds and conducts research—all fostered by decentralization inherent to its organization and funding streams. This characteristic serves the agency well and should be preserved. However, as science grows more complex, it is also converging on a set of unifying principles that link apparently disparate diseases through common biological pathways and therapeutic approaches. Today, NIH research needs to reflect this new reality. (E. Zerhouni)

In recognition of the “new vision of healthcare,” the NIH sought a new funding model to streamline biological research (Zerhouni and Alving). In 2005, this vision was, in part, operationalized through a new program to fund institutional centers, the Clinical and Translational Science Award (CTSA). The initial request for applications explained the intent of the CTSA program: “to enable applicants to engage in innovative and transformative efforts appropriate to their own environment that will develop and advance clinical and translational science as a distinct discipline within a definable academic home” (Hayward). The new CTSA centers were encouraged to consolidate disparate efforts in clinical research, such as General Clinical Research Centers, T32 and T12 programs, and other resources (Zerhouni and Alving).

The first 12 CTSA grants were awarded in 2006, and by 2008 the program had grown to 38 centers in 23 different states, representing all geographic regions of the country. By 2009, over ten thousand researchers, 70% of whom held a doctorate, received funding administered through CTSA grants. Subsequently, the National Center for Advancing Translational Science (NCATS) was created in 2011 to manage the CTSA program as part of its core mission of accelerating the translation of new treatments and cures from the lab to patients. Currently, there are 58 CTSA centers (*National Center for Advancing Translational Sciences (NCATS) FY 2020 Budget*).

A key characteristic of research funded by CTSA is the multidisciplinary and translational nature of the projects, with most CTSA offering a broad range of services (Table 1). Furthermore, the national CTSA program is supportive of entrepreneurship, with several CTSA sites emphasizing this aspect of clinical and translational research. For example, Duke University's CTSA has a focus on healthcare and entrepreneurship, fostered through an active partnership with the health sector management program at the Fuqua School of Business. A similar program at the University of California–Davis CTSA encourages faculty entrepreneurship, intellectual property, and business development (National Center for Research Resources) (see the chapters “Writing Business Plans for a Life Science Startup or Clinical Program”, “Intellectual Property: Ownership and Protection in a University Setting” and “Intellectual Property: Commercializing in a University Setting”).

Annual budgets for individual CTSA sites can vary widely, ranging from \$4 million to \$23 million in 2012, for example (Briggs and Austin). The total annual budget for the CTSA program in fiscal year 2019 from NCATS was \$559 million (“Budget | National Center for Advancing Translational Sciences”).

CTSA Site Organization

Each CTSA site is located at a U.S.-based academic health science center that has access to an affiliated health system, usually inclusive of pediatric healthcare. Many sites are housed within medical schools, and several are consortia of medical schools, universities, hospitals, and other local educational and research institutions. A hallmark of the CTSA program is that each site is given a large degree of flexibility in organizational structure to best meet its needs. Thus, CTSA sites vary considerably with regards to the specific research services they offer; these are generally funded by the U01 component of the CTSA (Table 1). One CTSA may offer extensive bioinformatics support, while another may choose to focus their funds on genomics. This highlights an important point for an academic entrepreneur to keep in mind, especially if they are considering transferring from one institution to another: the ability to conduct a research study at one CTSA may not necessarily mean that another CTSA can provide similar services (see the chapter “Careers in Academia and Industry: Transitions and Challenges”). Also, CTSA have different cost structures for their services, such that one CTSA may have reduced charges for using outpatient research suites for certain types of research studies, while another may have higher charges for those same studies.

Table 1. Examples of Research Services That May Be Available at a CTSA Site.

| Service | Example |
|--|---|
| Core Facilities | <ul style="list-style-type: none"> ● Translational technologies ● Laboratory services ● Embryonic cell lines ● Nanotechnology ● Epigenomics |
| Biomedical Informatics | <ul style="list-style-type: none"> ● Behavioral data analysis ● Geographic coding ● Proteomics ● Customized software |
| Pilot Funding | <ul style="list-style-type: none"> ● Institutional pilots ● Trainee and scholar pilot programs ● Partnerships with industry and not-for-profit programs |
| Regulatory Support | <ul style="list-style-type: none"> ● Auditing and compliance measures ● HIPAA compliance ● Conflict-of-interest management ● IRB agreements ● Protocol development |
| Biostatistics Support | <ul style="list-style-type: none"> ● Adaptive trial design ● Randomization and blinding ● Statistical modeling and analysis |
| Participant and Clinical Interaction Resources | <ul style="list-style-type: none"> ● Cost recovery planning ● Case report form development ● Research nurse support |
| Community Engagement Resources | <ul style="list-style-type: none"> ● Adult literacy assessment ● Cultural competency training ● Public databases |

Source: Adapted from Leshner (Leshner et al.)

In addition to these research services, a core mission of the CTSA program is to support training the research workforce. This is generally accomplished through KL2 (for researchers with an MD, PhD, or equivalent) and optional TL1 (for predoctoral trainees) awards, which provide access to the following components (“Scholar and Research Programs | National Center for Advancing Translational Sciences”):

- Clinical research mentor expertise
- Access to biomedical research specialized equipment and databases
- Training through courses, seminars, and workshops
- Administrative support for research protocols
- Pilot research project funding

Examples of training programs available through a CTSA include master’s or certificate degrees in translational research; these also vary widely by institution.

Each CTSA is also required to establish and maintain an external advisory committee that meets annually to discuss structure, progress, and challenges of the program and its research (Leshner et al.). Some CTSA also host internal advisory committees and other advisory and governance structures, such as executive committees and community advisory boards.

The NIH tasked CTSA with developing a national consortium to identify optimal research practices. Originally, this comprised a consortium steering committee staffed by CTSA primary investigators. From this main committee, subcommittees were formed around NIH-identified priorities like education, informatics, and regulation. At this time, there are an additional three main leadership committees (see Table 2).

Table 2: CTSA Committees.

| Committee | Membership Size | Membership Type | Purpose |
|---|--------------------------------------|--|-------------------------------------|
| Consortium Executive Committee | 31 total members; 21 voting members | PIs, staff, and other | Main governing body |
| Consortium Steering Committee | 175 total members; 85 voting members | PIs from each CTSA institution, representatives from NCATS | Setting strategic goals |
| Consortium Child Health Oversight Committee | 230 total members; 60 voting members | PIs, pediatric researchers, and staff | Promoting child health and research |

Source: Adapted from Berglund and Tarnatal (Berglund and Tarantal)

How Academic Entrepreneurs Can Access Support from Their CTSA Site

As noted earlier, a CTSA may provide several services that could be of use to an academic entrepreneur (Table 1). Broadly speaking, these include the following:

- **Educational opportunities:** As noted earlier, these are often provided by the KL2 or TL1 awards, or through dedicated workshops or other training events sponsored by the institution's CTSA award.
- **Research facilities:** These may include inpatient or outpatient suites for research study visits and specialized lab equipment. They may also provide access to research nurses and other trained staff, such as research echocardiography technicians, dieticians, etc., as well as core lab services and specimen storage.
- **Specialized expertise:** This often includes biostatistics and bioinformatics expertise.
- **Grant funding:** Pilot grants and other support are usually available through a competitive peer-reviewed process.

Because of the breadth of services offered, accessing these services can be daunting. Since each CTSA site has a different name and organization, as a first step, an academic entrepreneur should do an internet search for the term “CTSA” and their institution’s name. Typically, there is an option to sign up as a member of the CTSA or receive their email announcements. In addition, CTSA staff are often very willing to meet with researchers to discuss how the institution’s CTSA can benefit their specific project. One-on-one meetings are very helpful in matching the unique needs of a specific research project with beneficial services, training, and pilot grant support. This support is available to researchers at any stage of their career, from trainee to faculty member.

Columbia University’s Irving Institute: An Example of a CTSA Site

In 1971, the Columbia Presbyterian Medical Center received a grant from the NIH to establish a General Clinical Research Center (GCRC), the predecessor of the CTSA award. This monetary support provided for research space, beds, and equipment in early trials on volunteer patients; the program was later called the Irving Center for Clinical Research. In 2006, the GCRC funding ended, as Columbia was one of the twelve inaugural recipients of a CTSA grant. The initial award was \$54 million over five years. It allowed the Irving Institute to expand their core resources of medical informatics and biostatistics, which has led to the current resource and core offerings:

- Administrative Core and Evaluation
- Biomarkers Core Laboratory (BCL)
- Biomedical Informatics Resource (BMIR)
- Bionutrition Research Core (BRC)
- Biostatistics, Epidemiology, and Research Design (BERD)
- Clinical Research Resource (CRR)
- Community Engagement Core Resource (CECR)
- Integrating Special Populations Resource (ISP)
- Pilot and Collaborative Studies Resource (PCSR)
- Precision Medicine Resource (PMR)
- Regulatory Knowledge and Support and Ethics Resource (RKSER)
- Training and Education (TRANSFORM)
- Translational Therapeutics Accelerator (TRx)
- Trial Innovation Network

Characteristically for CTSA centers, the Irving Institute is multidisciplinary and collaborative, incorporating multiple institutions: the New York State Psychiatric Institute, the Mailman School of Public Health, and the Children’s Hospital of New York. While the focus of the Irving Institute is precision medicine, it has also pioneered a translational research accelerator program, the Columbia Technology Ventures (see the chapter “Accelerators and Incubators”). At the most recent

count, in 2017–2018, the Irving Institute CTSA served 380 researchers (including one of the authors of this chapter) and engaged in more than 500 research projects.

Table 3: Examples of CTSA Educational and Research Grant Support.

| Grant Type | Target Audience | Type of Support | Amount of Support |
|-------------------------------|---|--------------------------------|---|
| TL1 | Pre- and post-doctoral researchers | Salary and educational support | Dependent on PGY year; \$44,000–\$55,000 and benefits for two years |
| KL2 | Early career physician researchers | Salary and educational support | Up to \$100,000 per year for two years |
| Bench-to-Bedside Pilot Award | Assistant professors in clinical and basic science | Research supplies | \$40,000 for one year |
| Precision Medicine Fellowship | Clinical fellows with doctoral degrees | Salary | \$100,000 per year for two years |
| Irving Scholar | Full-time Columbia faculty at the rank of assistant professor | Salary support | \$60,000 per year for three years |

Academic entrepreneurs at Columbia University can access support from the Irving Institute through key funding opportunities organized by career stage (from trainees to faculty). Table 3 demonstrates examples of the types of services, training, and funding that an Irving Institute grant could support. As noted earlier, since each CTSA is different in terms of the services it offers, the types of grant support available also will vary.

In addition, even if the Irving Institute does not offer the services needed, an academic entrepreneur from Columbia can still access resources at a nearby CTSA since cross-institution collaboration is encouraged.

Conclusion

The Clinical and Translational Science Award debuted in 2006 as a funding mechanism for academic medical centers that serves to accelerate the translation of research findings into the world of patient care. It accomplishes this mission by centralizing clinical and translational research and education in its fifty-eight funded centers and has emerged as a key component in facilitating research in the U.S. The CTSA program is very supportive of biomedical entrepreneurship, and

thus can be an indispensable partner for an academic entrepreneur seeking to develop new technology and innovations in patient care.

Resources

1. A helpful summary of the success of the CTSAs in achieving their purpose and where they might be going in the future is provided by the National Academy of Medicine: https://www.ncbi.nlm.nih.gov/books/NBK144067/pdf/Bookshelf_NBK144067.pdf.
2. C TSA program hubs: <https://ncats.nih.gov/ctsa/about/hubs>.
3. Types of funded activities under the NCATS C TSA program: <https://ncats.nih.gov/files/ctsa-funding-information.pdf>.
4. Resources for career development: <https://ncats.nih.gov/ctsa/about/training>.
5. NIH RePORT Tutorials: <https://report.nih.gov/tutorial/index.aspx>.
6. NIH C TSA in Action: <https://ncats.nih.gov/ctsa/action>.
7. NIH Matchmaker: https://projectreporter.nih.gov/reporter_matchmaker.cfm.

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