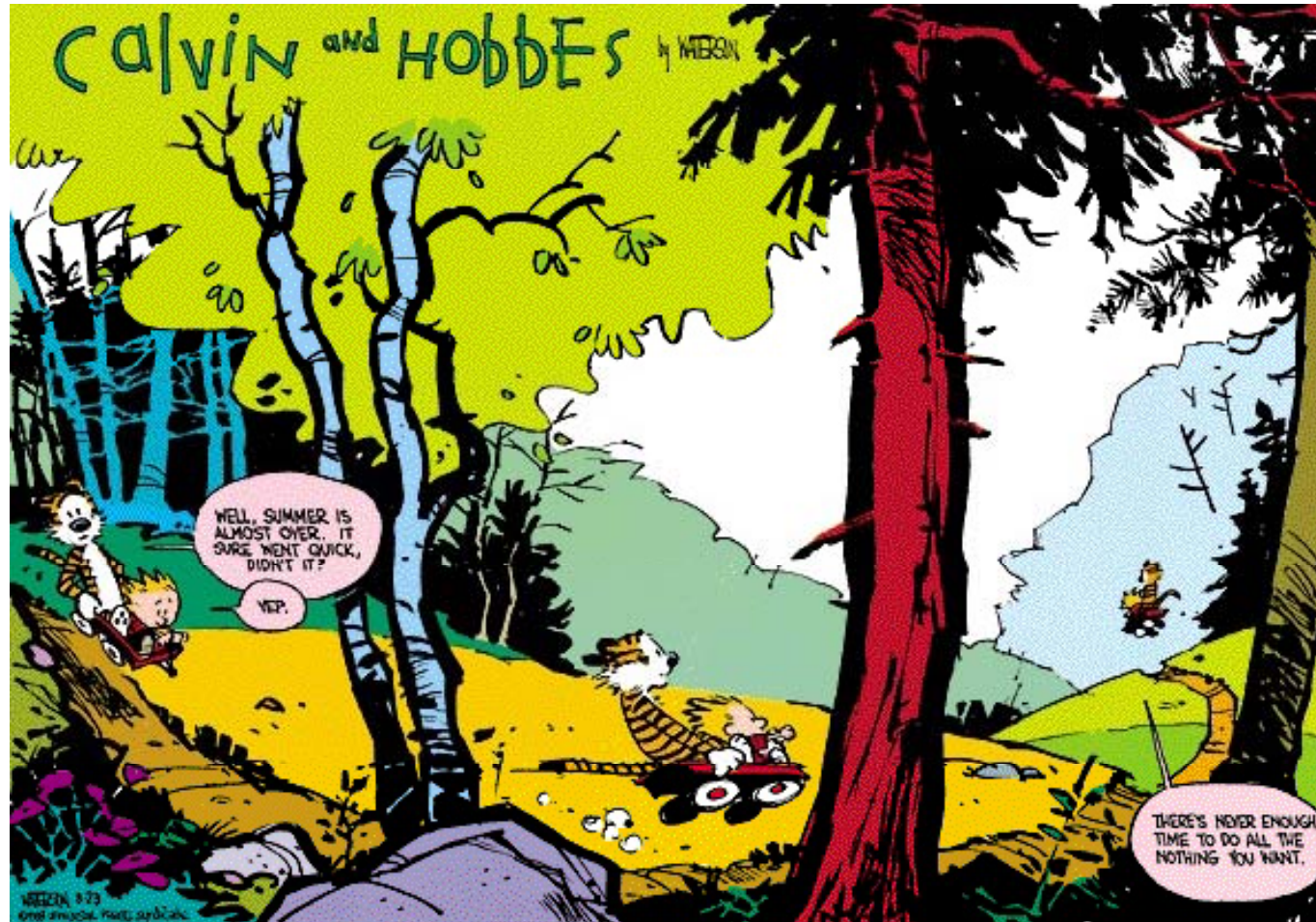

Study Schedule & Procedures

Patty Sheehan



Coordinating Center at Tufts Medical Center
www.d2dstudy.org | d2d@tuftsmedicalcenter.org

Lots to do



Study Visit Schedule: General Points

- **Time of Day**
 - All visits, except randomization are conducted fasting - early morning
- **Day of the Week**
 - Any day of the week
 - *Participants should not be scheduled for a visit involving specimen collection on a Thursday prior to a Monday holiday.*
- **Visit Window: +/- 2 weeks**
 - Follow-up visits maybe postponed for up to 8 weeks:
 - Participant experienced a condition that affects glucose tolerance
 - Infection
 - Blood donation or transfusion
 - Compelling social circumstance



Study Visit Schedule: Visit Window

Visit	Target Day*	Visit Window*
Screening		-49 to -7
Baseline		-21 to -5
Randomization	0	0
M03	91	77-105
M06	183	169-197
M09 (phone call)	274	260-288
M12	365	351-379
M15 (phone call)	456	442-470
M18	547	533-561
M21 (phone call)	638	624-652
M24	730	716-744
M27 (phone call)	821	807-835
M30	913	899-927
M33 (phone call)	1004	990-1018
M36	1095	1081-1109
M39 (phone call)	1186	1172-1200
M42	1278	1264-1292
M45 (phone call)	1369	1355-1383
M48	1460	1446-1474



Study Visit Schedule: EDC Presentation

SCRATCH

10004
Screening 12/Dec/2012
Eligibility
Baseline 15/Feb/2012

Consent and Enrollment

Visit	Date
Participant has not been randomized: study schedule is blank	

Task Summary: Subject

	Pages
NonConformant Data	0
Open Queries	0
Overdue Data	0

Participant Initials: AGP

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Study Visit Schedule: EDC Presentation

Task Summary: Subject

Task	Pages
NonConformant Data	0
Open Queries	0
Overdue Data	44

Participant randomized: study schedule triggered off randomization date

Visit	Date
Screening	01 Jan 2000
Baseline	15 Jan 2000
Randomization	25 Jan 2000
Month 3 (1)	22 Apr 2000
Month 6 (1)	09 Jul 2000
Month 9 (1)	07 Oct 2000
Month 12 (1)	05 Jan 2001
Month 15 (1)	05 Apr 2001
Month 18 (1)	04 Jul 2001
Month 21 (1)	02 Oct 2001
Month 24 (1)	31 Dec 2001
Month 27 (1)	31 Mar 2002
Month 30 (1)	29 Jun 2002
Month 33 (1)	27 Sep 2002
Month 36 (1)	26 Dec 2002
Month 39 (1)	26 Mar 2003
Month 42 (1)	24 Jun 2003
Month 45 (1)	22 Sep 2003
Month 48 (1)	31 Dec 2003
End of Study (1)	21 Dec 2003

Study Visit | Reminder Calls

Goals:

1. Determine if visit may need to be postponed or prepare for additional activities that may need to be conducted during the visit or obtain additional information prior to the visit.
2. Remind participant of visit and if needed reschedule it.
(Promote retention)
3. Remind participant of visit preparation. (Protocol compliance)

Have there been any changes in your health or visits to healthcare providers? What? Why?

Has the participant had any condition that would affect glucose tolerance (e.g. infection, blood transfusion or donation)?



Study Visit | Reminder Calls

Reminders

- Day, time and location of the visit
- Duration of visit
- Procedures planned for the visit
- Fast for at least 8 hours overnight
- Take study pill and morning medications on the morning of the visit with water
- Bring remaining study pills in the original bottle
- Bring all other medications and supplements they are taking
- Wear comfortable clothes with loose sleeves, as blood will be drawn (all visits except Randomization)



Study Visit Order of Activities

Order of Activities

- Efficiency for participant and research staff
- Avoid completing task if they are not needed

Follow-up Visit Activities

- Medical history/interim history
- Non-study medication review
- Vital signs and waist circumference
- Focused physical exam (prn)*
- Fasting specimen collection (start OGTT)
- Questionnaires*
- Lifestyle counseling*
- Study pill count*
- Study pill teaching, and dispensing*



Study Visits | Baseline

Visit Goals:

- Confirm glycemia eligibility
- Obtain baseline data



Study Visits | Baseline continued

Visit Activities:

- Interim medical history
- Review of concomitant medications and supplements.
- Physical Measurements:
 - Vital signs: height, weight, blood pressure, heart rate and *waist circumference*
- ~~Symptom-directed physical examination, prn~~
- **Comprehensive physical examination**

*Discussed at meeting:
Initial physical exam
moved from screening
visit to baseline visit*



Study Visits | Baseline continued

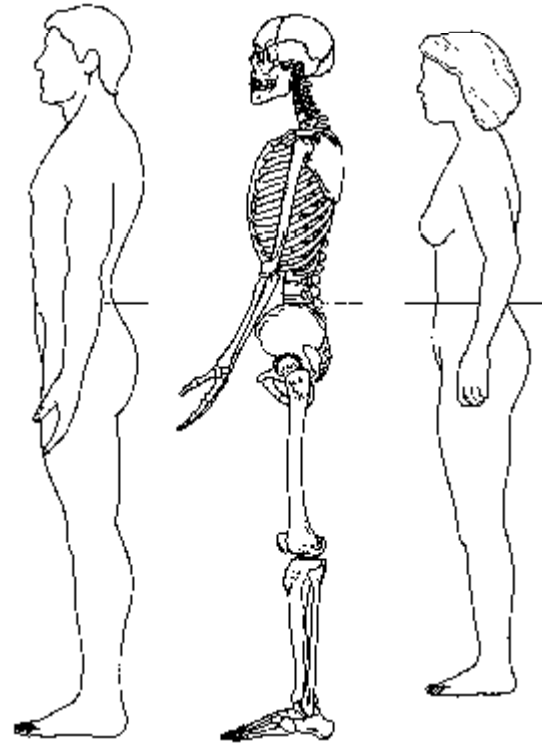
Vital signs: Accuracy and consistency of procedures is essential

- **Height:** Supplies: stadiometer
 - Stocking feet
 - Positioning: Back parallel to the ruler, legs should be together, arms at sides, shoulders relaxed, back of body should touch stadiometer.
 - Headpiece lowered until touches crown of head
 - Record height to nearest 0.5 cm.
- **Weight:** use the same scale at each visit
 - Participant should wear a light layer of clothing (pants, shirt, socks)
 - Shoes and belt removed and pockets should be emptied.
 - Balance scale at zero
 - Read weight to nearest 0.1 Kg.



Study Visits | Baseline continued

- **Waist circumference**
- Supplies: Cloth measuring tape
- Participant stands, arms at side, in a straight and upright position, feet together.
- Measurer is positioned at right of the participant.
- Palpate the upper hip-bone to locate the right iliac crest. Mark location.
- Measuring tape is placed in a horizontal plane, parallel to the floor, around the abdomen at the level of iliac crest.
- Record measurement to nearest 0.5cm.



Study Visits | Baseline continued

Visit Activities:

- Interim medical history
- Review of concomitant medications and supplements.
- Physical Measurements:
 - Vital signs: height, weight, blood pressure, heart rate, and *waist circumference*
- ~~Symptom-directed~~ Comprehensive physical examination, ~~prn~~
Discussed at meeting, moved from screening to baseline
- Central laboratory specimen collection, including OGTT, and repository.
- Local laboratory specimen collection: pregnancy (prn)
- Questionnaires: Food Frequency (FFQ), Physical Activity
- Lifestyle counseling
- Review of Participant Information pamphlet



Your Clinic Contact Information:

Add site name
And address/location

Study Coordinator: XXXXXXX
Email: xxxxxx@xxxxx.xxx
Phone: XXX-XXX-XXXX

Study Physician: XXXXXXXXXXX
Email: xxxxxx@xxxxx.xxx
Phone: XXX-XXX-XXXX

Please keep this brochure in a convenient location so you may refer to it during your participation in the D2d study.

Your Next Appointment:

Date

Time

On behalf of the entire D2d team, we greatly appreciate your participation and commitment to the D2d study



If you are prescribed any of the following medications, please call your study coordinator before starting the medication

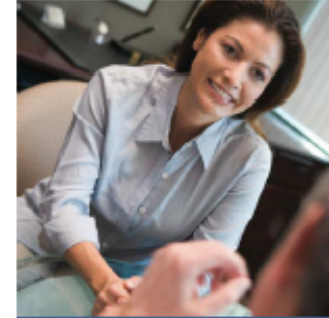
- Metformin** (Glucophage, Glumetza, Fortamet, Riomet)
- Glyburide** (Micronase, Glynase, and Diabeta)
- Glipizide** (Glucotrol and Glucotrol XL)
- Glimepiride** (Amaryl)
- Repaglinide** (Prandin)
- Nateglinide** (Starlix)
- Rosiglitazone** (Avandia)
- Pioglitazone** (Actos)
- Acarbose** (Precose)
- Meglitol** (Glyset)
- Canagliflozin** (Invokana)
- Sitagliptin** (Januvia)
- Saxagliptin** (Onglyza)
- Linagliptin** (Tradjenta)
- Exenatide** (Byetta, Bydureon)
- Liraglutide** (Victoza)
- Regular Insulin** (Humulin R, Novolin R)
- NPH Insulin** (Humulin N, Novolin N)
- Lispro** (Humalog)
- Aspart** (Novolog)
- Glulisine** (Apidra)
- Detemir** (Levemir)
- Glargine** (Lantus)
- Pramlintide** (Symlin)
- Bromocriptine mesylate** (Cycloset)
- Colesevelam** (Welchol)

_____ (Add med)

_____ (Add med)



Vitamin D and type 2 diabetes



PARTICIPANT INFORMATION

The study is sponsored by



www.d2dstudy.org



Participant Information Pamphlet

Provided and reviewed with participant at every visit

General Information

Your participation in the D2d study is very important and greatly appreciated

Please follow all recommendations in this pamphlet. Your active engagement will make your participation a worthwhile experience and will ensure that the D2d study will help people at risk for type 2 diabetes, like yourself.

Keep your appointments

There are 12 scheduled visits. Additional visits may be needed. Each visit is very important. If you need to change an appointment, please call your Study Coordinator to reschedule.

Let us know if your address changes

If you are moving, please contact your Study Coordinator as soon as possible to update your address and phone number. If you plan to move out of the area, please tell the Study Coordinator to arrange for you to continue participating in the D2d study, either at the current site or another site.

Going on an extended vacation?

Please let your Study Coordinator know ahead of time, so you will be given enough study pills to last through your trip and to reschedule your visits, if required.

Let us know if you become pregnant.

Please use an effective method of birth control throughout the study. If you become pregnant, please notify your Study Coordinator immediately.

Study Pill Instructions

Take one soft-gel pill daily with breakfast

If you forget to take your pill, please take it as soon as you remember that day.

Please contact your Study Coordinator if you are having problems taking the pills. Study personnel can provide you with options that may make it easier to take the study pills.

If you develop symptoms of abdominal or lower back pain or bloody urine, please contact your doctor and notify your Study Coordinator or Study Physician.

Medications and Supplements

Please contact the study coordinator before starting any new medications or supplements. It is important that we test your blood sugar and hemoglobin A1c before you start some medications. Please see the back panel for a list of these medications.

Please bring with you to each visit all the medications, supplements and vitamins you are taking.

Vitamin D supplement dosage during the study should be no more than 1000 IU per day.

Calcium supplement dosage during the study should be no more than 600 mg per day.

When in direct sunlight for longer than a few minutes, remember to wear protective clothing and apply sunscreen with an SPF of 15 or higher.

Study Pills Instructions

Please bring the bottles with study pills with you to each visit

Please come to all study visits fasting

Do not eat or drink (except plain water) for the 8 hours before the scheduled visit time. You will be given a snack at the clinic or you can bring food with you to eat at the end.

At the Screening, Baseline, 12, 24, 36, and 48-month visits a 2-hour oral glucose tolerance test (OGTT) will be done to determine how your body responds to a glucose (sugar) load and to screen for diabetes. You will have your blood drawn while fasting. Then, you will drink a sugar-containing beverage and will have blood drawn a few times during the next two hours. After the OGTT finishes, you will be given a light breakfast or lunch.

To prepare for the OGTT visit:

- Do not eat or drink anything but water for the 8 hours before the visit.
- Take all your morning medications with water before coming to the visit.
- Do not participate in vigorous physical activity for 24 hours before the visit.
- Do not drink alcohol for 24 hours before the visit.
- Do not smoke on the morning of the visit.

Study-related problems or questions

Please call your clinic if you experience any changes in your health, if you are hospitalized for any reason or if you have any other questions regarding participation in the study.

Participant Information Pamphlet

Provided and reviewed with participant at every visit



Your Clinic Contact Information:

Add site name
And address/location

Study Coordinator: XXXXXXX
Email: xxxxxx@xxxxx.xxx
Phone: XXX-XXX-XXXX

Study Physician: XXXXXXXXXXX
Email: xxxxxx@xxxxx.xxx
Phone: XXX-XXX-XXXX

Please keep this brochure in a convenient location so you may refer to it during your participation in the D2d study.

Your Next Appointment:

Date _____

Time _____

On behalf of the entire D2d team, we greatly appreciate your participation and commitment to the D2d study


D2d Vitamin D and type 2 diabetes

If you are prescribed any of the following medications, please call your study coordinator before starting the medication

Metformin (Glucophage, Glumetza, Fortamet, Riomet)
Glyburide (Micronase, Glynase, and Diabeta)
Glipizide (Glucotrol and Glucotrol XL)
Glimepiride (Amaryl)
Repaglinide (Prandin)
Nateglinide (Starlix)
Rosiglitazone (Avandia)
Pioglitazone (Actos)
Acarbose (Precose)
Meglitol (Glyset)
Canagliflozin (Invokana)
Sitagliptin (Januvia)
Saxagliptin (Onglyza)
Linagliptin (Tradjenta)
Exenatide (Byetta, Bydureon)
Liraglutide (Victoza)
Regular Insulin (Humulin R, Novolin R)
NPH Insulin (Humulin N, Novolin N)
Lispro (Humalog)
Aspart (Novolog)
Glulisine (Apidra)
Detemir (Levemir)
Glargine (Lantus)
Pramlintide (Symlin)
Bromocriptine mesylate (Cycloset)
Colesevelam (Welchol)



_____ (Add med)
 _____ (Add med)

D2d
 Vitamin D and type 2 diabetes





PARTICIPANT INFORMATION

The study is sponsored by

www.d2dstudy.org

Participant Information Pamphlet

Provided and reviewed with participant at every visit

Study Visits | Post-baseline Activities

Post Visit Activities:

- Review Central Laboratory glycemia results:
 - Fasting plasma glucose
 - Hemoglobin A1c
 - 2 hour plasma glucose
- Review Central Laboratory urine calcium creatinine ratio results
- Confirm participant meets the study inclusion and exclusion criteria



Study Visit | Randomization

Visit Activities:

- Randomize the participant in SPIRS
- Obtain printout of SPIRS study bottle assignment
- Review the Participant Information pamphlet with participant
- Confirm study pill bottle number being dispensed matches study bottle number on SPIRS printout
- Provide participant with a printout of the visit schedule (from EDC)
- **Post visit:** send letter to Primary Care Provider (template in MOP)



Study Visit | Month 3

Visit Activities:

- Interim medical history
- Assess study pill compliance
- Review of concomitant medications and supplements.
- Physical Measurements:
 - Vital signs: height, weight, blood pressure, heart rate
- Symptom-directed physical examination
- Laboratory specimen collection:
 - Local lab: serum calcium and serum creatinine, pregnancy (prn)
 - Central lab: urine calcium creatinine ratio
- Review of Participant Information pamphlet



Study Visit | Semi-Annual Visits

Visit Activities:

- Interim medical history
- Review of concomitant medications and supplements
- Physical Measurements:
 - Vital signs: height, weight, blood pressure, heart rate
- Symptom-directed physical examination (prn)
- Laboratory specimen collection:
 - Local lab: pregnancy (prn)
 - Central lab: FPG, HbA1c, (M06-repository specimens)



Study Visit | Semi-Annual Visits continued

Visit Activities:

- Study pill counts and compliance assessment
- Protocol reinforcement and review of Participant Information
- Dispense a new bottle of study pills
 - Bottle number assigned by SPIRS

Post visit:

- Send follow-up letter to Primary Care Provider



Study Visit | Annual Visits

Visit Activities:

- Interim medical history
- Review of concomitant medications and supplements
- Physical Measurements:
 - Vital signs: height, weight, blood pressure, heart rate
- Symptom-directed physical examination (prn)



Study Visit | Annual Visits continued

Visit Activities:

- **Laboratory specimen collection:**
 - Locally: serum calcium, serum creatinine, pregnancy (prn)
 - Central Laboratory specimen collection, including OGTT, repository
- **Questionnaires**
 - FFQ (M12 and M36 in participants without diabetes)
 - Physical Activity



Study Visit | Annual Visits continued

Visit Activities:

- Protocol reinforcement and review of Participant Information
- Dispense a new bottle of study pills
 - Bottle number assigned by SPIRS

Post visit:

- Send follow-up letter to Primary Care Provider (template in MOP)



Scheduled Phone Contact

Schedule: 9M, 15M, 21M, 27M, 33M, 39M, 45M

Objectives:

1. Promote retention
2. Assess and encourage compliance with study pill regime
3. Interim medical history (assess for AEs)
4. Remind the participant to contact the site prior to starting any new medications, and if they have been diagnosed with diabetes

* See MOP 4 and 17 for tips on contacting people

Study Visit | Unscheduled

Unscheduled visit will occur if:

1. At semi-annual or annual visit, participant met one glycemia criteria for diabetes that requires confirmation.
 - Confirmatory visit should occur within 8 weeks
2. Health care provider (outside of study) makes diagnosis of diabetes or plans to start diabetes-specific pharmacotherapy.
 - Visit scheduled as soon as possible (ASAP)
3. Participant reports symptoms of hyperglycemia.
 - Visit scheduled ASAP
4. Adverse event
 - Visit scheduled ASAP



Unscheduled | Confirmatory Visit

Required if at semi-annual or annual visit, participant met **one** glycemia criteria for diabetes.

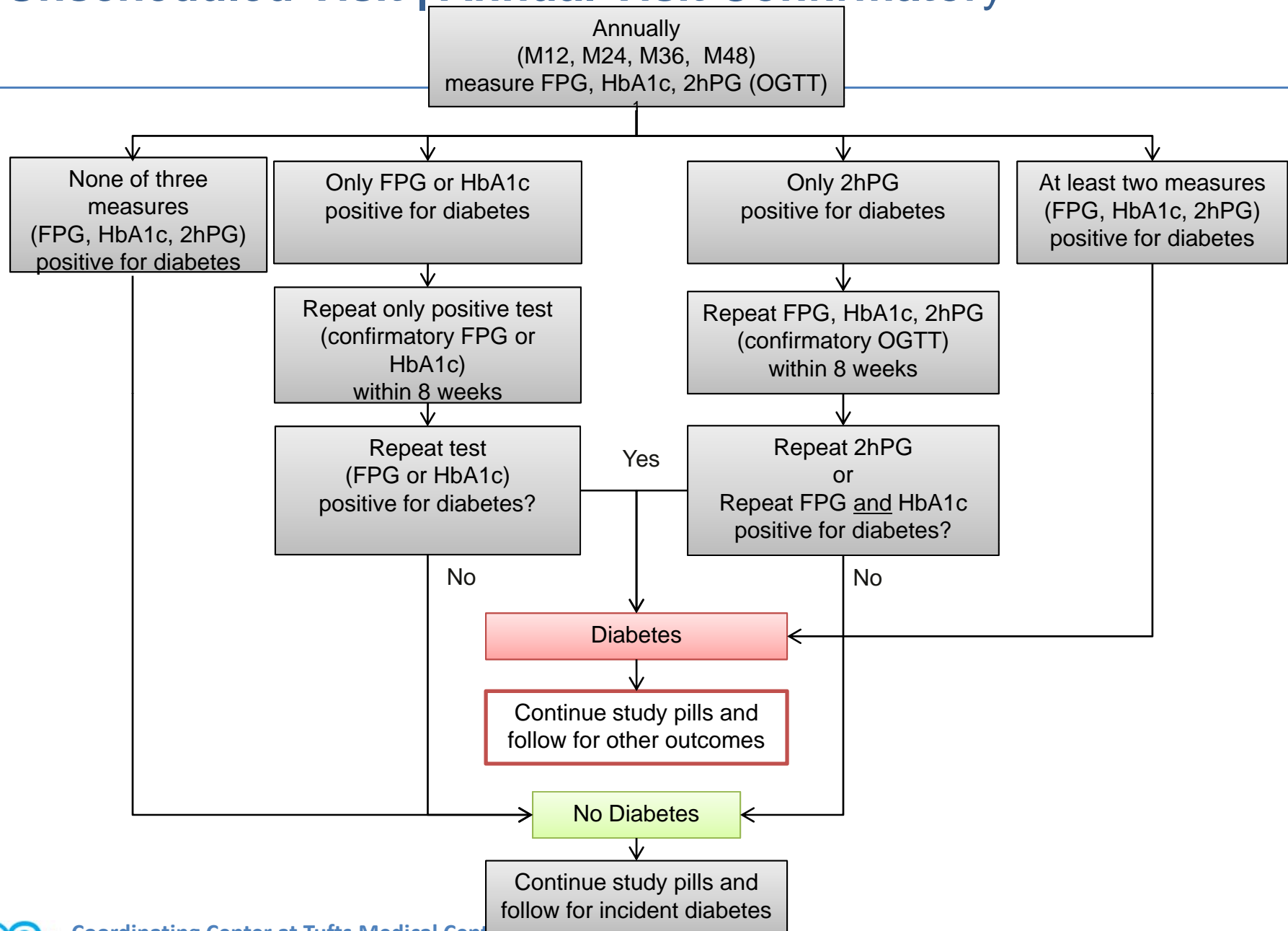
- Confirmatory visit should occur within 8 weeks

Activities:

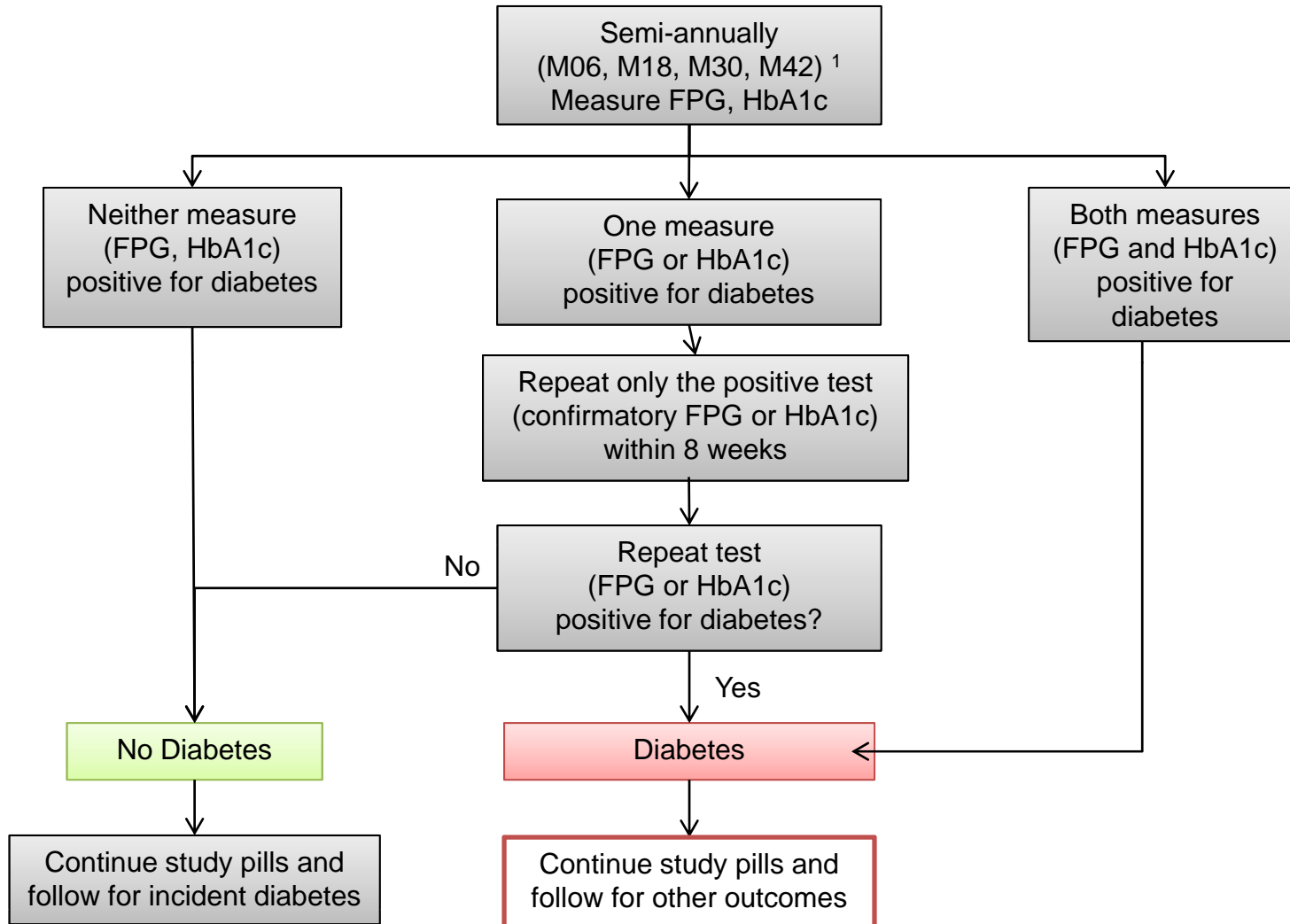
- Interim medical history
- Review of concomitant medications and supplements
- Collection of required sample(s) for Central lab



Unscheduled Visit | Annual Visit Confirmatory



Unscheduled Visit | Semi-annual Visit Confirmatory



Unscheduled Visit | Diabetes Diagnosed Outside of Study

Goal: Participant **returns to clinic for glycemia** testing **prior** to starting diabetes specific medications (for any reason).

Activities:

- Complete Non-D2d Diabetes Diagnosis worksheet
 - Start form when speaking with participant on phone
 - Complete form during the visit
- If participant **has not** started the diabetes-specific medication, collect FPG and HbA1c samples for the Central laboratory.

If participant **started** diabetes-specific medication, collect medical records for adjudication.

Unscheduled Visit | Symptoms of Hyperglycemia

Required if reports symptoms of hyperglycemia

- Visit should occur ASAP

Activities:

- Interim medical history
- Review of concomitant medications and supplements
- Collection of FPG and HbA1c for Central lab

Symptoms of hyperglycemia:

Blurry vision
Excessive thirst
Excessive hunger
Frequent urination

Extreme fatigue
Unexplained weight loss
Frequent infections

End of Study Visit

Visit Activities:

- Interim medical history
- Review of concomitant medications and supplements
- Physical Measurements:
 - Vital signs: height, weight, blood pressure, heart rate
- Symptom-directed physical examination (prn)
- Study pill compliance assessment and return of study pills.
- Laboratory specimen collection:
 - Local lab: serum calcium, serum creatinine, pregnancy (prn)
 - Central lab: Urine calcium creatinine, HbA1c, FPG

