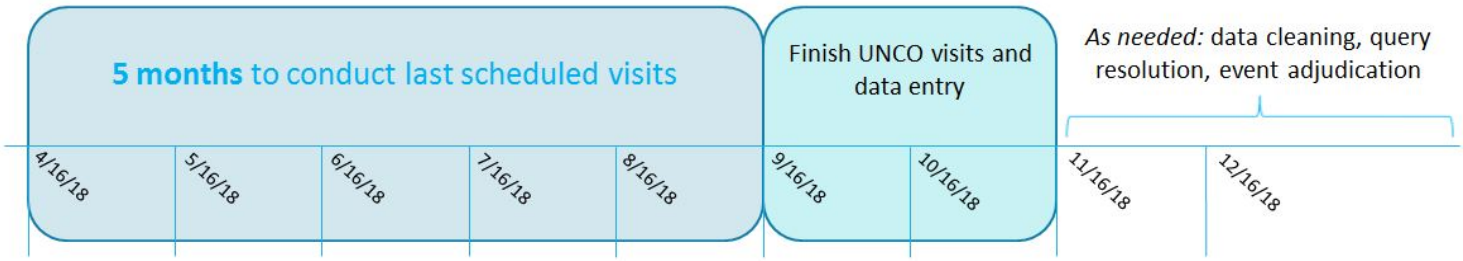
D2d Vitamin D and type 2 diabetes
diabetes prevention research matters

News and Information for Collaborating Clinical Sites

End-of-study procedures began on April 16, 2018

Going forward, the participant's next visit (whether semi-annual or annual) will be the Last Scheduled Visit (LSV). Please refer to MOP section 20 for a description of end-of-study procedures.



- Every effort should be made to have all inactive participants return for a final visit. However, sites should **prioritize efforts to engage newly inactive participants** (i.e. missed two or three visits) before moving on to long-term inactive participants (i.e. inactive for a year or more).
  - ➢ Check out the Re-engagement Retention Checklist, developed by RRS, available in MOP 17 appendix.
- If an interim contact is due, complete as scheduled. Inform the participant during the interim contact that the next visit will be his last scheduled (as UNCO may be needed) visit and that it is extremely important to complete the visit.
- Use the new End of Study source documents (MOP 13) for all encounters.
- Please complete the Cancer Screening Family History questionnaire at the last visit if not done previously.

Q: Should I try and schedule all participants for their last study visit as soon as possible?

A: **No**. The last visit should be as close to the target date as possible. Efforts must be made to reschedule visits that currently fall after 9/16/18 to before that date. If the participant has been unreliable, plans an extended vacation, or has upcoming surgery, you may consider scheduling him earlier.

Q: A participant has previously met the diabetes outcome and when she comes in for her visit, she will not receive pills. If the last visit is an annual visit, do I draw the safety labs?

A: **Yes**. Because she continued taking study pills up until the last visit, it is important to have final safety measures.

Contact the Coordinating Center with **any** questions or if there is anything we can do to assist you

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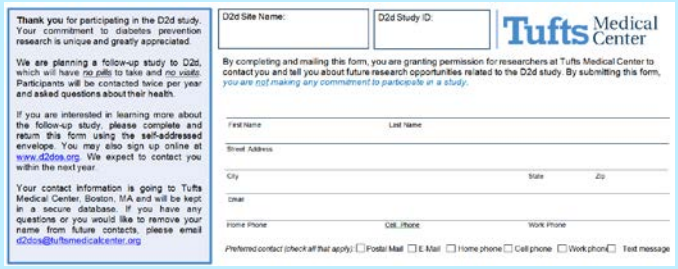
What's next? The D2d Registry

The D2d Steering Committee is exploring options for a follow-up observational study without study pills and without visits. Participants would be asked questions about their health and supplement and medication use. Because there is currently no study, Tufts Medical Center has established a centralized registry system for participants who may be interested in learning about a future D2d study to provide their contact information so that they may be contacted if a follow-up study is funded. If a follow-up study is funded it will enable site investigators to stay involved in D2d long-term.


Thank you for participating in the D2d study. Your commitment to diabetes prevention research is unique and greatly appreciated.

We are planning a follow-up study to D2d, which will have no pills to take and no visits. Participants will be contacted twice per year and asked questions about their health.

If you are interested in learning more about the follow-up study, please complete and return this form using the self-addressed envelope. You may also sign up online at www.d2dos.org. We expect to contact you within the next year.

Your contact information is going to Tufts Medical Center, Boston, MA and will be kept in a secure database. If you have any questions or you would like to remove your name from future contacts, please email d2dos@tuftsmedicalcenter.org

D2d Site Name:

D2d Study ID:

Tufts Medical Center

By completing and mailing this form, you are granting permission for researchers at Tufts Medical Center to contact you and tell you about future research opportunities related to the D2d study. By submitting this form, you are not making any commitment to participate in a study.

First Name Last Name

Street Address

City State Zip

Email

Home Phone Cell Phone Work Phone

Preferred contact (check all that apply): Postal Mail E-Mail Home phone Cell phone Work phone Text message

At the last visit, sites are providing participants with the opportunity to sign up in the D2d registry. Participants sign themselves up (via website or response card – shown on the left).

Sites should help interested participants sign-up during the last scheduled visit.

Meet the D2d study team | D2d individuals, sites, components that make a difference

L to R: Amy Orasko, Ana Surckla RN, Dr. Sangeeta Kashyap, Blair Martin.

D2d Site | Cleveland Clinic, Cleveland, Ohio

Cleveland, Ohio is the home of the 2016 NBA champion Cavaliers, the Rock and Roll Hall of Fame, and, most notably, the Cleveland Clinic. Founded in 1921, the Cleveland Clinic integrates clinical and hospital care with research and education and has a proud history of serving the needs of our community and nation.

Principal Investigator, Dr. Sangeeta Kashyap, has been a physician in the Endocrinology & Metabolism Institute at the Cleveland Clinic since 2004 and is an Associate Professor of Medicine at the Cleveland Clinic Lerner College of Medicine. Ana Surckla has been working at the Cleveland Clinic for 11 years and has clinical and research experience in diabetes, Cushing's disease and oncology. She serves as the primary Research Nurse Coordinator. Her energy, persistence, dedication, and ability to establish strong patient relationships have been critical to the study oversight and participant retention. Blair Martin joined the D2d team in July 2016 as a primary Research Coordinator. She has 11 years of research experience and contributes tremendously in all aspects of the study. Amy Orasko ensures study regulatory compliance and is the responsible for IRB coordination. We are fortunate to have a supportive and experienced Clinical Research Unit. The Cleveland Clinic D2d is proud to contribute to the D2d study.

Questions? Please contact D2d Coordinating Center at D2d@tuftsmedicalcenter.org or 617-636-**D2d**2 (3232)