MedStar Good Samaritan Hospital

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To the D2d Coordinating Center and Executive Committee,

It is with great interest and enthusiasm that we write this letter of support to be a subsite for the NIH D2d (Vitamin D and type 2 diabetes) study being conducted by MedStar Health Research Institute. We have met with the MedStar Principal Investigator for D2d, Vanita Aroda, MD, and have shared the available resources on the MedStar Good Samaritan Hospital campus to make D2d a success. We are a state-of-the-art community hospital in the northeast region of Baltimore City and have developed a reputation for our efforts in community engagement and chronic disease management.

We have a robust patient population in our catchment area, with an estimated **4998** patients who both meet the D2d eligibility criteria and received their care in our region within the last four months. We have reviewed the main site's approaches to patient and provider engagement within the MedStar Health system, including IRB-approved direct patient outreach and utilization of the EHR to enhance engagement and communication about the study, and would be supportive of similar approaches at the MedStar Good Samaritan Hospital subsite. In addition, we have numerous other community outreach channels that we will utilize to share this study opportunity with our community partners.

We have the space, storage capabilities, research staff, and investigators, to support the conduct of this study for an anticipated full 8 years, and further if there is an extension period. Dr. Adline Ghazi, our Director of the Diabetes Center at MedStar Good Samaritan Hospital, will be able to serve immediately as co-investigator on this study, and can dedicate up to 10% FTE toward this study. As her clinical supervisors, we can assure this protected time for the success of the study. Dr. Jean Park, a well-respected endocrinologist within the MedStar Physician Partners group on our campus, will also be available to join as co-investigator in July, 2014. We believe that a local collaboration between these two endocrinologists, who represent both hospital based and ambulatory based care, under Dr. Aroda's oversight, will support the goals of the study.

We have a track record for supporting high quality clinical research studies within the Good Health Center of MedStar Good Samaritan Hospital. The growth of community based research programs such as D2d is in direct alignment with the vision of the Good Health Center. We look forward to working closely with our main study site to contribute significantly to the study at large.

Sincerely,

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Medstar Good Samaritan Hospital/Medstar Union Memorial Hospital

Stuart M. Levine, MD, FACP
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Proposal for MedStar Baltimore Subsite for D2d Study

By way of introduction, MedStar Health is the largest healthcare provider in Maryland and the Washington DC region, consisting of 10 hospitals, MedStar Health Research Institute, and a comprehensive scope of health-related organizations. It has one of the largest graduate medical education programs in the country, training more than 1,100 medical residents annually, and is the medical education and clinical partner of Georgetown University. MedStar Health consists of 30,000 associates and 6,000 affiliated physicians. MedStar Health Research Institute (MHRI), the research arm for MedStar Health, provides scientific, administrative, and regulatory support for research programs throughout all of MedStar Health (1). Figure 1 below depicts the breadth and scope of services and locations of MedStar Health care facilities and potential research outreach.

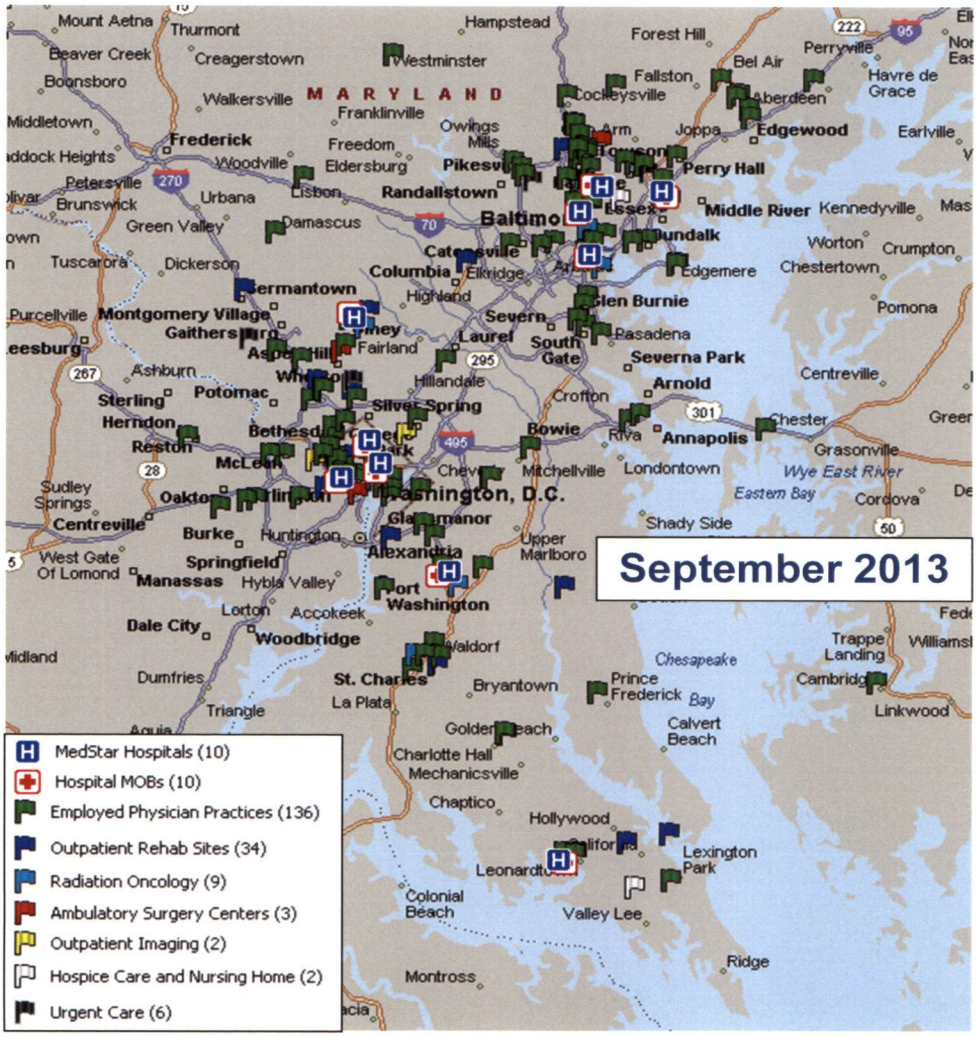

Figure 1. MedStar Health system sites, distributive care network. Two primary clusters of care are depicted, one in the Baltimore region, and a southern area surrounding the Washington DC area.

Relevant to the D2d (Vitamin D and type 2 diabetes) study is the rich outpatient population representative of the study at MedStar Health. In 2013 alone, there were a total of 3,778,908 outpatient visits. An IRB-approved database query evaluating the numbers of active patients seen in our ambulatory care network with that meet the inquiry criteria posed (Figure 2) reveals a count of: **4998** potentially qualified patients who have been cared for at a MedStar facility **since November 1, 2013** (query date 3/24/14, MedStar Health Research Institute).

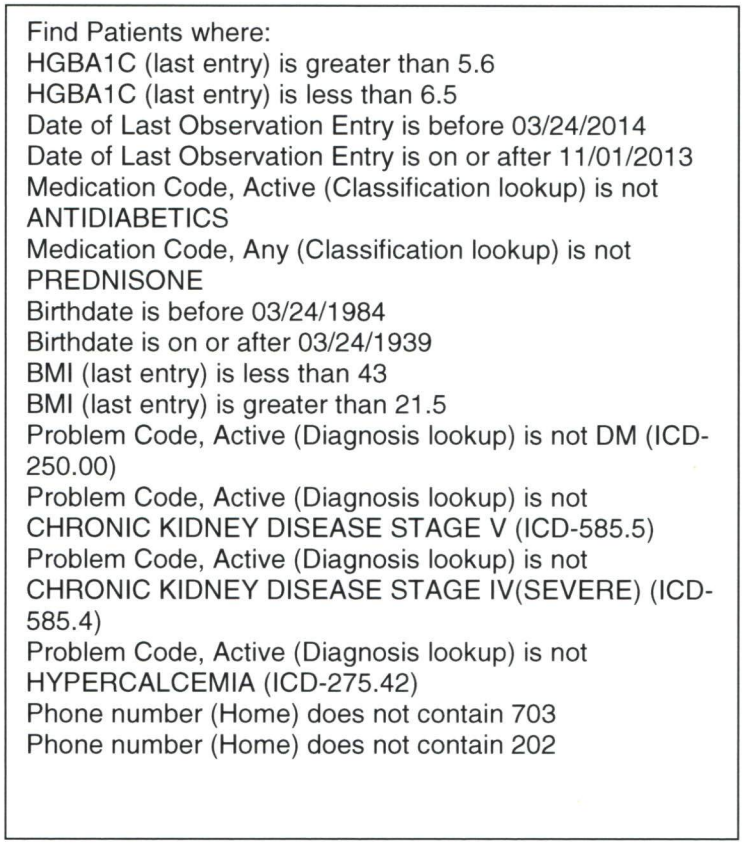

Figure 2. IRB-approved EHR query to identify individuals that may be potential candidates for the D2d study in the Baltimore region.

The outpatient ambulatory care network utilizes Centricity (General Electronic) electronic health record for out-patient care, with complete demographic information integrated with diagnostic codes, dates of diagnosis, problem lists, both active and inactive medications, and laboratory findings including most recent HbA1c. The entire database is searchable by each of these parameters, and we have been utilizing this resource for both de-identified information preparatory to research as well as identification of specific individuals for flagging for particular research studies. Established protocols approved by our Office of Research Integrity allow, with IRB approval, identification of potential study participants meeting criteria for IRB approved clinical trials, flagging of the charts to inform the primary care provider of the study and their patient's potential eligibility, and provision of information concerning the trial directly to the

enthusiastic support of all aspects of conduct of the D2d study at the Good Health Center of the MedStar Good Samaritan Hospital campus.

Study Management Plan: To maintain consistency in practices and performance across the MedStar D2d sites, the current MedStar Principal Investigator (Vanita Aroda, MD) will also serve as PI role of the MedStar Baltimore subsite. The PI has time and effort available to do this. The current PI has identified two local physician co-investigators, Drs. Adline Ghazi and Jean Park, and has obtained support from their leadership for their active involvement as physician investigators. To maintain consistency in practices at the program coordinator level, the current MedStar D2d program coordinator will dedicate effort toward overseeing the onboarding of the MedStar D2d Baltimore subsite and assuring its success.

Staffing and Training: All staff who conduct research within MedStar Health are required to go through orientation and training conducted by the institution. These training modules are reinforced through online training modules. Physician investigators also go through physician investigator orientation and are required to complete the same online training modules. The PI (V. Aroda) will be responsible for onboarding and training of the local co-investigators. This is within the realm of her role as Scientific Director, Ambulatory Research, MedStar Health. In addition, Dr. Stuart Levine, a seasoned investigator and Medical Director for the Good Health Center has agreed in kind to oversee and support physician investigator duties and mentorship for all studies conducted at The Good Health Center. As described in the study management section above, the current MedStar D2d program coordinator(s) will dedicate effort toward overseeing the onboarding of the MedStar D2d subsite, including any required coordinator training.

Specific Requests: We have consulted with our IRB and have confirmed that any additional IRB documents for the MedStar D2d Baltimore subsite can be submitted for expedited review. We will need to edit our current documents, including recruitment materials, to reflect the Baltimore site, staff, and investigators. We will also need to officially post the research coordinator positions per our Human Resources policies. **Therefore, we would request the green light to initiate these processes as soon as there is internal approval for moving forward.**

References

(1) MedStar Health 2013 Annual Report. https://www.medstarhealth.org/Documents/About-Us/2013-Annual-Report.pdf. Accessed January 21, 2013

patient. In addition, we are able to insert research progress notes and laboratory values directly into the individual subject's medical record to inform further therapy by their primary physician.

By working closely with Medical Director of Ambulatory EHR and Health IT Policy for all of MedStar Health, Dr. Peter Basch, a collaborating investigator on this study, we have been able to develop tools within the EHR that support patient and provider engagement with this study, including printing of IRB-approved D2d information handouts during office visits, EHR-merged mailing of IRB-approved letters to patients, placement of care alerts and flags for patients enrolled in the study, and direct input of laboratory values into the EHR. We will readily be able to activate the same processes in the Baltimore region.

Site Location

The proposed MedStar D2d Baltimore subsite would be at the MedStar Good Samaritan Hospital (MGSH) campus. MGSH has been named a Top 50 best hospital for 3 years in a row by *U.S. News & World Report*. It is a 317-bed community teaching facility located at the corner of Loch Raven Boulevard and Belvedere Avenue in northeast Baltimore City.

MGSH primarily serves the northeast section of Baltimore City, composed of the Chinquapin Park/Belvedere, Greater Govans, Hamilton, Harford/Echodale, Lauraville, Loch Raven and Northwood neighborhoods. The hospital also serves parts of Towson and Parkville, located in Baltimore County. Statistics provided by Thomson Reuters Market Expert Database show that the base population of these areas is approximately 414,200 and consists of Caucasians (41.9%), African Americans (50.9%), Hispanic/Latinos (2.1%), Asian/Pacific Islanders (3.1%) and Other (1.9%).

MGSH is known within the MedStar Health system for its community campus flavor, with strong community engagement and outreach. The 43-acre campus includes the main hospital as well as multiple primary care and outpatient facilities, including the Center for Primary Care, in addition to a MedStar Physician Partners' primary and specialty ambulatory care center, a rehabilitation center, and two senior housing complexes. The campus has multiple Community Benefit initiatives targeting chronic conditions including heart disease, cancer, stroke, and diabetes, with a focus on programs to prevent disease, manage chronic disease, and improve quality of life. To help meet the needs of the uninsured and underinsured, MGSH's Center for Primary Care has been committed to providing affordable and accessible primary care.

Some of MedStar Good Samaritan's specific community outreach efforts are listed below, and demonstrate additional avenues that messaging about **D2d to the community at large could take place:**

Blood Pressure Screening Program: MedStar Good Samaritan's Community Outreach and Parish Nurse programs work in partnership with community and religious organizations, including senior centers and senior housing facilities, to offer monthly free blood pressure screenings. The goal of this effort is to raise awareness, educate and identify people with high blood pressure. In 2010, 1,300 community residents were screened for hypertension;

approximately 50% of those screened had blood pressure readings over the normal range. For participants with no primary care physician, either because of lack of insurance or for some other reason, names and phone numbers of physicians are provided as well as contact information for MedStar Good Samaritan's Center for Primary Care, where the uninsured can gain access to health care.

Good Health Center: The Good Health Center provides an array of free and low-cost diagnostic screenings, educational seminars and preventive medicine services for the community. The Good Health Center is a comprehensive health enhancement facility that offers an active approach to improving well-being. A primary goal of the Center is to empower clients to take control of and address their health issues. Services provided by the Good Health Center include exercise programs, nutrition counseling, a diabetes support group, a comprehensive health screening program and other wellness programs.

The Good Health Center is the proposed physical location for D2d study conduct within Baltimore, and is currently staffed with research nurses, dietitians, diabetes educators, and physicians. Growth of a community based research program such as D2d is very much in line with the goals of the Good Health Center.

Chronic Disease Self-Management Program: This 6-week, 15-hour program, taught by MedStar Good Samaritan community outreach nurses, is offered several times throughout the year to people who suffer from chronic diseases. This program is also taken to local senior resident buildings to provide this service to those who are unable to travel. This program was developed at the Stanford Patient Education Research Center and is conducted in partnership with the Baltimore County Department of Aging and the Baltimore City Office of Aging. The goal of this program is to empower individuals to manage chronic illnesses, such as heart disease, diabetes, hypertension and arthritis.

Other community programs provided by MedStar Good Samaritan include support groups for individuals suffering with breast cancer, prostate cancer, diabetes, amputation, back pain, arthritis, dizziness, speech disorders, substance abuse and heart disease. In 2010, MedStar Good Samaritan participated in 474 community events with **14,164** in attendance.

Number of participants to be enrolled: Based on IRB-approved database queries, suggesting at least 4998 patients seen within the last 4 months at a MedStar care facility in the Baltimore region that would meet initial prescreening criteria for D2d as listed above, we estimate a feasible enrollment goal of **100** patients over the D2d recruitment period. Recruitment and patient/provider engagement practices would mirror those done at our main site, including both patient and provider engagement using corporate communications channels, EHR tools, and IRB and leadership-approved direct outreach to potential participants.

Approvals for study conduct: Please refer to attached letter of support from Dr. Stuart Levine, Vice-Chairman, Strategic Growth and Research, Department of Medicine, MedStar Good Samaritan Hospital, Medical Director, The Good Health Center (proposed location for subsite), from Dr. Dana Frank, Chairman, Department of Medicine, MedStar Good Samaritan Hospital/MedStar Union Memorial Hospital, and Dr. Martin Binstock, Vice President-Medical Affairs, MedStar Good Samaritan Hospital. Study details, facility, staffing, and storage requirements, physician and physician investigator involvement, in addition to patient and provider engagement practices have been reviewed in detail and the leadership is in