Minutes of the GMF Meeting

For Wednesday, July 15th, 2014

Mission: Building upon our existing clinical research infrastructure

Meeting started at 5:00 PM

Dr. Mondal welcomed the attendees. He informed the GMF that there will be three speakers. Following their presentations, he will announce the GMF Election Results.

Dr. Delafontaine, M.D. (Director of Tulane Heart and Vascular Institute)

Title: ***The Louisiana Clinical and Translational Science (LA CaTS) Center***

-- The LA CaTS Center represents a unified, comprehensive approach targeting the theme of "prevention, care and research of chronic diseases in the underserved population".

-- The IDeA CTR Program (www.LACaTS.org) was funded to Pennington Biomedical Center as the lead institution, and both Tulane and LSU as collaborating institutions. The website shows the key functions and resources available with this center, as well as funding and training opportunities that are available to the Faculty.

-- This CTSA program was initially launched by the NCRR to create a hub for clinical and translational research. The currently funded CTSAs include sixty grants nationwide. This was initially run by the NCRR, but now has transitioned to be a part of the NCATS (as of 2011).

-- The goals of this funded application (#PAR-11-229) were to serve the Medically Underserved population in the Idea States in the South. Key components of the LaCATS program are the funding of Pilot Grants for junior investigators, Education initiatives, Infrastructure development for Clinical & Translational research, increase the number of Investigators working on Health Disparity, and improve relationships with the community.

-- The grant consists of both internal and external advisory boards, as well as several Governance and Steering committees. At Tulane, Dr. Delafontaine is involved with the Clinical Research Unit. All the recent COBRE leaders (Drs. Navar, Deininger, Busija and Jazzwinsky) are also a part of the Internal Advisory committee.

-- The website for Tulane's clinical & translational unit will provide samples, education and training for the Clinical studies, statistical support and regulatory support (contact Dr. McDuffy for more details). A new program for streamlining Clinical Trials will also be offered at this LA-CaTS website through the CTSA program. Dr. Delafontaine urged everyone to check out the website and to utilize these resources available with this program towards their Clinical & Translational studies. Funding will offer primary care-based weight loss program in minority populations. The emphasis would be to demonstrate the successful outcomes from this funded grant, e.g. publications that list the center and grants that acknowledge the center. Dr. Delafontaine stated that there has been a significant jump in users in the use of LA CaTS resources in the second year.

-- Pilot grants offered by this program will be standard applications funded for 1-2 years study ($ ~30 K/year). These are for by Junior Faculty only. These projects are designed to support pilot studies of significance and impact that will allow the investigator(s) to compete for extramural funding (e.g. NIH, DOD, or Foundations). These projects should be relevant to understanding the epidemiology, etiology and pathophysiology of diseases, and help develop new approaches to prevent or treat them. The program will support research activities and will also provide eligible pilot projects with access to scientific, statistical and regulatory cores to facilitate their development. Four grants will be funded this year as was done last year. This time, both new and established investigators will be eligible.

-- Dr. Delafontaine ended with a reminder that a new multi-Institutional RFP [U-54] is going to be due in the next few months and preparations for this submission are in progress. This application will be

similar to the previous CTSA grant; however, this will include more educational, clinical training, and involve multi-institutional components. This new application will also be targeted towards the health status in underserved population (Health Disparity).

Dr. Weiner, M.D. (Associate Dean for Clinical Research and Training)

Title: *LaCATS Clinical Research Training Core: Preparing Young Faculty Investigators*

-- One of the key components of the LA-CaTS Idea grant was 'Career Development and Education', and Dr. Weiner is addressing this goal along with Dr. Gregory (at LSU). He stated that these are important issues in both the CTSA grant and his ongoing COBRE grant.

-- Enhancing academic Clinical Research has been a continued challenge and the NIH first recognized and dealt with this in 1998 and launched the K-30 Program. This program aimed to train the Basic Scientists in Clinical research. The COBRE grant by Dr. Weiner was funded in 1999 and has significantly evolved since that time, especially in the development of a 'Master of Science in Clinical Research (MS-CR) program, designed to prepare the next generation of clinical and translational researchers and to transform Louisiana into a destination for clinical research for both patients and the pharmaceutical industry.

-- The CTSA program also included this as a key function. From these grants, a cohort of people around the Nation will be funded for sustainable and independent career in clinical trial development. This provides opportunity for more competitive research in the Idea States. Mentoring is an important part of this academic training under both grants. Multi-Institutional collaborations and interdisciplinary collaborations are also important. The goal is to identify assessment tools and metrics, evaluate, identify and promote best practices in Clinical research and training.

-- The current 'Roadmap' for MS-CR scholars in the Clinical research course, includes conferences, seminars. Dr. Shenoy is the clinical research navigator in this course and spends. There is also an internal advisory committee who reviews and selects the MSCR scholars and Ph.D. Postdocs to be funded. They have two years of funding and will submit a K-award for another two years. The meritorious postdoc scholars will need to be at a stage of transition to independent position. The benchmark for progress are determined and reviewed periodically to prepare the scholars for K-award submission.

-- is an academic degree intended to prepare students for careers in clinical research with programs that emphasize understanding of clinical issues and the application of methods of clinical and translational research. The curriculum of this MS program is basic mechanisms, translational research, grant writing, journal club and elective courses, e.g. health disparity, communication, etc., for a total of 38 credits. These courses will also include protocol writing. There is a lot of individual tutoring for both grant writing and protocol writing.

-- The Roadmap scholars are junior Faculty members working with a subject-specific mentor and one that does not need to be subject specific. One postdoc is funded each year and will need to obtain a 10 credit certificate on epidemiological and biostatistics. This support is for three years and provides 75% of the salary support. There are currently seven scholars that have obtained nine grants in this program, and have published more than 20 papers in peer-reviewed journals (2011-2013). This is focused on NIH career development.

-- Dr. Weiner ended with the emphasis that funding opportunities (e.g. K-24) are also available for Mid-Career scientists, Associate Prof. and beyond. He stated that this Mid-Career funding opportunity has been an under-utilized.

Dr. Sartor, M.D. (Associate Director for Clinical Programs, Tulane Cancer Center)

Title: *Drug Development Issues and the Clinical Research Team*

-- Drug development: Dr. Sartor has been involved in a number of drug development projects around the Nation. It begins with Pharmacology of a disease, identification of a lead compound, pre-clinical validation in small animals, and demonstration of low toxicity and favorable pharmacokinetics.

-- Creation of intellectual property (IP) is the most important issue to engage a pharmaceutical company since scale-up to clinical trials takes significant amount of funding ($ Millions). Following the application of IND to the FDA, progression to the Phase-I to show low toxicity and then to –II and –III studies can then take place to demonstrate efficacy.

-- Most clinical trials do not progress to the phase-III and thus most companies are very wary of the funds spent and its recuperation. Companies hire groups of experts that work with them to facilitate this process. Multiple expertise are needed to move this progression in the clinical trials. These will include Basic scientists, Clinical Research Organizations (CRO), institutional review boards (IRB), data monitoring committee (DMC). Staying compliant with the IRB is one of the most important issues. Safety of the patient is the primary goal of the IRB and they directly interact with the regulatory and advisory boards of the Company, and discuss the findings with the FDA.

-- The sites for clinical trials are critical and involvement with all aspects of the financial contracting and trial progression is needed to decrease later legal issues. Therefore, the role of Research Associates are very crucial and regular meetings with the associate, regarding proper handling of patient forms and samples, and monitoring of the proper guidelines and treatment protocols are very important issues. The significance of the clinical trial team, and regular interactions with the financial and regulatory committees are principle requirements for a successful drug development process.

-- At Tulane, one of the key clinical trial successes has been with Dr. Coy's group towards the development of Somatostatin analogs (e.g. Lanreotide).

Dr. Mondal, Ph.D. (Associate Professor of Pharmacology, GMF Chair)

Title: ***GMF Election Results and Business Updates***

-- Dr. Mondal thanked the Faculty for taking part in the voting process. This was a very successful election with high level of Faculty participation. He announced that the new GMF chair will be Dr. Chayan Chakravarty, M.D., the new Vice-Chair will be Dr. David Franklin, Ph.D.; and Dr. Kathy Lazarus, M.D. will be the new Secretary. Dr. Mondal then went on to announce all the other newly elected members and stated that the updated list can be found at the GMF website.

-- Dr. Mondal presented a brief over-view of the last three GMF meetings, the presenters and their topics of discussion. Dr. Mondal then went on to present the GMF expenses incurred in the last four meetings and reminded the Faculty to submit their ideas and criticisms in the new 'Suggestion Boxes'.

Meeting adjourned at 6:05 PM.

Sincerely Yours,

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