Miami CTSI Highlights, Milestones and Challenges Report

The deliverables of the Miami CTSI are aligned and on target with vision in our original application. We have built a home for clinical and translational research at UM, transforming not only clinical and translational research processes and infrastructure but significantly impacting workforce development and the research emphasis at UM towards an agenda that will better serve the health needs of our diverse community.

Over the past year, we have continued to scan the research infrastructure horizon to identify opportunities for transformation. This scanning has led us to develop a more meaningful relationship with our research partner, Jackson Health System, and jointly seek to streamline research across the two Institutions. We are building significant team science projects at UM by fostering multidisciplinary collaborations, such as health disparities-focused biomedical nanotechnology projects. We have partnered with the Sylvester Comprehensive Cancer Center to better understand the prevalent health disparities that affect our community's health and wellbeing. We also partnered with UM central offices to develop and promote the institutionalization of education, training, ethics, and career path initiatives. Together with these same offices, we have reduced the burden on investigators by focusing on major areas of concern, including our IRB and pre-award accounting processes. In addition, we have paved the way for institutional transformation in key areas, such as the inclusion of race and ethnicity identifiers in our Electronic Medical Records. Finally, we have begun collaborations with the University of Florida under our OneFlorida initiative, intended to leverage each other's strengths as the only two CTSAs in the State of Florida.

We dedicated a significant amount of time this year to strategize on how to align the University of Miami to address the vision set forth in the 2014 CTSA Funding Opportunity Announcement. This new direction set by NCATS has led to a reprioritization of our current activities and the creation of new initiatives, as described below.

Some of the highlights and milestones of the year were:

Participation in Consortium Projects: Dr. Jonelle Wright serves as co-investigator of the "Enhancing Clinical Research Professionals' Training and Qualification" CTSA consortium-wide supplement grant award. In addition to serving on the overall leadership team, in Phase 1, Dr. Wright chaired the Metrics and Evaluation Subcommittee that developed the set of metrics proposed to NCATS for evaluating the workforce development standard of GCP training for individuals involved in the conduct of clinical research. The leadership team (Shipley, Barohn, Wright, Luzuniaga, and Rubinstein) has now progressed well into Phase 2, with goals to define a set of competencies within broader performance domains that the clinical research professional is expected to possess to optimally perform their professional tasks, identify corresponding assessment measures, and develop/refine/provide curricular tools and training approaches that teach these competencies using a variety of training strategies. Dr. Wright chairs the Team Science/Team Work Competency Work Group for Phase 2.

OneFlorida: The University of Florida (UF) CTSI and Miami CTSI are fully aligned to serve as a catalysts for efficiency, quality, innovation and impact across the full spectrum of translational research, and to avoid duplication and redundancy. Several activities are of notice:

- Our institutions have established a reciprocal data and safety monitoring MOU, and we have a data coordinating and analysis service agreement in progress. The OneFlorida vision allows us to further integrate and streamline infrastructure and recruitment for multi-site studies, including a statewide cooperative IRB and Consent2Share program.
- Scientific collaborations are underway to leverage existing infrastructure between the UF CTSI and Miami CTSI in cancer, nanotechnology and metabolomics research.
- Under the Department of Health funded OneFlorida Cancer Control Alliance grant, we established a partnership with the University of Florida, Florida State University, and Health Choice Network to facilitate conduct of statewide pragmatic and implementation science clinical trials. The ultimate goal is for the placement of limited EMR datasets from patients in select clinical sites into a OneFlorida Data Trust using an honest broker system, and Interface linkages to other data such as Medicaid data and Consent2Share for patients willing be contacted to be enrolled in clinical trials.

Jackson Health System (JHS) Partnership: For the first time in the long history of our partnership, we established recurring monthly UM/JHS Research Leadership meetings to address opportunities for process improvement. Meeting attendees include: Dr. Omaida Velazquez (Executive Dean for Research), Dr. Roberto Heros (Director for Clinical Research and Senior Vice President and Chief Medical Officer, International & Physician Development for JHS), CTSI leadership (Drs. José Szapocznik, Jonelle Wright, Elaine Van der Put), Dr. Dushyantha Jayaweera (Head of UM IRB), Ms. Eve Sakran (JHS Corporate Director of Clinical Research), Ms. Jill Tincher (UM Office of Research Administration). In addition, the CTSI has hired an expert research liaison/facilitator, reporting directly to Dr Roberto Heros, to assist him in the daily JHS management of UM-generated grant proposals, study protocols, and implementation plans.

Team Science Impacting the Health of our Community: Collaborations with the Dr. John T. Macdonald Foundation Biomedical Nanotechnology Institute at the University of Miami (BioNIUM) have led to the development of a paper-based assay to rapidly conduct cervical cancer screening at the point-of-care. Currently, funding has been obtained to further validate the assay in a broad population, including women with HPV. A provisional patent is in place, and the study team is pursuing a commercialization grant to develop a prototype. This work is of particular relevance to minority women disproportionately affected by HPV in South Florida.

Highlights in improved research infrastructure and tools:

The University Research Informatics Data Environment (URIDE) system: The Miami CTSI has developed informatics tools that enable investigators to work with EMR and research data in a secure environment. Our URIDE tool was launched University-wide in October 2014. To date, URIDE has been used to successfully expedite cohort assessments, strengthen proposals with demonstrated patient populations, and accelerate access to PHI. URIDE had 91 users in the first six months, representing 21 different departments and divisions. We are now developing a platform to utilize EMR to support clinical predictive modeling and population health management and facilitate research patient recruitment by creating and alert at the patient point-of-care for future contact about research opportunities. Through URIDE we identified shortcomings with our current method of collecting racial/ethnic information, which we have corrected. Moreover, all URIDE users are encouraged to conduct analyses by race/ethnicity in their area of interest.

Comprehensive Data to Improve Cancer Research: The BioResource program implemented a new reporting tool called mTuitive to convert the free-text format of pathology reports for all cancer samples. The synoptic data is now exported regularly to URIDE. Moving forward, this will allow investigators to identify cohorts in URIDE with specific pathologic staging and tumor types combined with specific clinical laboratory parameters.

Standardizing Laboratory Data for Clinical and Research Use: LOINC (standardized medical laboratory observation) and RxNorm (normalized names for clinical drugs) ontologies have been incorporated in URIDE. Data using these ontologies began being imported into the EMR in March 2015. Approximately 10,000 laboratory result components now have LOINC codes associated to them, including all commonly ordered labs. Enabled by these common ontologies, our Biomedical Informatics and BioResource programs are collaborating to push synoptic lab data from the mTuitive interface into the EMR and ultimately feed URIDE.

U Innovation and Office of Technology Transfer Output: A revitalized innovation program (UInnovation) which includes the Office of Technology Transfer and the Wallace H. Coulter Center for Translational Research was created by the CTSI. The program has successfully provided investigators with the resources to protect and commercialize their research. From Year 1 to Year 3 the number of license agreements has increased by 57%, growth in IP revenue from $1.2 million to $2 million, and there were 51 invention disclosures. 18 of the 30 UM start-ups were established in the last 18 months, with 10 start-ups this past year alone. A 12-person Industry Advisory Board (IAB) was also established this year to facilitate fast-track development of ideas as well as identify process improvements areas at UM that have the potential to expedite translation from the laboratory to commercialization.

Implementation of Core Management Platform: With the support from the CTSI, a common e-Platform (iLab Solutions) is being implemented for the management of core and shared resources, including service request,

tracking and billing. This will bring increased efficiency to the cores, optimize collections and contribute towards their sustainability.To date, 13 cores have been identified for iLab implementation. Four cores are currently being transitioned, with nine more planned over next 12 months.

Clinical Trials Process Improvements: This year, IRB7 was deployed as a replacement for UM's outdated eProst system. The system has now been fully operationalized, and data shows that the average number of days from creation to submission by PI's for new studies has gone down from nearly 70 days to approximately 20 days.

Process Improvement to Decrease Administrative Burden: The CTSI led an initiative to move the institution towards a pre-award guarantee account process. Prior to the CTSI's initiative, manual cost transfers led to a highly inefficient system. The volume of journal entries per person had decreased 98 percent by Year 2 of the CTSI

Development of Innovative Biostatistical Methods and Modules: Fifteen new biostatistical methods research areas were developed, with three focusing on health disparities. In addition, 10 statistical software modules were developed, with two focusing on health disparities. See details in the Research Design and Biostatistics narrative. Of notice, we developed the PRISM statistical analysis software, which enables examination of complex interactions across multiple levels of influence (e.g., neighborhoods and epigenetics) on health disparities.

REDCap Utilization: We introduced REDC in Year 02 and saw a threefold increase in the number of research projects using REDCap, with 239 total projects this year - a 173 percent increase in the number of users. As a corollary, a pilot is in progress to collect patient data via REDCap and MyUHealthChart (web-based patient portal to EMR) questionnaires prior and at the time of visit via mobile devices.

Creation of an Internal Pool of Intramural Grant Reviewers: 102 reviewers with a track record of recurring funding and NIH study section participation are now available as reveiwers for all members of our Pilot Federation. These reviewers represent 22 departments across the three UM campuses. It should be noted that obtaining quality reviewers had been the major complaint of administrators of all internal award programs.

Highlights in Workforce Development

Grant Writing Workshops Have Improved Grant Award Success Rate: The success rate of the participants of our grant writing workshop is 40 percent, as compared to the overall success rate of 17 percent for the University as a whole; 63 grants were submitted and 25 grants funded following program participation.

Clinical Research Professionals Training: The "U-Way" workshop, a forum to teach clinical research staff how to efficiently navigate the UM research processes, went from pilot phase to full implementation in September 2014 with the participation of 17 institutional offices and 53 attendees. We recorded the workshop and developed online video modules for future workshops. Also, this year we offered to the Network of Clinical Research Professionals nine seminars, tailored towards basic education and training of clinical research staff, with over 480 encounters. The seminars consistently rate "Excellent" (61 percent) or "Very Good" (32 percent). The surveys also rate participant's learning and gather feedback for new topics.

CITI course for Clinical Research Professionals: As part of a CTSA consortium activity, our Regulatory Program developed a new CTSI-specific CITI module for Clinical Research Professionals and made it available for review and comment by representatives of the CTSA hubs.

Clinical Research Career Ladder and Job Descriptions: UM Human Resources has adopted the CTSI-developed framework and it is scheduled for rollout in April 2015.

Highlights in Culture and Community

Capturing Diversity Data and Mapping Disparities: We included race and ethnicity identifiers in the EMR data and in URIDE, based on NIH-defined criteria. This inclusion of identifiers will enhance the study of health disparities in medical data available for research use and population health initiatives. Significant efforts are

also underway to map the geographic distribution of disparity across South Florida. In collaboration with the Center for AIDS Research and the UM Sylvester Comprehensive Cancer Center Disparities and Community Outreach Core, this map will enhance disparities research and participant recruitment efforts. A smartphone application to document in real-time UM's presence in the local community is also currently being developed.

Community Health Worker Certification: Our Community Engagement program helped create a certification for a new community health (and research) worker category in Florida. The Florida Certification Boar approved of the certification, with Florida becoming only the 17th state in the United States to do so.

Challenges

Institutional Transformation: Transforming research process infrastructure (policies, procedures, resources, standards) and support for team science requires significant change in organizational culture, decision making, communication strategies, and institutional reward mechanisms. We are addressing these challenges by consistently involving the institutional research leadership in the initiatives spearheaded by the CTSI. We reconfigured our Executive Committee, creating a smaller, more focused "Alignment Committee" just for these matters. The new committee is composed of the Vice Provost for Research (Dr. John Bixby), the Executive Dean for Research of the Medical School (Dr. Omaida Velazquez) and a spokesperson for the Clinical Chairs of the Medical School (Dr. Ralph Sacco, Chair of the Department of Neurology). The Alignment Committee meets regularly once a month and often more frequently, as needed. We also have striven to engage key stakeholders at UM by regularly communicating our goals and progress. For example, a series of CTSI-focused meetings were held over the course of three months as part of the Medical School Research Cabinet. Each CTSI program gave a presentation and fielded questions and received feedback from the Medical School Dean and the entire research leadership at UM.

Balance of Senior and Junior Directors for the CTSI program: Some of our exceptional leaders initially recruited to serve as Program Directors have been institutionally promoted and/or their research programs have flourished, so much so that they no longer have bandwidth to meet the effort initially committed to CTSI responsibilities. We reconfigured the CTSI management by reducing these leader's effort and adding supporting faculty/staff to better leverage the CTSI role of these Institutional leaders while increasing operational efficiency. We will continue to tweak leadership participation in Year 4, always aiming for greater efficiency and impact. Examples of these changes are:

CTSI Program	Role	Name	Year 2 effort	Year 3 effort
Evaluation	Director	Sara Cjaza	15 %	10 %
Evaluation	Co-Director	Margaret Byrne	10 %	0 %
Evaluation	Evaluation manager	Rosalina Das	0 %	100 %
Novel Methods	Director	Norma Kenyon	10 %	0 %
Novel Methods	Co-DIrector	Alessia Fornoni	0 %	15 %
Research Education	Sr Advisor curriculum	Daniel Arrmstrong	15 %	5 %
Research Education	Co-Chair Curriculum	Joshua Hare	5 %	0 %
Research Education	Co-Chair Curriculum	Tatjana Rundek	0 %	20%
Research Education	Assistant Chair Curriculum	Barry Hudson	0 %	15 %

Institutional Support

The Institutions has honored its commitment to support the CTSI with adequate cost sharing. In addition to the NIH funds, the University of Miami contributions to the CTSI in Year 2 (June 2013 - May 2014) and estimated Year 3 (June 2014 - May 2015) are:

	YEAR 2 (Actual)			YEAR 3 (Estimated)		
	Direct Cost	IDC	Total	Direct Cost	IDC	Total
UL1	$3,172,325	$1,485,977	$4,658,302	$3,231,566	$1,699,480	$4,931,046
KL2	$ 281,900	$ 22,552	$ 304,452	$ 356,624	$ 28,530	$ 385,154
Total	$3,454,225	$1,508,529	$4,962,754	$3,588,190	$1,728,010	$5,316,200

New Directions and Shift in Funds

Participant Recruitment Initiative: Several initiatives need to be created and/or strengthened to efficiently participate in the national network of multi-site studies that is conceived as CTSA 2.0; and to further improve our ability recruit our diverse population into clinical studies. We started a due diligence to understand and address the perceived barriers in clinical research participation recruitment and retention. We conducted a survey in February 2015 with 102 respondents, 60 percent coming from Clinical Research Professionals and 40 percent from faculty. The following information was gleaned from this survey:

Participant-related Issues

- Transportation challenges (long travel time and cost) (70 percent)
- Work and/or family responsibilities (50 percent)
- Lack of awareness/knowledge of the public of clinical trials (46 percent)

Study-related Issues

- Lack of personnel/resources (39 percent)
- Lack of awareness/knowledge of public about clinical trials (38 percent)
- Ineffectiveness of the recruitment strategies (34 percent)

Institution-related Issues

- Lack of help/resources/guidance at UM to do effective recruiting (51 percent)
- Lack of help/resources/guidance at UM to identify places/clinics to recruit (45 percent)
- Lack of access to potential volunteers to find studies (34 percent)

We are currently reviewing the literature for best practices and have set aside resources in our Year 4 budget for three pilot initiatives of evidence-based solutions to improving recruitment into clinical research. Lessons learned from these pilots will help us structure bold University-wide initiatives in our reapplication.

Expansion of the Grant Writing Workshop series: Given the success of the Grant Writing Workshops, we are doubling its offering in Year 4.

Request for Shift in Funds: We are requesting to shift $147,983 from the UL1 awards to the KL2 award. Our notification of award was received in July of 2012, one month into the award period. It took us a few months to structure the KL2 Request for Applications, announce it, collect applications, and review them. The first round of KL2 scholars was awarded in February of 2013, eight months into our first year. As a consequence, there is a need to further support this first year cohort an additional eight months into Year 4, in addition to the six scholars we are currently budgeted to support during Year 4.