

# Novel Team-Based Approaches to Advance Academic Translational Research

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**T**he Academic Health Center (AHC) at the University of Minnesota (UMN) has multiple internal, peer-reviewed grant programs that support biomedical research. Our programs have several themes including preferential support for early career faculty, support of novel ideas that have not matured to the point of being competitive for federal funding, and bridge grants to support faculty who are experiencing a temporary lapse in federal funding. Many of the funded projects are conducting translational research that aspires to have an impact on human health. This research often culminates in publications and new NIH grant submissions. However, it frequently loses momentum in the quest to develop new diagnostic products and therapies, due to the absence of a process and a paucity of institutional resources that can facilitate the evolution of successful translational research to a practical impact on human health.<sup>1,2</sup>

Facilitating translational research into outcomes that have an impact on human health can be hindered in research environments that still emphasize independent investigative achievement and autonomy. There can also be a general lack of understanding regarding the challenges and best practices necessary to achieve success. Many faculty do not have the expertise necessary to understand the business, regulatory, and intellectual property issues that must be successfully navigated in order to maximize the potential for their research to move past translational discovery and into practical application.<sup>3,4</sup> In an effort to overcome these challenges, the UMN CTSA has created the Office of Discovery and Translation (ODAT) to develop unique approaches that provide translationally focused support through funding programs and project teams.

## Principles of the ODAT Approach

In early 2012 ODAT set out to break the mold of traditional academic grant programs by attempting to identify and address the fundamental gaps in academic translational research through three core principles: (1) ODAT focuses on projects with the highest potential for translatability, (2) ODAT provides both operational and technical project management support for milestone-based projects within cross disciplinary team-based models, and (3) ODAT aims to advance projects along the continuum between discovery and eventual patient application by helping investigators to better understand the full spectrum of decision points, timelines, costs, and key considerations along the development pathway.

In project selection, ODAT's emphasis is on practical application to improve human health. Toward that end, every project submitted for ODAT funding undergoes a peer-reviewed scientific and translational feasibility assessment as a part of the evaluation process. Translational feasibility is reviewed by technology-transfer professionals with experience in assessing

development potential. Projects selected for funding must have identified a novel technology or approach and have a clear understanding of the potential target patient population. ODAT does not require PIs to have already filed on intellectual property; however, the potential for intellectual property is heavily evaluated and prioritized.

Successful translation of medical devices, diagnostics, and therapies requires skillsets beyond those of a single researcher, and often beyond those traditionally found in the academic setting. Recognizing that this limitation frequently impedes the progress of academic innovations, ODAT was built upon the foundation that team-based partnerships between individuals with technical and operational expertise and academic investigators is the key to success.

## Putting the ODAT Principles into Practice

The cornerstone of the Office of Discovery and Translation is a program and project management staff with experience spanning academia and industry; representing both the operational and technical aspects of medical device, diagnostic, and therapeutics development. ODAT has established a framework of core capabilities to support investigators in their translational research goals. ODAT provides essential guidance for projects; helping investigators to overcome development barriers using their own capabilities or facilitating the engagement of experts. ODAT pursues this mission with the philosophy that without this level of technical and operational support, lifesaving and life-improving inventions may never achieve wide spread application.

ODAT utilizes a team-based approach to product development more traditionally found in industry R&D programs. ODAT has developed an expansive network of more than 125 UMN and industry-based scientific and technical experts, including regulatory, intellectual property, manufacturing, reimbursement, market analysis, preclinical study design, clinical trial design, and biostatistics. ODAT collaborates with these experts to create cross-disciplinary project teams and standing advisory committees that provide guidance for each project.

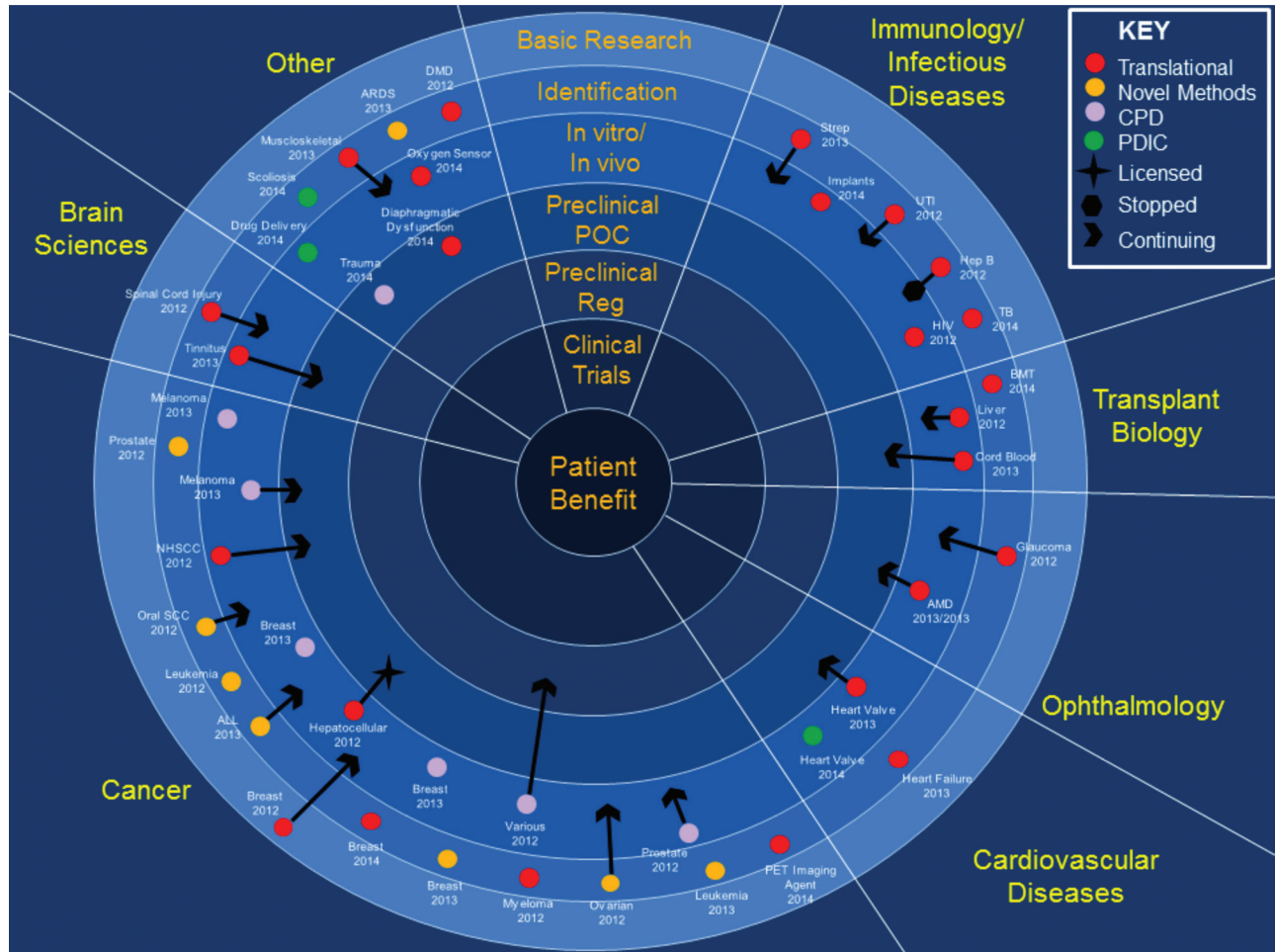
ODAT has instituted novel funding programs that deviate from traditional academic granting programs in their milestone-based team approach. For early-stage projects ODAT utilizes Project Development Teams (PDTs) created specifically for each project. This concept was adapted from the Indiana CTSI PDT model which utilizes standing committees to assist investigators in obtaining external grant funding. UMN PDTs include members with the expertise required to advance the development of the technology. Later-stage pharmaceutical projects are supported by the Committee for Pharmaceutical Development (CPD), a standing advisory committee of internal and external experts with proven track records in drug development. ODAT has

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DOI: 10.1111/cts.12211

**Figure 1.** ODAT projects supported through individual Project Development Teams and standing committees are indicated by filled circles. The color of each circle corresponds to specific funding programs. Each project is assigned a project stage at initiation of support and translational progress is tracked as the project advances. To determine the longer term impact of ODAT funding and support, projects will be tracked for up to 5 years following completion of support. Continuing indicates that the project met a specific milestone and has advanced to the next stage. (Adapted from UW Institute for Clinical and Translational Research/WARF presentation.)



recently entered into a pilot partnership with the Pediatric Device Innovation Consortium at the UMN (an advisory and consulting program), in which ODAT provides project management infrastructure and funding for selected projects.

Once projects are funded, ODAT provides technical project management to assist in establishing a development plan with appropriate scientific, business and regulatory milestones, as well as operational project management to facilitate and document team discussions, address development barriers and track study progress. Together, the ODAT team serves as a constant resource for investigators both throughout the course of the study, and beyond the ODAT funding period to support long-term development efforts.

### Measuring Success

ODAT's primary measure of success is advancement of projects along the continuum between discovery and patient application. Projects are evaluated for stage of development at the beginning and end of the funding period to determine the level of advancement achieved under ODAT funding and leadership.

Projects are also tracked beyond the funding period to determine long-term outcomes. *Figure 1* reflects one method ODAT utilizes to monitor its portfolio by disease area and project progression. ODAT intends that investigators will gain beneficial insight from their experiences working with cross-disciplinary development teams, and will apply that knowledge to future research projects. Over time, this type of exposure transitions from awareness raising to behavior changing; arming investigators with the know-how to successfully navigate the path from discovery to practical application. Other key measures include additional funding obtained, licensing agreements, entry into clinical trials, intellectual property filings, and publications. Less tangible outcomes such as knowledge transfer to the research community about the translational development process are more difficult to quantify, but just as impactful in creating awareness and changing behaviors towards more translationally focused research. The research community at UMN appears to be engaged with the support ODAT is offering as evidenced by positive feedback from investigators and a steady increase in proposal submissions throughout the past 3 years.

As of July, 2014, ODAT has reviewed more than 220 proposals, and provided more than \$2.7M in funding to 62 projects through five funding programs. Of the 62 funded projects, 43 have been provided team support through individual PDTs or standing committees.

It is too early to determine how successful the ODAT team-based project management approach will be long term; however, ODAT-funded projects have demonstrated early translational successes—in addition to several IP filings and new grant awards, one supported technology has been successfully licensed and two start-up companies have been established.

### Examples of ODAT Involvement

Example 1: ODAT awarded funds to a UMN junior investigator and coinvestigator from the Mayo Clinic to identify and test novel ATP-sensitive potassium channel openers for the treatment of glaucoma. ODAT organized a Project Development Team with membership from both UMN and the Mayo Clinic and has taken the principal project management role for this partnership research program. Two lead compounds have been identified and a provisional patent application was filed in January 2014. The PDT is currently mapping out the preclinical development program to support the filing of an investigator IND and initiation of a phase 1 clinical trial. The scientific expertise of the researchers is augmented by a PDT that includes a clinician, regulatory consultant, preclinical development advisor, IP expert and GMP drug manufacturing representative.

Example 2: In 2013 a senior investigator in the Medical School approached the Committee for Pharmaceutical Development (CPD) for assistance in determining the path to an IND application for a compound to treat hemorrhagic shock. The research team had thoroughly demonstrated efficacy in small and large animal models, but wanted to ensure that future studies would support an IND submission and recognized that the development plan would require expertise outside of their domains. The CPD supported this project by assembling and covering consulting fees for a team of expert advisors. The team for this project has 16 members including UMN faculty and staff, and industry experts (regulatory, CMC, toxicology). It is co-led by ODAT's technical and project management team made

up of individuals with industry development experience. The project deliverable is a detailed development plan through Phase II including tasks, dependencies, estimated costs, and timelines. The final development plan can be utilized to focus development efforts and aid in fund raising.

### Adapting and Innovating

ODAT is evaluating the addition of resources to support the expanding translational goals of the UMN research community. Staffing efforts require careful consideration related to maintaining key priorities and high-quality support through selection of staff with the necessary skills and experience. ODAT is exploring additional partnerships to reach a broader audience, and approaches to bring together and leverage resources from groups that are traditionally isolated at major research institutions. The research behind many novel technologies is increasingly crossing the boundaries of disciplines and institutions. ODAT envisions being at the leading edge of that trend by setting standards for best practices and methods of creating cross-disciplinary teams united toward a common goal in the academic setting.

### Acknowledgments

Material reported in this publication was supported by the National Center for Advancing Translational Sciences of the National Institutes of Health Award Number UL1TR000114. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

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