

Kick-off Meeting Agenda

7:00 – 7:45 am	Breakfast	Brookside A/B
7:45 – 10:00 am	General Session	Brookside A/B
9:30 – 9:45 am	Break	Brookside A/B
9:45 – 12:00 pm	General Session	Brookside A/B
12:00 – 12:45 pm	Lunch & Committee Meetings	White Oak B
12:45 – 1:15 pm	Committee Reports	White Oak B
1:20 – 3:00 pm	Break-out Session A - Coordinators Break-out Session B - Investigators	Brookside A Brookside B
3:00 – 3:15 pm	Break	Brookside
3:15 – 5:30 pm	Break-out Session C - Coordinators	Brookside A



Goals:

- Review the D2d protocol and procedures
- Invite discussion and answer questions
- Stay on schedule

Agenda

General Session

7:45	Welcome
	Overview of the Agenda, Study Organization
8:00	Background on Vitamin D and Type 2 Diabetes
8:15	Protocol review Review of Primary Outcome
9:30	Break
9:45	Statistical Plan
10:00	Good Clinical Practice and D2d Safety Reporting
10:45	Drug Distribution Center (DDC) Overview and SPIRS
11:10	Central Laboratory overview
11:35	Recruitment Timeline and Expectations Participant Retention
12:15	Lunch - tables arranged by Committees (ASES, SEP, PPS, RCs)
12:45	Committee Reports (RRS, COI, Safety, SEP)

Break-out session A, Research Coordinators

Time	Topic
1:15	Screening Process and Procedures Study Schedule and Procedures
2:10	Central Laboratory Procedures
2:40	Questionnaire Administration

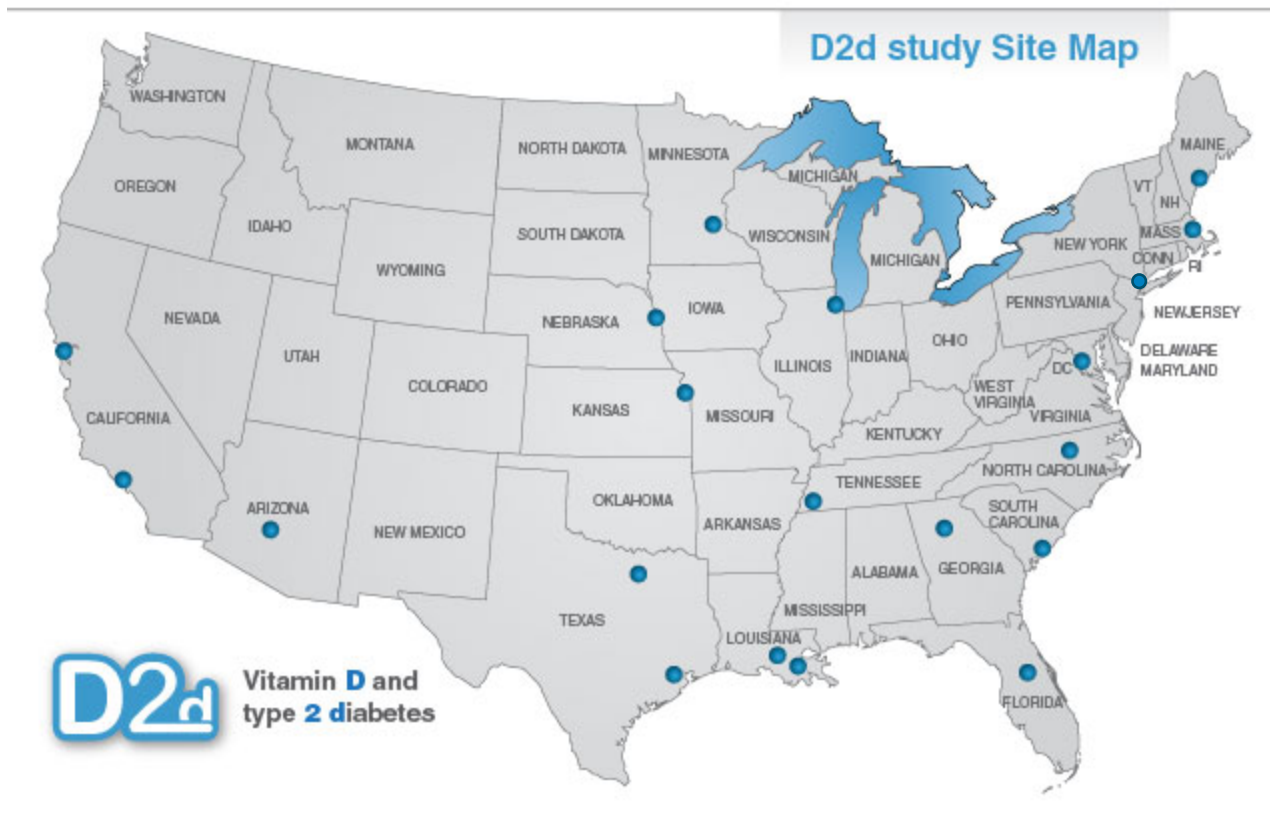
Break-out session B, Investigators

Time	Topic
1:15	Publications and Presentations
1:30	Ancillary Studies
1:45	eCRF Introduction for Investigators

Break-out session C, Research Coordinators

Time	Topic
3:15	Source Data Requirements
3:45	eCRF Introduction
5:00	Support and Education Program

Collaborating Clinical Sites



Housekeeping

- Hotel check-out
- Transportation to Reagan National
- Reimbursement Form



Conflict of Interest Policy

- D2d COI policy is found in MOP section 2.
- Covered individuals are D2d research staff who:
 - ✓ Have participant contact
 - ✓ Have contact with identifiable data or biological samples
 - ✓ Make substantive contributions
- Covered individuals must complete an annual disclosure form.

Conflict of Interest Policy

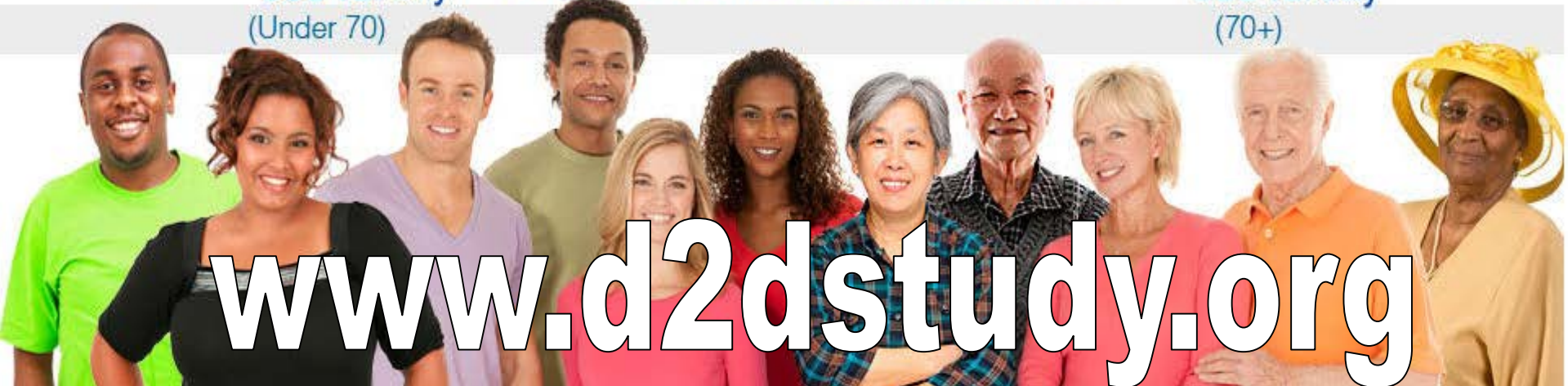
- Site PI submits their COI forms to CC.
- Site PI reviews forms from all Covered Individuals at her site.
 - Form(s) with disclosures (i.e. “yes” responses) are submitted to the CC.
 - PI retains completed Form(s) for Covered Individuals who answer “no” to questions.
- Covered Individuals not affiliated with a site will also need to submit their forms to CC.

Website (public and web portal)

2011 Institute of Medicine
Vitamin D Intake Recommendations

600 IU/day
(Under 70)

800 IU/day
(70+)



www.d2dstudy.org